ACLIM ANNUAL MEETING
58TH ANNUAL HEALTH LAW & LEGAL MEDICINE
THE OLD. THE NEW. THE NOW.

in conjunction with
THE 10TH ANNUAL ETHICAL & LEGAL ASPECTS
OF DENTISTRY CONFERENCE
FEBRUARY 23 – 25, 2018
FRANCIS MARION HOTEL  |  387 KING ST, CHARLESTON, SC

INVITED PRESENTERS

F. LEE BAILEY, JD
Cyril Wecht Luncheon

ANABEL PELHAM, PHD
Annual Awards and Networking Banquet

CAVAN DOYLE, JD, LLM
Stewart Reuter Lecture

THE HONORABLE
JOSEPH P. RILEY, JR., JD,
FORMER MAYOR OF CHARLESTON,
SOUTH CAROLINA
Sandy Sanbar Lecture

PROGRAM CHAIRS: Leon Aussprung, MD, JD, FCLM; John Adam McLaughlin, MD, JD, FCLM; Bruce Seidberg, DDS, JD, FCLM

WWW.ACLM.ORG
The dental conference and the ACLM foundation is supported by the kindness of

Thank You

Tulsa Dental Center

WWW.TULSADENTALCENTER.COM
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Program schedule is subject to change.
Inclusion of Speaker Bios, Abstracts and Program Materials as available at publication of this program.
**PRESIDENT’S WELCOME RECEPTION**  
**Date:** Friday, February 23, 2018  
**Time:** 6:45 – 8:30 pm  
**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.

**DR. DOROTHY RASINSKI-GREGORY WOMEN’S LEADERSHIP BREAKFAST**  
**Date:** Saturday, February 24, 2018  
**Time:** 6:45 – 7:45 am  
**Attire:** Business Casual  
**Cost:** Included in registration fee  
Join us for the 12th 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 24, 2018  
**Time:** Noon – 1:15 pm  
**Attire:** Business Casual  
**Cost:** $45 - pre-registration ticket price  
$55 - ticket price purchased at conference. Tickets are not included in the registration fee.

**ANNUAL AWARDS AND NETWORKING BANQUET**  
**Date:** Saturday, February 24, 2018  
**Time:** 7:30 – 9:15 pm  
**Attire:** Business  
**Cost:** $50 - pre-registration ticket price  
$100 - ticket price purchased at conference. Tickets are not included in the registration fee.
HOTEL AND TRAVEL INFORMATION

FRANCIS MARION HOTEL

387 King Street
Charleston, South Carolina, 29403
843-722-0600
www.francismarioncharleston.com
https://reservations.travelclick.com/76320?groupID=1783674

HOTEL RESERVATIONS

ACLM Room Rates: $229.00/night (excluding fees and taxes - taxes are subject to change)
ACLM must meet certain minimum hotel room pickup requirements or ACLM will face attrition penalties. In order for the College to continue to provide a reasonable registration fee, we need your help. Please take advantage of the room rate we have negotiated.

Reservation Deadline: Wednesday, February 1, 2018
Online Reservations: https://reservations.travelclick.com/76320?groupID=1783674
Online Code ACLMA

American College of Legal Medicine encourages you to make your reservation early, as the hotel and discount block may sell out before this date. After this date, reservations will be accepted based on availability, and higher rates may apply.

TRAVEL INFORMATION

Charleston International Airport (CHS)
www.iflychs.com

Travel To and From the Airport
www.iflychs.com/Travel-Information/Hotel-Information

Getting Around Charleston
www.iflychs.com/Ground-Transportation/CARTA-Bus-Info

Charleston Attractions
www.charlestoncvb.com
Conference Room Information

Mezzanine/Meeting Level

The Gold Ballroom/Second Floor

The Colonial Room/Lobby Level
Presented by: American Board of Legal Medicine, American College of Legal Medicine, and American College of Legal Medicine Foundation.

Cost: $195 (This session is not included in your ACLM Annual Meeting registration fee.)

Time: 1:00 PM – 6:00 PM The Sims Mock Trial will include 5 Hours of presentations in video and live discussions.

This course qualifies the attendee for up to a maximum 5.0 AMA PRA Category I Credits™ as defined by the American College of Legal Medicine.

SUMMARY OF FACTS:

• A 60-year-old male underwent resection of a benign frontal lobe meningioma.

• On September 13, 1995, at 1300 hours, during his first time out of bed, he fell from the bedside commode. There appeared to be no injury as a result of the fall.

• Three days after the fall, he was brought back to surgery for an emergency craniotomy secondary to an acute pneumocephalus. After surgery, the patient remained in a vegetative state until his death soon after.

PLAINTIFF, PATIENT’S DAUGHTER, ALLEGED THAT:

• Nurse and Hospital were negligent for failing to provide adequate safety, which lead to the fall and ultimately the patient’s demise.

• Nurse and Hospital failed to recognize a neurological emergency and failed to respond appropriately.

• The defense will argue that the acute pneumocephalus was a known risk of the neurosurgical procedure and that there was no malpractice on the part of the Nurse or Hospital.

TRIAL PROCEDURE:

• Jury Selection
• Opening Statements
• Plaintiff Presents Evidence
• Defense Presents Evidence
• Closing Arguments
• Jury Instructions & Deliberations
• Verdict, Judgment, & Post-Trial Motions

PRESENTERS:

Mert Aksu, DDS, JD, FCLM
Oren Asman, LL.D., Esq.
F. Lee Bailey, JD
David Benjamin, PhD, FCLM
Ken Berger, MD, JD, FCLM
Francois Blaudeau, MD, JD, FCLM
Paul Blaylock, MD, JD, FCLM
Michael Brooks, MD, JD, FCLM
John Busowski, MD, JD, FCLM
Jack Conomy, MD, JD, FCLM
Dale Cowan, MD, JD, FCLM
Jonathan Davies, LLM
Cavan Doyle JD, LLM
Marjorie Eskay-Auerbach, MD, JD, FCLM
Randi Etten, PhD
Toan Than Foeng, DDS, JD, FCLM
Bernard Friedland, DDS, JD, FCLM
Chester Gary, DDS, JD, FCLM
Joseph Graskemper, DDS, JD, FCLM, DABLM
Jamison Green, PhD
Victoria Green, MD, JD, FCLM
Richard Harold, DMD, JD, FCLM
Robert Harrison, MHA, JD, LLM
Margaret Hill, DMD
Alexander Holden, BDS, MDPh, LLM
Laurence Jerrold, DDS, JD, FCLM
Michael Kaner, DMD, JD
Alexandra Karydi, PhD
Richard Kelly, MD, JD, FCLM
Robert Liles, JD
Dean Irving McKennzie, DDS
Mark Monasky, MD, JD, FCLM
Roger Moore, DDS
Lillian Obucina, DDS, JD, FCLM
Daniel Orr, DDS, MD, JD, FCLM, DABE
Olivia Palmer, DMD, JD
Nicholas Panometros, DDS, JD, FCLM
Annabel Pelham, PhD
Joe Piorkowski, MD, JD, FCLM
Eric Ploumis, DMD, JD
David Preble, DDS, JD, FCLM
Frank Recker, DDS, JD, FCLM
Frank Riccio, DDS, JD, FCLM
Joseph P. Riley, Jr., JD, Former Mayor of Charleston, South Carolina
Sandy Sanbar, MD, JD, FCLM
Eric Shore, DO, JD, FCLM
Jack Snyder, MD, JD, PhD, FCLM
Jennifer Sullivan, DMD, JD, FCLM
Veling Tsai, MD, JD, FCLM
Mary Wall, MD, JD, FCLM
Richard Wilbur, MD, JD, FCLM
Michael Williams, JD
Samuel Wolfman, MD, JD, FCLM
Pamela Zarkowski, JD, FCLM

MODERATORS:

Monique Anawis, MD, JD, FCLM
Leon Aussprung, MD, JD, FCLM
Eli Avila, MD, JD, FCLM
Robert Bitonte, MD, JD, FCLM
Robert W. Buckman, PhD, FCLM
President ACLM Foundation
Chris Burkle, MD, JD, FCLM
David Donnersberger, MD, JD, FCLM
Chester Gary, DDS, JD, FCLM
Weldon Havins, MD, JD, FCLM
Bill Hinnant, MD, JD, FCLM
Raymund King, MD, JD, FCLM
Ted LeBlang, JD, FCLM, ACLM Past President
Kalu Ogbruweke, DDS, JD, FCLM, DABE
Daniel Orr, DDS, MD, JD, FCLM, DABE
ACLM Past President
Bruce Seidberg, DDS, MScD, JD, FCLM, DABE
ACLM Past President
Cyril Wecht, MD, JD, DABE, Founder
ACLM Past President
Karin Zucker, JD, FCLM
EDUCATIONAL NEEDS

Physicians, dentists, attorneys and educators who practice in the health care 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 marketplace that will impact the practice of medicine, special and vulnerable populations in particular. Key changes impacting the practice of medicine and law during the past one to two years include: fraud investigations against health professionals, the ethical and legal issues of individuals with traumatic brain injury, the push delivery of care models that emphasize quality and safety within multidisciplinary teams, challenges to the Affordable Care Act, issues with vaccinations and personal exemptions, and individuals with mental health problems in front of civil and criminal courts.

OBJECTIVES

The 58th Annual Conference of the American College of Legal Medicine will focus on topics related to the intersection of health law and vulnerable/special populations. 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. Identify techniques for overcoming personal impediments to a fulfilling professional practice.
4. Explain legal and ethical challenges of dealing with vulnerable and special populations.
5. Translate the impact of globalization on public health, epidemics and the use of police power to enforce quarantines and mandate vaccinations.
6. Integrate new regulatory changes into current practice.
7. Identify the advantages and disadvantages of Medicare/Medicaid fraud enforcement.
8. Explain the legal issues affecting adolescents refusing medical care or accessing certain medical services on their own.

REGISTRATION DESK HOURS/EXHIBIT HOURS

Location: Jubilee Ballroom
Registration/Information Desk hours are as follows:

<table>
<thead>
<tr>
<th>Day</th>
<th>Hours</th>
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<tbody>
<tr>
<td>Thursday, February 22, 2018</td>
<td>12:00 pm – 6:00 pm</td>
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<tr>
<td>Friday, February 23, 2018</td>
<td>6:30 am – 5:30 pm</td>
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<tr>
<td>Saturday, February 24, 2018</td>
<td>6:30 am – 5:30 pm</td>
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<tr>
<td>Sunday, February 25, 2018</td>
<td>7:00 am – 1:00 pm</td>
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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 21.25 AMA PRA Category I Credits™, which includes a maximum of 3.5 of Medical Ethics hours 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 21.25 hours of Continuing Legal Education (CLE) credit, which includes a maximum of 3.5 Legal Ethics credits (1.5 Substance Abuse). The precise amount of the CLE will vary by state.

DENTAL CREDITS
The American College of Legal Medicine designates this program for up to 21.25 hours of Program Approval for Continuing Education (PACE) credits.

This activity has been planned and implemented in accordance with the standards of the Academy of General Dentistry Program Approval for Continuing Education (PACE) through joint efforts between UNLV School of Dental Medicine and American College of Legal Medicine (ACLM). UNLV School of Dental Medicine is approved for awarding FAGD/MAGD credit. (Approved from 06/01/2017-05/31/2021 - Provider #213111.)

DENTAL CREDITS
This activity has been planned and implemented in accordance with the ADA Continuing Education Recognition Program (ADA CERP) through joint efforts between UNLV School of Dental Medicine and American College of Legal Medicine (ACLM).

UNLV School of Dental Medicine is an ADA CERP approved provider. ADA CERP is a service of the American Dental Association to assist dental professionals in identifying quality providers of continuing dental education. ADA CERP does not approve or endorse individual courses or instructors, nor does it imply acceptance of credit hours by boards of dentistry. UNLV SCHOOL OF DENTAL MEDICINE designates this activity for 21.25 continuing education credits.

GENERAL DISCLAIMER
The statements and opinions contained in this program are solely those of the individual authors and contributors and not of the ACLM. 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 ACLM 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) 752-5355 or email info@aclm.org 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.

PHOTOGRAPHY, VIDEOGRAPHY
As part of our mission to provide education, best practices and other information from leaders in their fields, speakers, panelists and audience members should be aware that we may record all or part of the events we organize, including comments from speakers, panelists and audience members. The resulting raw and edited materials, including still photographs, video and audio recordings, and associated verbatim transcripts, may be used by ACLM without restriction, in press releases, white papers, conference collateral, websites and other publications. By attending our events, you acknowledge that you are in a public place, and that attendees (including ACLM volunteers) may capture your image in photos and videos. Nevertheless, we encourage event attendees to exercise common sense and good judgement, and respect the wishes of other attendees who do not wish to be photographed at the events. ACLM uses photos and videos taken at its events for a variety of purposes, including publication on the website. If you see any photos or profiles about yourself on www.aclm.org that you would like removed, please email info@aclm.org.
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<th>Time</th>
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<tr>
<td>12:00 pm - 6:00 pm</td>
<td>Registration/Information Desk</td>
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<tr>
<td>12:00 pm - 5:00 pm</td>
<td>ACLM Board of Governors Meeting</td>
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<td>7:00 pm - 10:00 pm</td>
<td>Committee Meetings</td>
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**FRIDAY, FEBRUARY 23**

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<th>Time</th>
<th>Event</th>
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<tr>
<td>6:30 am - 5:30 pm</td>
<td>ACLM Past Presidents’ Breakfast</td>
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<tr>
<td>6:30 am - 7:40 am</td>
<td>Continental Breakfast</td>
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<td>6:45 am - 8:00 am</td>
<td>Poster Session</td>
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<td>7:40 am - 7:50 am</td>
<td><strong>Welcome to ACLM 2018</strong> Leon Aussprung, MD, JD, FCLM; John Adam McLaughlin, MD, JD, FCLM (Program Chairs)</td>
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<tr>
<td>7:50 am - 8:00 am</td>
<td><strong>Introduction of ACLM Annual Meeting &amp; Dental Chairs/Announcements</strong> Leon Aussprung, MD, JD, FCLM; John Adam McLaughlin, MD, JD, FCLM; Bruce Seidberg, DDS, JD, FCLM</td>
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<tr>
<td>8:00 am - 9:50 am</td>
<td><strong>General Session I: Update on Recent Developments in Legal Medicine</strong> Moderator: Ted LeBlang, JD, FCLM, ACLM Past President</td>
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<td>Federal and State Legislative Update Veling Tsai, MD, JD, FCLM</td>
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<td>Federal and State Case Law Update Mary Wall, MD, JD, FCLM</td>
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<td>Federal and State Regulatory Update Robert Harrison, MHA, JD, LLM</td>
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<td>9:50 am - 10:00 am</td>
<td>Break</td>
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<td>10:00 am - 11:00 am</td>
<td><strong>SANDY SANBAR LECTURE</strong> The Tragedy, Politics, and Public Policy of the Charleston Church Shooting (Ethics credit) Invited Presenter: The Honorable Joseph P. Riley, Jr., JD, Former Mayor of Charleston, South Carolina</td>
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<td>11:00 am - 12:00 pm</td>
<td><strong>STEWART REUTER LECTURE</strong> Alternative Decision Makers for Incapacitated Patients: Ethical Substituted Judgment (Ethics credit) Invited Presenter: Cavan Doyle JD, LLM Moderator: Robert W. Buckman, PhD, FCLM; President ACLM Foundation (This lecture made possible through an ACLM Foundation grant.)</td>
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<tr>
<td>10:00 am - 12:00 pm</td>
<td><strong>Dental Session I</strong> Moderator: Joseph Graskemper, DDS, JD, FCLM, DABLM</td>
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<tr>
<td></td>
<td>Protecting Your Dental License and Privileges Amy Kulb, JD</td>
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<td>Ethical &amp; Legal Issues with Real Life Scenarios (Ethics credit) Bernard Friedland, DDS, JD, FCLM</td>
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<td>Emerging Technologies, Emerging Risks: Legal and Ethical Considerations when Utilizing New Technology in the Dental Office Eric Ploumis, DMD, JD</td>
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<td>Comparison of Legal &amp; Professional Positions Towards Tooth Whitening Alexander Holden, BDS, MDPH, LLM</td>
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<tr>
<td>12:00 pm - 1:00 pm</td>
<td>JLM Board Meeting/Lunch</td>
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<td>12:00 pm - 1:00 pm</td>
<td>LUNCH</td>
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<td>1:00 pm - 2:45 pm</td>
<td><strong>Breakout Session I: LAWYERS, DOCTORS, HOSPITALS AND PATIENTS</strong>       Moderator: David Donnersberger, MD, JD, FCLM</td>
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<td></td>
<td>• Legal &amp; Medical Aspects of “Observation” Admitting Status Eric Shore, DO, JD, FCLM</td>
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<td>• Patient Safety &amp; Medical Error Richard Wilbur, MD, JD, FCLM</td>
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<td>• Patient Privilege &amp; Law on Defense Counsel Contact with Treating Physicians Joe Piorkowski, MD, JD, FCLM</td>
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<td></td>
<td>• Ethical, Legal and Medical Staff Consequences of Physician Employment (Ethics credit) Dale Cowan, MD, JD, FCLM</td>
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<td>• Q&amp;A Breakout Session I</td>
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<td>1:00 pm - 2:45 pm</td>
<td><strong>Dental Session II</strong> Moderator: Chester Gary, DDS, JD, FCLM</td>
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<td>• Ethical &amp; Legal Aspects of Dental Advertising (Ethics credit) Lillian Obucina DDS, JD, FCLM</td>
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<td>• Advertising, Specialty Status and Board Regulations Pamela Zarkowski, JD, FCLM</td>
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<td></td>
<td>• Advertising, Specialty Status and Board Regulations Mert Aksu DDS, JD, FCLM</td>
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<td></td>
<td>• Q &amp; A Dental Session II</td>
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<tr>
<td>2:45 pm - 3:00 pm</td>
<td>Networking Break</td>
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<tr>
<td>3:00 pm - 5:00 pm</td>
<td><strong>Breakout Session II: Current Issues in Transgender Development, Health, Civil Rights and the Law</strong></td>
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**MEETING PROGRAM SCHEDULE | 2018 ACLM Annual Meeting**

**THURSDAY, FEBRUARY 22**

**MEETING PROGRAM SCHEDULE | 2018 ACLM Annual Meeting**

**FRIDAY, FEBRUARY 23**

**MEETING PROGRAM SCHEDULE | 2018 ACLM Annual Meeting**

**MEETING PROGRAM SCHEDULE | 2018 ACLM Annual Meeting**

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**2018 ACLM 58TH ANNUAL MEETING**
FRIDAY, FEBRUARY 23 (continued)

Moderator: Eli Avila, MD, JD, FCLM
This presentation made available through support from the World Professional Association for Transgender Health (WPATH)

- Transgender Issues in Children and Adolescents Alexandra Karydi, PhD
- Transitioning: Bathrooms are Only the Beginning Randi Ettrner, PhD
- Transgender Civil Rights in the Workplace, in Healthcare and Beyond Jamison Green, PhD
- Q&A Breakout Session II

3:00 pm - 5:00 pm Dental Session III
Moderator: Daniel Orr, DDS, MD, JD, FCLM, DABE, ACLM, Past President

- Tort Liability and the Mini Dental Implant Olivia Palmer, DMD, JD
- The First Amendment and Dentistry: The Revolution Frank Recker, DDS, JD, FCLM
- Dental Ethics in a Small Island Nation (Ethics credit) Michael Williams, JD
- Update on E-Mailng Patient Records Joseph Graskemper, DDS, JD, FCLM, DABLM

5:00 pm - 5:15 pm Distribution of Proposed Bylaws Changes and Brief Q & A
Leon Aussprung, MD, JD, FCLM

6:45 pm - 8:30 pm PRESIDENT’S WELCOME RECEPTION
(One ticket is included in your registration fee. Please specify on your registration if you plan to attend this reception.)

SATURDAY, FEBRUARY 24

6:30 am - 5:30 pm Registration/Information Desk

6:45 am - 7:45 am DR. DOROTHY RASINSKI-GREGORY WOMEN’S LEADERSHIP BREAKFAST
Moderator: Monique Anawis, MD, JD, FCLM
(Included in your registration fee. Please specify on your registration if you plan to attend.)

7:00 am - 5:00 pm Poster Session

7:45 am - 9:30 am Continental Breakfast

8:00 am – 9:45 am Breakout Session III: A Comprehensive Review of the Opioid Epidemic: Its Impact on Law and Medicine
Moderator: Bill Hinnant, MD, JD, FCLM

- The Epidemiology and Science of Opioids: Tolerance, Dependence and Addiction Richard Kelly, MD, JD, FCLM
- Iatrogenic Opioid Addiction David Benjamin, PhD, FCLM
- Risk Evaluation & Mitigation Strategy (REMS) in Opioid Risk Management Jack Snyder, MD, JD, PhD, FCLM
- The Impact of the Opioid Epidemic on Policy, Legal Practice and Medicine Ken Berger, MD, JD, FCLM
- Q&A Breakout Session III

8:00 am - 9:45 am Dental Session IV
Moderator: Frank Riccio, DDS, JD, FCLM

- Opioid Crisis, Really? Daniel Orr, DDS, MD, JD, FCLM, DABE
- Practice Transactions: Worst Case Scenarios Chester Gary, DDS, JD, FCLM
- History of the Prescription Epidemic in the US Richard Harold, DMD, JD, FCLM
- Legal Issues in Dental Education Margaret Hill, DMD; Roger Moore, DDS

9:45 am - 10:00 am Networking Break

10:00 am - 11:50 am Breakout Session IV: Current Medicolegal Issues in Israel and America
Moderator: Weldon Havins, MD, JD, FCLM

- Sham Peer Review in Israeli Hospitals Jonathan Davies, LLM
- Legal and Ethical Dilemmas of Statutory Tribunals in Determinations of Involuntary Hospitalization in Israel Samuel Wolfman, MD, JD, FCLM
- Trumpcare, Jack Conomy, MD, JD, FCLM
- Q&A Breakout Session IV

10:00 am - 11:50 am Dental Session V
Moderator: Bruce Seidberg, DDS, MScD, JD, FCLM, DABE, ACLM Past President

- Examining Legislative & Regulatory Framework Aimed at Redesigning Jamaican Oral Health System for Improving Access to Care Dean Irving McKennzie, DDS
- Appellate Decisions Concerning the Doctor - Patient Relationship Laurence Jerrold, DDS, JD, FCLM
- Employee or Independent Contractor: Categorizing Associate Dentists in the Dental Office Jennifer Sullivan, DMD, JD, FCLM
- The Dentist as an Expert Witness Frank Riccio, DDS, JD, FCLM
- Q&A Dental Session V

11:50 am - 1:15 pm CYRIL WECHT LUNCHEON
1:30 pm - 3:30 pm  Breakout Session V: Credentialing, Privileging and Peer Review
Moderator: Cyril Wecht, MD, JD, FCLM, DABE, Founder, ACLM Past President
- Process of Credentialing and Privileging Healthcare Providers Victoria Green, MD, JD, FCLM
- Negligent Credentialing and Corporate Responsibility/Liability John Busowski, MD, JD, FCLM
- Peer Review: Confidentiality; Discoverability; Admissibility; and Privilege Marvin H. Firestone MD JD FCLM
- Telemedicine Credentialing of Health Care Providers Michael Brooks, MD, JD, FCLM
- Q&A Breakout Session V

1:30 pm - 3:30 pm  Dental Session VI  Moderator: Kalu Ogubreke, DDS, JD, FCLM, DABE
- Forensic Dentistry Michael Kaner, DMD, JD
- Use of Patients for Dental Licensure Examinations Nicholas Panometros, DDS, JD, FCLM
- Use of Patients for Dental Licensure Examinations David Preble, DDS, JD, FCLM
- Q&A Dental Session VI

3:30 pm - 3:45 pm  Networking Break

3:45 pm - 5:00 pm  General Session II: Physician/Attorney Financial Planning, Business and Asset Protection
Moderator: Raymund King, MD, JD, FCLM
- Retirement and Asset Protection Trusts, Mark Monasky, MD, JD, FCLM
- Winding Up and Practice Transfers, Mark Monasky, MD, JD, FCLM
- Q&A General Session II

5:00 pm - 6:45 pm  Annual Meeting of the Fellows
7:00 pm - 7:30 pm  Networking Reception
7:30 pm - 9:15 pm  ANNUAL AWARDS BANQUET (Ethics credit)
Age Friendly Cities: Promoting, Health, Ethics and Justice
Presenter: Anabel Pelham, PhD

SUNDAY, FEBRUARY 25

7:00 am - 1:00 pm  Registration/Information Desk
7:00 am - 10:00 am  Poster Session
7:00 am - 9:30 am  Continental Breakfast
7:45 am - 9:30 am  General Session III: Hot Topics in Health Law and Legal Medicine  Moderator: Robert Bitonte, MD, JD, FCLM
- America Gone to Pot: The Medical Legal Impact of Recreational Marijuana Legalization Paul Blaylock, MD, JD, FCLM
- Top Regulatory and Billing Risks Facing Dentists and Dental Practices Robert Liles, JD
- Q&A General Session III

9:30 am - 10:30 am  General Session IV: Student Writing Awards  Moderator: Robert Buckman, PhD, FCLM, President, ACLM Foundation
(This Session made possible by an ACLM Foundation Grant.)
- Student Writing Awards -- Hirsch Award
- Student Writing Awards -- Orr Award
- Student Writing Awards -- Gene Basanta Poster Award

10:30 am - 10:45 am  Break
10:45 am – 12:30 pm  General Session V: Daubert at 25: Where Have We Come? Moderator: Leon Aussprung, MD, JD, FCLM
- Daubert and Expert Witnesses: A Historical Perspective Jack Snyder, MD, JD, FCLM
- Daubert: Plaintiff's Counsel's Perspective Francois Blaudeau, MD, JD, FCLM
- Daubert: Defense Counsel's Perspective Joe Piorkowski, MD, JD, FCLM
- Q&A General Session V

12:30 pm  Closing Remarks and Farewell Leon Aussprung, MD, JD, FCLM
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Marvin Firestone, MD, JD, FCLM
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<td>Daniel Orr, DDS, MD, JD, FCLM, DABE</td>
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<td>Thomas R. McLean, MD, MS, JD, FCLM</td>
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<td>* Rueben M. Dicker, MD, LLM, FCLM</td>
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<td>Thomas T. Noguchi, MD</td>
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<td>Matthias I. Okoye, MD, JD</td>
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<td>Dorothy Rasinski-Gregory, MD, JD, FCLM</td>
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The U.S. Anti-Vaccination Epidemic: Increasing the Acceptance of Vaccinations Without Risks to Patients’ Personal Autonomy

Emily Cline Arellano, BA; Sabrina Farboody; Jennifer Hunt; and Robert A. Bitonte, MD, MA, JD, LLM, FCLM

The Effectiveness of Organizations in Assisting Disadvantaged Groups to Reach Full Academic Potential

Robert A. Bitonte, MD, MA, JD, LLM, FCLM; and Michelle Gutierrez Harris, MHS

Full Disclosure of Economic Incentives Coincident with the Establishment of the Physician-Patient Relationship

Robert A. Bitonte, MD, MA, JD, LLM, FCLM; and Michelle Gutierrez Harris, MHS

Physicians’ Anti-Retaliation Statutes Need to Be Bolstered to Be More Effective

Robert A. Bitonte, MD, MA, JD, LLM, FCLM; and Michelle Gutierrez Harris, MHS

Physicians’ Duty to Perform Should Be Synchronized with Payors’ Duty to Provide and Pay for Medically Necessary Treatment

Robert A. Bitonte, MD, MA, JD, LLM, FCLM; and Michelle Gutierrez Harris, MHS

Reconciling Opiate Guidelines in the State of California

Robert A. Bitonte, MD, MA, JD, LLM, FCLM; and Michelle Gutierrez Harris, MHS

Social Security Disability (SSI & SSI) and Homelessness: A Proposal for a Mobile Disability Determination Services Division (MDDSD)

Martin J. Boyle, JD; Karin W. Zucker, MA, JD, LLM, FCLM; and Joseph R. Yancey, LTC, MC, USA, MD, FAAFP, MHA/MBA administrative resident

Where Are We on Physician-Assisted Death in the United States?

Mollie F. Christiansen, CPT, AN, USA, BSN, RN, MHA/MBA student; and Karin W. Zucker, MA, JD, LLM, FCLM

Legal and Ethical Implications of the Concierge Primary Care Practice Model

John Daniels, JD, DO, MBA, MPH, MT (ASCP), DABP, FACP

100 Years of Blood Banking: How Many More Years Before a Long Lasting Artificial Blood Substitute is Available?
Marisa De Santo, MS-1; and Robert A. Bitonte, MD, MA, JD, LLM, FCLM

**State Mandated Waiting Times for Pregnancy Termination and the Resulting Burden to Women**

Michelle Gutierrez Harris, MHS; and Robert A. Bitonte, MD, MA, JD, LLM, FCLM

**Understanding the Link Between Rape and Poor Physical Health**

Veronica Kot, MBS candidate; Ashley Remeza; and Thomas Bojko, MD, MS, JD, FCLM

**Medical Effectiveness and Potential Legal Implications of Robotic-Assisted Devices in Rehabilitation and Gait Training in Patients with Paraplegia**

Jonathan D. Levenson, LCDR, NC, USN, BSN, MHA, RN; Joseph L. Taylor, CDR (Ret.), NC, USN, BSN, MHA, RN, FACHE; and Karin W. Zucker, MA, JD, LLM, FCLM

**Request for Religious Accommodation in the Inpatient Environment: What Are the Employee’s Rights to Exercise Sincerely Held Religious Beliefs?**

Lauren E. Masters and Robert A. Bitonte, MD, MA, JD, FCLM

**Military Sexual Assault: Damaging Physical, as Well as Mental Health, and in Need of Continued Research and Awareness**

Kim Meathrel, MD, FRCSC, JD candidate

**Cosmetic Genital Surgery Is Conceptually the Same as Female Genital Mutilation and Should be Criminalized**

Kim Meathrel, MD, FRCSC, JD candidate; and Eric Knutsen, BA, JD, LLM

**The Development of a Competency Based Medico-Legal Curriculum for Residents**

Kim Meathrel, MD, FRCSC, JD candidate

**Physician Self-Regulation: Conceptualization of the Legal Sphere of Influence of Professional Regulatory Bodies**

Kim Meathrel, MD, FRCSC, JD candidate; and Eric Knutsen, BA, JD, LLM

**Public Authority - Based Enterprise Liability: A Proposal for Malpractice Reform**

Kim Meathrel, MD, FRCSC, JD candidate

**Tort Law and Naturopaths: The Need to Litigate for Patient Safety**
Ashley Remeza and Thomas Bojko, MD, MS, JD, FCLM  
**Legal Implications of Cyber Security Failures in Healthcare Institutions**

Kimberly C. Salazar, LTC, MC, USA, MD, MHA/MBA student; and Karin W. Zucker, MA, JD, LLM, FCLM  
**Legal Implications of the United States Opioid Epidemic**

Kathryn M. Stewart, CDR, NC, USN, BSN, CPNP-AC, CNS, RN, MHA student; and Karin W. Zucker, MA, JD, LLM, FCLM  
**Implications and Effects of Nurse Practitioner Clinics**

Aaron Zohar-Bondar, MBS candidate; Ashley Remeza; and Thomas Bojko, MD, MS, JD, FCLM  
**Application of Motion-Sensing Depth-Cameras for Use in Rehabilitation Following Orthopedic Surgery and Potential Legal Implications**

Karin W. Zucker, MA, JD, LLM, FCLM; Jason D. Unsworth, CH, LTC, USA, M.Div., MBE, BCC; Martin J. Boyle, JD; Harris A. Abbasi, MAJ, MSC, OD, MHA administrative resident; Laura T. McMullen, CDR, NC, MHA student; and Travis L. Robbins, MAJ, SP, USA, DPT, MHA/MBA administrative resident  
**The Book Club: A New, Medical Humanities Course in the Army – Baylor Graduate Program in Health and Business Administration**

Karin W. Zucker, MA, JD, LLM, FCLM; Douglas C. Swift, CH, LTC, USA, MA, MS, MTS; and Martin J. Boyle, JD  
**Cultural Considerations: Saints Preserve Us!**

I thank my colleagues (C. Scott Kruse, PhD; R. Reyn Price, PhD; and Michael Wegner, MHA) who assisted me in formatting and editing these abstracts. Any errors are mine.  
Karin W. Zucker
The U.S. Anti-Vaccination Epidemic: Increasing the Acceptance of Vaccinations Without Risks to Patients' Personal Autonomy

Many families fear to have their children immunized. These fears seem to be associated with an alarming decrease in vaccination rates. In spite of sincere efforts, physicians have failed to persuade these vaccination-hesitant (VH) families to accept the recommended immunizations. Thus, the vaccination goals in the United States have not been realized. Without effective enforcement of immunization laws and without some new approach, this situation may not improve. The anti-vaccination surge developed after the public became complacent about infectious diseases that could be prevented by vaccines. This grew as misinformation about vaccinations spread. With a goal of improving vaccination rates, the authors explore a few ethical limits for immunization providers. Meeting population goals for improved vaccination...
rates, without abridging some essential human dignity/free-will, requires patients to give their informed consents. In this context the authors reviewed the National Committee for Quality Assurance's (NCQA) vaccination risk-selection incentive, which may actually motivate doctors to remove families from their patient rosters if they refuse vaccination. The authors ask that the NCQA modify its current vaccination rate ratio by adopting methods that recognize distinct patient cohorts. Further, there must be an educational program which corrects the public's misinformation about the serious risk of infectious diseases and the minimal risks associated with immunizations.
Emilia Cline Arellano, BA; Health Education Program, CruzMed Foundation, Santa Cruz, CA; E-mail - 5210plus@cruzmed.org
Sabrina Farboody, University of California, Irvine, CA
E-mail - sfarbood@uci.edu
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The Effectiveness of Organizations in Assisting Disadvantaged Groups to Reach Full Academic Potential

Special interest societies and groups have been used to provide confidence and instill pride in some populations that are less advantaged than others in American society. These support networks are sustained in the belief that they result in the increased likelihood of disadvantaged individuals reaching their full academic potential.

Despite the stereotypical belief that opportunity for higher education for all classes is equal, socioeconomic theory demonstrates that this is not truly the case. Ethically, it would seem just that all should be given equal opportunities, but it becomes apparent that greater social standing within society provides more resources for one to succeed. Socio-economic theorists suggest that being in a higher social class provides a greater opportunity for personal success,1, 2 often demonstrated by easy access to institutions of higher education.3, 4 However, well-run social organizations in poorer communities can create a positive influence toward success by challenging the social barriers that disadvantaged communities face, such as a lack of access to institutions of higher education.

Earlier socio-ecological studies showed that organizations are effective in representing disadvantaged communities. Foundations have been created to help communities gain individuals access to higher education, thus, allowing them to succeed in obtaining their chosen professions.

In 2002, the California Medical Association (CMA) created the subgroup, Network of Ethnic Physicians Organization (NEPO), whose mission statement tells us that it was—
designed to build the capacity of ethnic physician organizations and physicians serving safety-net populations in order to reduce health disparities, improve access to health care for their communities and address diversity and cultural competency in the healthcare workforce.5

The Network provides support by awarding grants and scholarships as well as hosting summits where physicians and students coming from underprivileged communities may meet.6 These types of organizations help students to complete their scholastic requirements regardless of socio-economics. They are effective at promoting academic achievement in disadvantaged groups.

In his ethnography, *Tally’s Corner: A Study of Negro Streetcorner Men*, Elliot Liebow describes an underprivileged community that did not wait for a government agency or political leader to aid its citizens, but used the limited resources it had to provide its own positive influence within their society. The men on this street corner have "[promoted] their own self interests, just as other ethnic and religious groups and the working class have done before them." NEPO has the same goals –to initiate a better future within its society.

We encourage the formation of special interest groups for disadvantaged students, as such groups promote the students' interests as legitimate and their academic goals as achievable and pride worthy.

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Full Disclosure of Economic Incentives Coincident with the Establishment of the Physician-Patient Relationship

Economic incentives are a reality and a powerful force in human behavior. The provision of medical care is influenced by these economic incentives just as any other market place.

The realization by the public that economic incentives often have a great impact on the care they are receiving has caused some loss of trust in the medical profession and the American physician, MD or DO.1, 2

These economic incentives can generate behavior to do more medical procedures or provide more services, or withhold medical procedures or services, or do studies that can generate economic gain.

In response to these concerns, the California Legislature has enacted statutes to protect the public from economic incentives that could impact their medical care. In addition, the California courts have rendered judicial findings designed to protect the public from certain economic incentives regarding the provision of medical care. Examples are:

CA Health & Safety Code 1367 (g) indicates "The plan shall have the organizational and administrative capacity to provide services to subscribers and enrollees. The plan shall be able to demonstrate to the department that medical decisions are rendered by qualified medical providers, unhindered by fiscal and administrative management." This statute is aimed primarily at health plans. Moore v. Regents of the University of CA, 51 Cal. 3rd 120 (1990), stated "a physician who is seeking a patient’s consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient’s informed consent,
disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect his medical judgment.”  

3 This fiduciary duty attached to the physician after the physician-patient relationship had been established. Statutes and judicial court findings regarding economic incentives almost always are in effect after the physician-patient relationship has been established.

It is imperative to restore confidence in the physician-patient relationship. Therefore, we recommend that the legislature make it the affirmative duty of physicians to disclose any and all financial incentives regarding the provision of healthcare by a physician coincident with the establishment of the physician-patient relationship.

Reconciling Opiate Guidelines in the State of California

There has been significant attention brought to the medical community and the public regarding opiate abuse and accidental overdose deaths secondary to opiates. "More than 40 people die every day from overdose involving prescription opioids. Since 1999, there have been over 165,000 deaths from overdose related to prescription opioids. 4.3 million Americans engaged in non-medical use of prescription opioids in the last month."¹

Regardless, there are inconsistent California State statutes and guidelines affecting both the public and medical practitioners regarding the prescribing, and requesting, of opiates.

California Health and Safety Code, Pain Patient’s Bill of Rights, enacted in 1997, 124960 (h) states "A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her pain."² In addition, 124961 (a) states "A patient who suffers from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her pain."³ The conflict occurs if the patient rejects the use of any or all other modalities, the physician then has severely reduced options for pain relief, and this increases the risk for the allegation of inadequate care.

Contrarily, the 2017, Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain, on its cover page, under Clinical Reminders, states "Opioids are not the first-line or routine therapy for chronic pain."⁴
In addition, CDC Guidelines for Prescribing Opiates for Chronic Pain—United States, 2016 states:

Determining when to initiate or continue opioids for chronic pain. Nonpharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.  

This is a conflict with California Health and Safety Code 124960-124961 which allows patients to reject all other modalities for treating pain.

Obviously, these CDC guidelines and the California Health and Safety Code, Pain Patient’s Bill of Rights are at odds. If patients can refuse and reject any and all other modalities, the physician options to relieve pain are limited. This may also lead to an allegation of inadequate care. Therefore, we recommend reconciling the laws of California and CDC Guidelines to give clear guidance to patients and physicians about the preferred opiate use and a patient’s right to request opiates in the alternative to other treatments.

3 ibid 2
Physicians’ Anti-Retaliation Statutes
Need to Be Bolstered to Be More Effective

There are at least two current statutes in California that are intended to encourage physicians to advocate for medically appropriate healthcare for his or her patients. The first statute was enacted pursuant to Wickline v. State of California, 239 Cal.Rptr. 810 (1986). In this case, the court found that physicians were reluctant to advocate for medically necessary care for fear of retaliation by payors, specifically government payors. In response to this finding, the legislature enacted California Business and Professions Code 2056. This statute specifically states "b) it is the public policy of the State of California that a physician and surgeon be encouraged to advocate for medically appropriate health care for his or her patients." Intended to protect and encourage physician advocacy, it has been used effectively in court cases, specifically in Nordella v. Blue Cross and Blue Shield of California, 130 S. Ct. 257 (2009).

California Health and Safety Code 1278.5 "(a) The Legislature finds and declares that it is the public policy of the State of California to encourage patients, nurses, members of the medical staff, and other health care workers to notify government entities of suspected unsafe patient care and conditions...."

This statute has additional benefits, such that –
(g) A member of the medical staff who has been discriminated against pursuant to this section shall be entitled to reinstatement, reimbursement for lost income resulting from any change in the terms or conditions of his or her privileges caused by the acts of the facility or the entity that owns or operates a health facility or any other health facility that is owned or operated by that entity, and the legal costs associated with pursuing the case, or to any remedy deemed warranted by the court pursuant to this chapter or any other applicable provision of statutory or common law.

While these statutes do provide protection and have been utilized effectively in the past, the remedies of the reinstatement and the recovery of lost income will probably not be enough to encourage physicians’ advocacy for the provision of medically necessary care for their patients. To return a physician to his previous employment and award him lost income is not likely to encourage advocacy behavior when one is looking at years of litigation, time lost, and the psychological stress of court proceedings.

We recommend legislation that enhances physicians’ courage in advocating for medically necessary care. This would incorporate the amendment of California Business and Profession code 2056 to include statutory attorney fees and minimum punitive damages, as well as compensatory damages. We also recommend that California Health and Safety 1278.5 be amended to add minimum punitive damages as well as the remedies that are already stated in the statute.

We feel such changes will encourage physician advocacy and will also make retaliation less likely because of the potential of enhanced remedies.
Physicians’ Duty to Perform Should Be Synchronized with Payors’ Duty to Provide and Pay for Medically Necessary Services

Physicians have a duty to perform at a certain expectation. This expectation is articulated in California Jury Instruction CACI 502, 2017, which states—

A [type of medical specialist] is negligent if [he/she] fails to use the level of skill, knowledge, and care in diagnosis and treatment that other reasonably careful [type of specialist] would use in similar circumstances. This level of skill, knowledge, and care is sometimes referred to as the standard of care.

Presumably, this requirement mandates services and diagnostics that are medically necessary services.

CA Civil Code 3428 (a) mandates "For services rendered on or after January 1, 2001, a health care service plan or managed care entity. . . shall have a duty of ordinary care to arrange for the provision of medically necessary health care service to its subscribers and enrollees…"

Problematic is the finding that medical necessity has different definitions for government and for private payors. For example, California law in the Medicaid program is defined in CA Welfare and Institution Code 14059.5 which states "A service is medically necessary or is a medical necessity when it is reasonable and necessary to protect life to prevent significant illness or significant disability, or to alleviate severe pain," Another example is from the Settlement with Private Insurance Companies (Aetna, CIGNA, Health Net, Prudential, WellPoint/Anthem, and Humana) which was part of the RICO Cases of the mid-2000s. This states—

Medically Necessary or Medical Necessity shall mean health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing,
evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: a) in accordance with generally accepted standards of medical practice; b) clinically appropriate, in terms of type, frequency, extent, site, and duration, and considered effective for the patient’s illness, injury or disease; and c) not primarily for the convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

These definitions are certainly more verbose than the physician's duty cited above and could lead to much discussion about what is medically necessary. California Supreme Court Case, Sarchett v. Blue Shield of California, 729 P.2d 267 (1987), found "there will be few cases in which the physician's judgment is so plainly unreasonable, or contrary to good medical practice, that coverage will be refused."

CA Jury Instruction CACI 502 and Sarchett v. Blue Shield (1987), above, both demand reasonableness on the part of the physician and conformity with good medical practice (community standard).

We recommend that all payors’ (government and private) definitions of medical necessity be reconciled to coincide with the physician’s duty to perform; which is the provision of recommendations for reasonable services made by a competent physician reflecting community standards under similar circumstances. This definition would also be consistent with Sarchett v. Blue Shield of California (1987) which requires payors to provide and pay for reasonably necessary care and treatment consistent with community standards.
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Social Security Disability (SSDI & SSI) and Homelessness: A Proposal for a Mobile Disability Determination Services Division (MDDSD)

Background

In the United States, the federal "social welfare" program is administered through the Social Security Administration (SSA) Disability program. This is specifically known as Social Security Disability (SSD) Insurance (SSDI) if you have worked previously; and Supplemental Security Income (SSI), if you never worked or have always made below the "substantial gainful activity" (SGA) threshold, perhaps due to "medical determinable impairment." Both programs are for individuals, who in their current status, make less than the SGA amount which changes from year to year, depending on the economy. Adverse situational issues such as homelessness, dire need, military injury (physical or mental/emotional) are considered, but oftentimes cases are adjudicated on the basis of the individual's objective "medical evidence of record" (MER).

The image of American homelessness in 2016 is devastating: "On a single night . . . 549,928 people experience homelessness. 39,471 veterans are homeless. Nearly 97% were homeless in households without children. 77,486 individuals and 8,646 people in families with children have chronic patterns of homelessness. There are 35,686 unaccompanied homeless youth, 89% are between the ages of 18-24; the remaining 11% were unaccompanied children under the age of 18." ¹ In the City of Los Angeles, CA, in 2017, there were 34,189 homeless people, 33% of those with serious mental illness.² Many of those applying for SSDI or SSI are facing homelessness. This population unfortunately has the least access to resources—food and shelter, and transportation, ability to receive mail, access to a phone, and access to physical and mental health treatment as well as long-term care. Often times, the homeless are subjected to mental health problems that can disrupt their ability to obtain help in the application process.
Current Efforts

The Commission on Disability of the City of Los Angeles recommended that Social Security reach out to the homeless population in an expanded manner. Current efforts include a program called SSDI/SSI Outreach Access and Recovery (SOAR) in which SSA trains non-profit organizations to assist the homeless in completing the applications for Social Security benefits. County Health Department non-profits called County-wide Benefits Service Teams (CBESTs) whose personnel receive training from SOAR also assist the homeless in completing applications for Social Security benefits and in submitting these applications to the SSA. Also, Disability Evaluation Analysts (DEAs) and Medical Consultants (MCs) take homelessness into account when making a medical decision about each claim.

Recommendations

The SSA and State Social Services program can do more to combat the homelessness epidemic. Currently, it can take many months to process SSDI/SSI applications. The application process is dependent on physical exams, radiographs, pathology reports, treating notes, and so forth from medical providers. These often take a long time to obtain. Further, the program is adverse for individuals who do not have access to a treating provider, long-term medical care, or any transportation to obtain these services, despite the opportunity for individuals who apply to go to a Consultative Exam (CE).

We propose a "mobile SSD office" complete with a SSA agent, DEA, physical MC, mental health MC, phlebotomist, and radiographic technician along with radiologic equipment. Essentially, the SSA agent and the DEA can work on case processing; while the MCs can perform CEs and interpret radiographs and labs and address other problems presented by the homeless. Even if labs and imaging need to be completed, it should take no longer than 3 days to have a completed application. This mobile SSD office could be situated in cities that have a high proportion of homeless individuals and would decrease processing time immensely; SSDI and/or SSI decisions could be made in a near instant. If such claims were granted, individuals could use their benefit to end their homelessness.

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Where Are We on Physician-Assisted Death in the United States?

More than 10 years ago, in January of 2006, the United States Supreme Court upheld Oregon’s Death with Dignity Act, in the face of a challenge by the federal government, *Gonzales v. Oregon*, 546 U.S. 243. Now, five additional states (Washington, 2009; Montana, 2011; Vermont, 2013; Colorado, and California, 2016) and the District of Columbia, 2016, effective in 2017, have joined Oregon in permitting physician-assisted death. This poster reviews the law --statutes in the States of Oregon, Washington, Vermont, Colorado, and California, as well as in the District of Columbia; and case law in the State of Montana. It notes that while no new states were added to the list of those permitting physician-assisted death in 2017, the issue has not gone away; 27 states considered such legislation. This poster also addresses the Assisted Suicide Funding Restriction Act of 1997, 42 U.S.C. §14401 et seq., which limits physician-assisted death by prohibiting the use of federal funds and/or federal facilities and the participation of federal personnel when acting within the scope of their federal employment; *Gonzales v. Oregon*, 546 U.S. 243 (2006); and the Centers for Medicare and Medicaid Rules, 2015, effective in 2016, which permit payment of physicians for end-of-life counseling.

(Complete references are available upon request.)

The Operations Security Officer and the Public Affairs Officer, US Army Medical Department and School, Ft. Sam Houston, Texas, have approved this abstract (and poster) for general release. The views expressed are those of the authors only.
Legal and Ethical Implications of the Concierge Primary Care Practice Model

Background

In an ever-evolving healthcare landscape, primary care providers are being held more accountable than ever before by third-party payers to provide high-quality care while managing costs. At the same time, these providers are being overburdened with administrative tasks required by this system. Primary care physicians all over the United States are becoming more and more frustrated with "paperwork, low reimbursement and restrictions on time spent with patients," (Doherty, 2015, p. 915), and instead are testing the waters of direct payment systems, including concierge care. On the demand side, consumers are becoming more engaged in their own healthcare, and, therefore, providers will need to continue to increase quality to remain competitive in the healthcare marketplace. One growing trend in primary care is the concierge care practice model. Rather than working through a third-party payer, concierge care allows a direct financial relationship between the patient and the provider.

Restructuring traditional primary care practice to a direct payment model has shown positive impact on both patient and provider satisfaction, while also decreasing costs to providers. From under the "direct payment" umbrella, many innovative practice models have emerged. These include 100% direct payment models, hybrid models (a mix of direct care and traditional insurance), online or telehealth models, and direct relationships with employers or labor unions, to name a few. However, the long term legal and ethical implications of the expansion of direct payment, concierge, and hybrid models are yet to be determined.
Legal Implications

While the concierge practice model may seem simple to implement, there are legal considerations that need to be examined. First, physicians who choose to transition from a traditional model to a concierge model should be concerned about possible patient abandonment, if the transition is not accomplished in an open and equitable manner (Dalen, 2017, p. 881). Another concern is the potential for overlap when using a hybrid concierge model. Providers must closely look at the services they are providing and ensure that they are following all guidance put out by the Centers for Medicare and Medicaid Services (Cascardo, 2014).

Finally, it is important for providers to know the specific laws in their state regarding the use of Health Savings Account (HSA) funds for concierge care fees, as laws vary by state (Childs, 2015). However, there is evidence that this may be changing. Proposed national legislation, the Primary Care Enhancement Act, would make monthly fees HSA-approved (Huff, 2015). Until national legislation is passed, it is essential that providers stay up to date on their current state law.

Ethical Implications

Perhaps one of the most commonly cited criticisms of concierge care is the idea that direct payment primary care will create a two-tier system, offering higher quality and access to those who can afford to pay (Huff, 2015). However, concierge medicine is not just for the wealthy. Many concierge plans cost as low as $100/month (or $1,200 annually); however, others can cost up to $80,000/per year (Cascardo, 2014). With monthly premium costs for traditional insurance rising every year, many Americans may not be able to afford the premiums for traditional insurance, but they might well afford primary care and preventative services for a modest monthly amount.

(Complete references furnished upon request.)

The Operations Security Officer and the Public Affairs Officer, US Army Medical Department and School, Ft. Sam Houston, Texas, have approved this abstract (and poster) for general release. The views expressed are those of the authors only.
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100 Years of Blood Banking: How Many More Years Before a Long Lasting Artificial Blood Substitute Is Available?

In November 1917, Captain Oswald Robertson, U.S. Army Medical Officer Reserve Corps, built the world’s first "blood depot" – the precursor of the modern blood bank. This collection system, using sodium citrate as an anticoagulant, was put to the test in the Battle of Cambrai, France, on the Western Front during the "Great War." Approximately two cups of whole blood were collected from relatively healthy soldiers with type O blood and stored in glass containers on sawdust and ice. During the battle, Captain Robertson used 22 bottles of donor blood to resuscitate 20 wounded soldiers triaged as too deeply in shock to tolerate surgery; nine of the soldiers survived their wounds. By the end of the war in 1918, approximately 30,000 soldiers had received blood transfusions with historians describing transfusion as the most important medical advance of the Great War.

After the war, in 1930, the Soviets were the first to establish a network of facilities to collect and store blood for use in transfusions in hospitals. The term "blood bank" was first coined by Dr. Bernard Fantus of Chicago’s Cook County Hospital in 1937, and he is often credited with establishing the world’s first blood bank. Dr. Fantus’ blood bank allowed whole blood to be stored for an unprecedented 10 days inside the hospital. Whole blood can now be stored up to 35 days with current technology, and packed red blood cells can be stored up to 42 days if the whole blood is separated into its components, i.e., packed red blood cells, plasma, and platelets.
Issues involving the use of biological blood include risks of disease transmission and immune suppression, chronic blood donor shortages, and religious objections of certain groups to receiving transfused blood. To address some of these concerns, research has been done on creating a blood substitute or "artificial blood." Two broad categories of blood substitutes have been developed: perfluorocarbon-based oxygen carriers (PFOC) and hemoglobin-based oxygen carriers (HBOC). The first oxygen-carrying blood substitute (Fluosol-DA20) was approved by the FDA in 1989, but was withdrawn in 1994 because of side effects and limited benefits. Fluosol remains the only FDA fully approved oxygen therapeutic. By 2001, the first hemoglobin-based blood substitute, Hemopure, was approved for Phase III trial (for elective orthopedic surgery) in the U.S. and more widely approved for human use in South Africa. In December 2003, a new HBOC, PolyHeme, was used in field tests in a Phase III trial on emergency trauma patients. This trial closed in 2006 with results suggesting PolyHeme is more likely to trigger adverse effects than biological blood, and so it was not pursued. In 2011, Luc Douay of the Universite Pierre et Marie Curie in Paris proved the concept of creating artificial blood from hematopoietic stem cells was possible and, in 2013, the Indian Institute of Technology - Madras, India, was approved to mass-produce stem-cell-derived artificial blood. Most recently in 2015, Marc Turner at the University of Edinburgh produced blood from induced pluripotent stem cells (iPS) with the hopes of a limitless supply of type-O, disease free, red blood cells able to be transfused into anyone. However, none of these discoveries can yet fulfill the annual need of five million Americans who require blood transfusions.

Given all of the advances in artificial blood product production, the quest for blood substitutes remains unsuccessful. There are still many scientific barriers, as well as federal regulatory requirements, and, lastly, social apprehension, to overcome in order to provide a safe, efficacious, long-lasting blood substitute. Hopefully, this will not take 100 years to see fruition.
State Mandated Waiting Times for Pregnancy Termination and the Resulting Burden to Women

Legislation varies state to state regarding pregnancy termination and the precautions/tests, waiting periods, and counseling associated with the care of each patient. Currently, the majority of states in the US (26 specifically) require a waiting period of a minimum of 18 hours to receive a pregnancy termination after initial counseling, although a requirement of 72 hours is the maximum waiting time after initial counseling. Further, there are 14 states which require a minimum of two clinic visits for in-person counseling prior to an abortion procedure. Many states have a combination of these two restrictions, which could push these procedures past the minimum waiting time. Collectively, these restrictions are a roadblock to safe and fair access to pregnancy termination and take little account of women’s ability to travel or to the constraints of their employment. Moreover, any delay in treatment causes increased risk to the patient (Castadot, 1986). Any “undue burden” to a woman is unlawful and unacceptable, Rust v. Sullivan, 500 U.S. 173 (1991). We propose that these waiting times be reconsidered to ensure fair access and decreased risk to pregnancy termination for those women who have made an informed decision.

Reference

Understanding the Link Between Rape and Poor Physical Health

Background

Rape is a phenomenon that is prevalent in the United States today and the awareness of this behavior has skyrocketed. "Every 98 seconds, an American is sexually assaulted," specifically, "on average there is [sic] 321,500 victims (age 12 & older) of rape and sexual assault each year in the United States." The majority of these rape victims are under 30. One out of every 6 women has been victimized due to attempted or completed rape in the U.S. According to the FBI Uniform Crime Report (UCR) program definition, rape is defined as the "carnal knowledge of a female forcibly and against her will." This definition was revised in 2013 to describe "penetration, no matter how slight, of the vagina or anus with any body part or object, or oral penetration of a sex organ of another person, without consent of the victim." Attempts or assaults to commit rape are also included; however statutory rape and incest are excluded. The mental sequelae of this unconsented to physical intrusion is commonly appreciated, discussed, and studied. This inquiry, however, focuses on the physical manifestations of rape, their recognition, reporting, and follow-up. We then propose some recommendations regarding this aspect of rape.

Current Research

A simple Medline search of "rape victims' health" would showcase a multitude of articles focusing on rape victims' mental health. Poorly documented, and under highlighted, in medical literature and legislation is the recognition of the long-term physical health consequences that are caused by rape. Rape victims, in particular those with mental health disorders, show a high correlation for physical health problems and in general, poor overall health status. Sexual assault and rape are known to have long-term, broad reaching effects on health; specifically being linked to heart disease, obesity, hypertension, diabetes, gynecological problems, musculoskeletal problems and much more. Poor self-rated health was reported by 11.4% of a sample of 3001 American women; though subjective, this can provide insight into their health status. There is limited current literature documenting the long term physical affects of rape, and little literature indicating long term series studying this issue. Moreover,
more literature was found regarding the cost of rape than of its long term physical sequelae of rape. The more severe the mental difficulties encountered by the rape victims, the stronger the correlation with adverse physical consequence. Few long term studies focus on the overall physical well being of rape victims independent of their mental difficulties.

Recommendations

1) Funding and public awareness of the physical health issues of rape victims needs to be highlighted and expanded.
2) Standardized protocols and treatment plans need to be established at the onset of care of rape victims, to ensure adequate care and follow-up.
3) Enhanced education about this issue needs to be provided to medical students early in their medical training, as well as during post-graduate training.
4) Long term data need to be collected from standardized protocols and care plans to allow for modification of treatment recommendations for ongoing care. In addition, this long term data collection should encourage and propel legislation regarding the overall physical well being of rape victims.
5) Legislation, such as California Health and Safety Codes, needs to be amended to include a mandate consistent with monitoring and treating the physical, as well as mental, conditions of rape victims.

5 Supra note 4.
7 Supra note 6.
Medical Effectiveness and Potential Legal Implications of Robotic-Assisted Devices in Rehabilitation and Gait Training in Patients with Paraplegia

As technological advances in medicine continue their rapid evolution, the use of robotic exoskeletons has become an increasingly prominent feature in physical rehabilitation centers across the United States. Patients experiencing impaired movement caused by stroke, traumatic brain and spinal cord injuries, and muscular disorders are turning to robotic-assisted device therapy in hopes of improving their recovery outcomes over conventional therapies. This new wave of alternative therapies include direct transcranial magnetic electrostimulation and robotic-assisted exoskeletons, specific for gait training, that can be self-guided or assisted. Though these technologies are still being tested for reliability and safety, early results show they are potentially superior to traditional therapy.¹

Cases vary based on the type of injury sustained, length of time the patient has been injured and paralyzed, and the location of the paralysis (paraplegia, tetraplegia, etc.). With the recent application of robotic-assisted devices, there has been little discussion of the negative effects on the patient’s recovery,
supporting the idea that the use of this therapy may be a more effective method of rehabilitation. Ongoing studies comparing patients using conventional methods and those wearing exoskeletons are important in understanding the benefits that technology has to offer in today's medicine.

To date, studies have found that the recovery rates of patients utilizing electromechanical training devices are just as positive as those rates found in patients using conventional methods across most types of trauma. Despite this, however, there is much speculation as to the effectiveness of these devices as being superior to those conventional methods.

If studies continue to show promising results, the introduction of exoskeletons into medical practice is predicted to become an innovative - albeit costly - staple in mobility therapy. In such cases, robotic technologies will have significant implications on the results of litigation in cases involving impaired mobility, both in terms of potential injuries sustained during the use of robotic devices, and damages received by patients in loss of mobility cases. Further studies over extended periods of rehabilitation are necessary to determine the long-term benefits of robotics in therapy as well as the legal implications that they may have on the patient and provider.

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Request for Religious Accommodation in the Inpatient Environment: What Are an Employee’s Rights to Exercise Sincerely Held Religious Beliefs?

Consideration of religious accommodation of an employee’s religious observance or practice is a requirement placed on the employer by section 701 of Title VII of the Civil Rights Act of 1964. Once a request for accommodation is made, the employer must grant it or provide a reasonable compromise if the request will not cause an undue hardship on the conduct of the employer’s business. The literature and legal precedents regarding what actually constitutes an undue burden are vague at best. In Trans World Airlines, Inc v. Hardison, 432 U.S. 63 (1977), the US Supreme Court defined an accommodation hardship as anything more than de minimus cost or a cost that is too trivial to merit consideration. The Equal Employment Opportunity Commission further attempted to clarify undue burden by considering compromises in workplace safety, decreases in workplace efficiency, infringing on the rights of other employees, or requiring other employees to do more than their share of potential hazardous or burdensome work as undue burdens.
When considering the undue burden of an accommodation request, the decision whether to accommodate or not usual centers around the burden placed on the employer’s ability to operate efficiently, ultimately leading back to the impact on profit. The inpatient environment presents a unique challenge as the disruption of a unit’s operation directly impacts the safety and quality of care for the admitted patient. When a request for accommodation is for a permanent, weekly (Sabbath) adjustment to a relatively fixed schedule of 24-hour care on an inpatient unit, the patient’s rights must be carefully considered. Leonard Weber contends in his *Business Ethics in Healthcare*, 2001, that if one has a right to something, it is to say that "one can make a binding claim upon others" (p. 36). Since it is the patient’s right to safe, quality care while admitted to the hospital, whose individual right takes precedence, the employee's or the patient's? What about the employer's rights?

--Complete references are available on request.--

The views expressed here are those of the authors only and do not reflect the official policy of the Army – Baylor Graduate Program in Health and Business Administration, the Department of the Army, the Department of the Navy, the Department of Defense, or the United States Government.
Military Sexual Assault: Damaging Physical, as Well as Mental Health, and in Need of Continued Research and Awareness

Military sexual assault (MSA) is a term becoming more familiar to clinical investigators and the lay public. It means sexual assault on a member of the U.S. military. Recent statistical information shows a marked increase in reporting since the military began a definitive effort in surveying MSA.¹ Despite this effort, reporting of MSA has been limited, probably due to the fear of "retaliation, professional reprisal, ostracism and maltreatment."²

Sexual assault, whether a single attack or ongoing abuse, can have effects well beyond the documented mental effects. Nonetheless, there is a paucity of medical literature outlining the long-term physical health consequences of sexual assault in the military, as well as the civilian population. The shortage of studies regarding the long-term physical effects of sexual assault on males is particularly disturbing.

A study by Frayne et al. found that the most common physical issues plaguing the survivors of MSA, indicate increased risk of cardiovascular disease, thyroid disease, arthritis, breast cancer, future obstetrical consequences (such as hysterectomy), irritable bowel syndrome, frequent headaches, chronic fatigue, respiratory issues such as asthma, and peptic ulcer disease.³ Overall, however, there is a lack of long-term studies documenting the physical consequences of sexual assault, whether in the military or civilian environment.

Frayne et al. concluded that there is correlation between sexual assault and poor future physical health. Because of the unique military situation of a robust electronic health record, the ability to track and schedule patient follow-up visits, and expanded and considerable resources, the military can take a prominent position in following these long term physical consequences and making recommendations for their treatment and for prevention. This would be beneficial for the military and the civilian population as well. These long-term military medical studies and the recommendations that come forth from the studies will be useful for military medical educators, non-military medical educators, as well as the civilian population.

2 Ibid.

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Cosmetic Genital Surgery Is Conceptually the Same as Female Genital Mutilation and Should Be Criminalized

Cosmetic surgery is rapidly increasing in popularity and being sought out in rising numbers by youth in Canada, USA, UK, and Australia. The concept of cosmetic surgery was once taboo but has now become commonplace with reality TV shows and celebrities normalizing the practice in North America.

While the practice of body modifications is not unique to Western cultures, it is contentious. There is a great deal of debate in the feminist literature about the concept of cosmetic surgery, often framed in debates juxtaposing issues of consent, self-determination, and bodily integrity against the continued oppression of the patriarchy and its continued domination over the female body. The debate over cosmetic genital surgeries brings these issues to the forefront; further fueling the debate, is the assertion that Western female cosmetic genital surgeries are no different than female genital mutilation in terms of their respective societal roles and exist on the same continuum of domination of the female reproductive track and control of the female sexual capacity.

While female genital mutilation is illegal in Canada under Criminal Code § 268 (aggravated assault) there is no specific regulation of cosmetic genital surgeries. These surgeries are tacitly accepted as fulfillment of autonomous self-determination while overtly condemning female genital mutilation as barbaric.

On this poster, I will argue that cosmetic genital surgery is on the same scale conceptually as is female genital mutilation and should be interpreted as criminal under Section 268. Section 268(3), provides that "wounds" or "maims," in the definition of aggravated assault, includes "to excise, infibulate or mutilate, in whole or in part, the labia majora, labia minora or clitoris" and § 268(4),
consent is not valid unless the surgery is performed "for the benefit of the physical health of the person or for the purpose of that person having reproductive functions or normal sexual appearance or function" or "the person is at least 18 years of age and there is no resulting bodily harm." In the case of children undergoing cosmetic genital surgery, both parents and healthcare providers should be prosecuted criminally under these provisions. Additionally, § 268(3)(b), with regard to persons of adult years, should be repealed as arguments for autonomous choice fail under scrutiny from a perspective of feminist-relational-autonomy.

It is a generally accepted principle that in order to interpret a statute, the words of an Act are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament. In order to do so, I will first explore and define the practice of female cosmetic surgery and, then, female genital mutilation. Thereafter, I will then consider the history, object, and intent of the 1997 revisions to § 268 of the Criminal Code. I will then apply an understanding of the intent and object of § 268 to the legal and ethical concepts of autonomous consent from a perspective of relational autonomy and I will conclude that the current provision of cosmetic genital surgeries to girls under age 18 is aggravated assault under § 268, and I will support the repeal of § 268(3)(b). Finally, I will conclude with arguments for the social utility of prosecuting those who provide cosmetic genital surgeries to minors under § 268.
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The Development of a Competency Based Medico - Legal Curriculum for Residents

In 2017, Queen’s University moved into competency based residency programs for its postgraduate medical education model. Residency training is now tailored to meet specialty-specific core competencies in order to transition to practice, and residents will move through the curriculum at their own pace. The CanMeds 15 guidelines of the Royal College of Surgeons of Canada provide the outline for expectations of the practice of medicine in Canada, and residency training must be focused to achieve these expectations. The CanMeds 15 guidelines include expectations of professionalism training including accountability to professional regulatory authorities; commitment to patient safety, quality improvement, and professional standards; and medico-legal frameworks governing practice.

During clinical rotations there is often not time for discussions on professionalism in the practice of medicine. The focus of trainees and supervising faculty is on the acquisition of clinical skills, whereas the focus of boot camps, seminars, and rounds is on the acquisition of clinical knowledge. The professionalism aspects of training tend to not be overtly addressed, rather they are included as part of a "hidden curriculum." This project focuses on the recognition that training in professionalism is a necessary component of residency to address the CanMed 15 expectations. We address the specific components of medico-legal frameworks, professional standards, quality improvement, patient safety, and accountability. This project allows for inter-
professional teamwork, collaboration, and communication. Several authors have addressed the need for a dedicated medico-legal educational component for medical learners in order to bring the content out of the "hidden curriculum." Attempts at incorporating medico-legal content into residency curriculum have been made previously by physicians without lawyers, and trial simulation has been used by lawyers without physicians. To date, there are no publications on the creation of a medico-legal curriculum through the joint cooperation and expertise of a medical school faculty and a law school faculty.

We have created and tried a CanMeds 15 based medico-legal curriculum that was introduced into competency based residency training though the collaborative efforts of faculty of the Queen’s University Department of Surgery and the Faculty of Law. This collaborative curriculum is the first of its kind in Canada. On this poster, we outlined the curriculum, measured competencies, and documented resident-perceived need for this curriculum.
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**Physician Self-Regulation: Conceptualization of the Legal Sphere of Influence of Professional Regulatory Bodies**

Traditionally, self-regulation has been afforded to those members of society with complex bodies of knowledge and skills beyond the understanding of the average citizen or layman. This has its roots in medieval times when the first professionals, doctors, lawyers, and clergy (Roman Catholic priests who were theologians and university professors) were allowed to self-regulate. The fundamental principles of self-regulation of a profession include: agreed-upon standards for those entering the profession; the responsibility for teaching other professionals how to exercise the required standards on a day-to-day basis; and enforcement of those standards, including deciding when, and how, those who violate the standards would be disciplined. For physicians an added principle has been recognized --a set of moral values that guides and constrains physicians' behaviour including honesty, altruism, integrity, caring, confidentiality, and community focus. The process of self-regulation has been critiqued as having the possibility for both under-regulation and over-regulation. Under-regulation would lead to self-serving behavior and insulation of its members from the public through a lack of transparency and accountability.

In Ontario, Schedule 2 to the Regulated Health Professions Act sets out the structure, duty, and objectives of each of the self-regulating colleges with the colleges' mandate to serve the public interest, including investigating allegations of professional misconduct. The term "conduct unbecoming a physician" is not defined in the regulation but is a common finding, or judgement, in professional
misconduct hearings. The lack of clarify of definition leaves the term wide open to interpretation and application. This leads to the question of how far into a physician’s personal life can a college reach and when does a physician cease to be a physician and become a private citizen with privacy rights?

After reviewing case reports of disciplinary committees, I propose the Sphere of Influence Theory. I argue that the influence of the regulatory colleges over physician’s behaviour should be considered to be falling into four zones: The Zone of Core Power, The Zone of Justified Regulation, The Indeterminate Zone, and the Zone of Unjustified Infringement.

This poster develops the Sphere of Influence Theory as related to physician self-regulation and suggests a legal "bright line test" for Unjustified Infringement on a private citizen by regulatory bodies.
Public Authority - Based Enterprise Liability: A Proposal for Malpractice Reform

Introduction

Our current adversarial system of tort law does not recognize the new reality of the practice of medicine in Ontario. Physicians are functioning in a resource limited environment and are being actively told by their credentialing boards that practicing within the limitations of the system is their responsibility, while the courts hold that resource limitations are not an excuse for limitations on patient care. Bills 41 and 87, recently introduced by the Ontario government would impose further resource limitation and unprecedented intrusion into physician self-regulation.

In this paper, we propose changes to the current medical malpractice structure in Canada to recognize the reality of the fiscal constraints within which physicians are forced to make clinical decisions and the unprecedented levels of Ministry of Health intrusion into self-regulation.

Methods

A focus group of 110 practicing Ontario physicians was recruited to participate in the study.

An e-survey was designed to collect data in the following domains: personal demographics, physician's satisfaction with the Canadian Medical Protective Association (CMPA), physician’s perspective on current medical malpractice, physician's perspective on malpractice reform options, and the impact of government funding cuts on physician's medical practice and decision-making. Physicians were asked to answer a series of close-ended questions using a standard, 5-part Likert scale, and an open question was answered with free text answers. The data collected were analyzed using Microsoft Excel. The free text answers were analyzed by content analysis to develop themes within or among answers.
Results

Participants were from all areas of medical specialty and practice settings. Overall, the physicians were very happy with the function of the CMPA. 93% agreed the government should be liable for patient harm that occurs due to lack of resources, but only 65% agreed that hospitals should be held liable for patient harm that occurs due to lack of resources. 96% believed the government should be held liable for harm that occurred while patients are on wait lists. Only 11% of physicians agreed that they always have the resources they need to provide optimal care to their patients; 90% did not think they had the resources to make optimal care choices. 77% agreed government funding cuts have influenced their clinical decision-making due to lack of resources, 83% agreed that government funding cuts have negatively impacted the quality of care they can provide. 72% agreed or strongly agreed that they are often rushed and overbooked due to limited resources.

Discussion

The goal of enterprise liability is to shift the burden of responsibility onto the entity that can most efficiently effect change and respond to errors in the system. Given that a significant proportion of physicians feel their ability to meet standards of care is compromised by the policies of the current government, we propose a shift to a Local Health Integration Network - based enterprise liability model to enhance patient safety.
Tort Law and Naturopaths: The Need to Litigate for Patient Safety

Complementary and alternative medicine (CAM) is a term used to describe health care practices that are offered outside of the Western, or allopathic, mainstream of the evidence-based medical (EBM) establishment. It includes, but is not limited to chiropractic, massage therapy, naturopathy, homeopathy, acupuncture, and traditional Chinese medicine.

Canadians are seeking the services of CAM practitioners in growing numbers with the percentage of Canadians seeking the services of naturopaths nearly doubling between 1997 and 2016. According to the 2017 Fraser Institute report, as of 2016, 79% of Canadians had accessed some form of complementary or alternative care practitioner in their lifetime, with the highest incidence of usage in British Columbia and the lowest in Quebec. The most popular therapies were massage therapy and chiropractic care. Canadians spent 8.8 billion on CAM in 2016 with 6.5 billion going to providers and the remainder for the products and remedies they sell.

The use of these practitioners is increasing and it is big business, but unlike the situation for MDs, there is no mandatory reporting of injuries caused by products; the practitioners are generally working outside of the accountability mechanism of a hospital environment; and the regulation of the practitioners is inconsistent across the country.

No data exist from Canadian Naturopath Associations; however, the California Naturopathic Doctor Association reports no cases of injury since their association began licensing in 2005, although it is difficult to believe that no injuries have occurred. In fact, several recent high profile news stories in Canada have highlighted cases of injury caused by naturopathic practitioners, and multiple case reports have been published in the medical literature. A 2017 study in the *Journal of the National Cancer Institute*, clearly showed the harm occurring from rejection of evidence-based cancer therapy for CAM, with a statistically significant decrease in survival rates for those patients choosing CAM. Due to the inconsistent regulation and lack of any mechanism of centralized reporting, it is impossible to accurately determine the number of patients injured by these practitioners each year. A 2017 informal survey by the author of 112 Canadian MDs reported 182 cases of patients who had suffered
significant medical injury at the hands of alternative care practitioners, including chiropractors, naturopaths, and acupuncturists. The 182 patient injuries included 64 deaths, 57 significant permanent injuries (paralysis, brain injury, necessity for an organ transplant) and 44 patients salvaged by aggressive intervention using evidence-based medicine. These injuries appeared to disproportionately impact women and children, with 24 women dying of possibly curable breast cancer, 22 children suffering significant injury, and 3 who died after being denied standard treatment for cancer, asthma, diabetes, and allergies. This informal survey is in no way meant to be an accurate representation of the true number of injuries, and is likely a significant underestimation as the Fraser Institute report indicated that 58% of respondents had not discussed their CAM treatments with their MD. This is not to imply that evidence-based medicine has no errors; certainly we understand that there are systematic errors and practitioner-negligence occurs. However, mandatory reporting, consistent educational standards, in-house accountability systems in hospitals; and a cultural shift within evidence-based medicine are all serving to identify and address areas for improvement.

While the extent of the harm to patients coming from CAM therapies is unknown, it is undeniably happening and, with the growing numbers of Canadians seeking these therapies, it is imperative that patient safety initiatives in CAM are given paramount importance. Along with self-regulation, tort law has played a role in regulating the behavior and care provided by medical doctors through both general and specific deterrence. However, tort law alone offers compensation to patients who are injured by negligence.

On this poster, I will argue for an expanded role of tort law in the regulation of CAM practitioners. Because of the particularly rapid increase in Canadians seeking naturopathic care and the recent media reports focusing on deaths and injury by naturopathic practitioners, I will specifically argue for the need for negligence claims to control naturopaths and improve their patient safety by reviewing the current regulation of CAM practitioners in Canada and explaining why it is ineffective. Further, I will review the case law relating to chiropractic and its application to naturopaths and will explain why applying tort law will improve patient safety. I will also explore why naturopaths currently do not face litigation.
Legal Implications of Cyber Security Failures in Healthcare Institutions

Cyber security has become a top concern for hospitals and other entities of the healthcare continuum. In 2016 alone, the records of 16.6 million Americans were exposed due in large part to hacking. 2017 witnessed two major worldwide hacking events targeting hospital systems and other institutions. These attacks used ransomware, a type of malware that blocks access to a user's computer or data until a ransom is paid.

Patient records are particularly vulnerable to these attacks due to the "holy trinity" of information they contain: name, social security number, and date of birth, making them prime targets for identity theft and blackmail.¹ These records are sold on the dark web for ten times more than stolen credit card numbers, with a single Medicare or Medicaid Electronic Health Record fetching $500 or more.

Failing to prevent cyber attacks does not necessarily equate to liability under the Health Insurance Portability and Accountability Act (HIPAA), but if a hacked institution is found to have had insufficient protections in place, entities may face legal consequences, both under the Act and common law. In February of 2017, South Florida’s Memorial Healthcare System paid a $5.5 million settlement to the Department of Health and Human Services for potential violations of HIPAA when unauthorized users accessed patient information.
The number of healthcare institutions facing these fines is on the rise as HIPAA violations pertaining to Electronic Protected Health Information (e-PHI) are being more strictly enforced. While HIPAA does not provide the individual the right to sue in federal court, healthcare institutions face liability and damages should individuals choose to sue for invasion of privacy and/or breach of doctor-patient confidentiality in state courts. In such cases, HIPAA standards may be used to establish negligence.2

Healthcare institutions should conduct a risk analysis to ensure that e-PHI is not at risk and that all protocols meet HIPAA regulations.

Legal Implications of the United States Opioid Epidemic

Background

The opioid crisis has been escalating in the United States (U.S.) over the last two decades (The Opioid Therapy for Chronic Pain Work Group, 2017). More than 165,000 people in the U.S. died from opioid overdose between 1999 and 2014 (Dowell, Haegerich, & Chou, 2016). In 2015 alone, there were 52,404 opioid overdose deaths in the U.S., and preliminary data suggest that this increased by a staggering 19% in 2016, the largest annual increase ever recorded (Katz, 2017). To put this in perspective, "unintentional poisoning" or drug overdose has surpassed motor vehicle accidents as the leading cause of injury-related death in the U.S. (Kochanek, Murphy, Xu, & Tejada-Vera, 2016).

The growing problem with opioid misuse at least partially correlates with the timing of the release of The Joint Commission’s 2001 standards for pain management. These standards effectively made a patient’s pain level the "fifth vital sign" and many believe created unrealistic expectations that patients should have no pain, thus placing enormous pressure on providers to prescribe increasingly more opioids (Baker, 2017). Some suggest that the pharmaceutical companies seized the opportunity by funding pain management education programs and aggressively marketing to providers which further contributed to the opioid epidemic (Chhabra & Leikin, 2017).
Legal Implications

Pharmaceutical companies that manufacture prescription opioids provide a medication which has legitimate clinical indications for acute and end-of-life pain; however, concern has been raised about their business practices to include marketing their drugs as safe options for chronic pain. In May 2017, the state of Ohio filed a lawsuit against five pharmaceutical companies seeking to recover money the state has spent on the opioid prescriptions themselves through Medicaid as well as on addiction treatment (Perez-Pena, 2017). Multiple other States have followed suit to include Missouri, Florida, and Alaska. Furthermore, four cities in West Virginia filed a class-action lawsuit against the Joint Commission in November 2017, asserting that the healthcare accrediting body participated in a "widespread misinformation campaign" which resulted in over- and inappropriate prescription of opioids by medical providers (Rizzi, 2017).

Conclusion

The U.S. opioid epidemic is a complex issue which will require a multifaceted solution to bring about meaningful change. The pending, large lawsuits are seen as an important step in the fight against the opioid epidemic and have been likened to lawsuits brought against the tobacco industry in the 1990s which resulted in multi-billion dollar settlements. The outcome of the lawsuits has the potential to shed light on the roles the Joint Commission and drug makers played in the growing opioid crises and to hold them financially accountable, if appropriate. The resulting pay-out could provide critical funding for addiction treatment programs and other public health interventions that would finally help turn the tide in the battle against opioid addiction.

(Complete references available upon request.)

The Operations Security Officer and the Public Affairs Officer, US Army Medical Department and School, Ft. Sam Houston, Texas, have approved this abstract (and poster) for general release. The views expressed are those of the authors only.
Implications and Effects of Nurse Practitioner Clinics

The United States healthcare system is currently in disarray with an impending primary care physician shortage over the next decade. This deficit will result in widespread challenges to access, if not quality. The physician shortage is anticipated to be at a deficit of 66,000 by 2025 (Buerhaus, DesRoches, Dittus, and Donelan, 2015). In contrast to this startling statistic, registered nurses are flocking to graduate schools to become nurse practitioners. According to Auerbach (2012), the nurse practitioner population will increase by 94% from 2008 to 2025, with an anticipated 6,000-7,000 nurse practitioners graduating and joining the healthcare field annually. As research demonstrates that nurse practitioners produce quality health outcomes for a variety of patients, the natural assumption is that they can serve as one of the solutions to improve patient access.

Currently, 22 states and the District of Columbia allow nurse practitioners to function independently without a requirement for oversight by physicians. The other remaining states dictate some collaboration or supervision by a physician.
for the nurse practitioner to practice (Poghosyan & Carthon, 2017). This independence, along with the gaps in access to primary care across the country, has spurred a small percentage of nurse practitioners to enter the field and open their own clinics without physician supervision. These clinics may improve access to primary care and result in cost-savings across the United States healthcare system.

However, opening a nurse practitioner run clinic is not a simple feat, and consideration for perceptions, overall practice standards, quality of care, and limitations of practicing without a physician must be required. Controversy surrounds this topic as many physicians question whether these clinics will provide safe, quality care. Additional debate centers around scope of practice legislation as physicians argue that the more restrictive states protect patients, but advocates of nurse practitioners assert that the laws serve as anticompetitive restrictions to prevent competition for patients among physicians and nurse practitioners (McMichael, Safriet, & Buerhaus, 2017).

This poster will address research to determine whether nurse practitioner run clinics can effectively offer quality, legal, cost-effective care without placing patients at risk.

(Complete references are available upon request.)

The Operations Security Officer and the Public Affairs Officer, US Army Medical Department and School, Ft. Sam Houston, Texas, have approved this abstract (and poster) for general release. The views expressed are those of the authors only.
Application of Motion-Sensing Depth-Cameras for Use in Rehabilitation Following Orthopedic Surgery and Potential Legal Implications

The development of high quality 3D motion-sensing cameras has expanded technological capabilities in numerous fields including healthcare. The Microsoft Kinect, originally introduced as an accessory to the Xbox game console for interactive game-play, is a popular option for 3D cameras. Kinect is placed atop one’s TV set, and uses its advanced features to allow users to play games by simply moving their limbs rather than touching anything or using a controller.¹

In 2011, Microsoft released the Kinect Software Developing Kit (SDK), allowing their unique technology to expand beyond the confines of gaming, giving the Kinect new purpose in areas such as healthcare.

Reflexion Health Inc. has employed Kinect technology to develop the Virtual Exercise Rehabilitation Assistant (VERA). This technology is used to deliver prescription rehab exercises, measure patients’ movements/form, make functional assessments, and provide a dashboard for clinical review that displays the information and progress from home therapy sessions. It is now available at a reputable New England hospital as an option for patients who are
scheduled to have musculoskeletal surgery, and placed in patients’ homes for both pre- and post-op rehabilitation uses.²

The application of depth cameras has a promising future in rehabilitation therapy, though potential legal implications may arise from these technologies. They include: potential HIPAA violations when using a recording device in settings where sensitive information may be compromised and potential non-compliance with a therapy plan can result in lawsuits for negligence. Healthcare providers should carefully identify scenarios where the use of these cameras could put sensitive information or patient welfare at risk and examine ways to reduce such risks, thereby avoiding legal misconduct where possible.

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Cultural Considerations: Saints Preserve Us!

In 2014 and, at the request of the College President, again in 2017, we displayed a poster entitled Cultural Considerations: Heaven Help Us at the annual meeting. It looked at religion as an aspect of culture and at Roman Catholicism and the veneration of saints in particular. We examined the belief that many of our patient's have in the power of intercessory prayer and identified the patron saints of medical and paramedical personnel; for example, St. Luke is the patron saint of healers (and the ill) in general, while Saints Cosmas and Damien are the patron saints of pharmacists and Saints Appolonia and St. Antipas are the patron saints of dentists.

On this poster, we will examine, as we did before, one aspect of cultural awareness, religion –specifically, the belief that many of our patients hold in the intercession of saints or the power of intercessory prayer. We will look at the patron saints of the ill, the disabled, and the deformed. It is not unusual today for a provider to be asked to pray to his patron saint before intervening medically or surgically or to be asked by the patient if he or she may do so on the physician's behalf –last year's poster. It is probably even more common for patients and visitors to pray to the patron saint who is believed to be a special intervener for those suffering from the patient's illness or infirmity and for providers to be asked to pray to these saints (the subject of this year's poster) or to join in the prayers of others who are doing so.

Among those not familiar with the practice, this may seem to be confusing a saint with God, but it is not. We are not suggesting that you adopt this practice, only that you consider that many people do believe in it; and that the beliefs of others, specifically our patients, are due our respect. Many of the saints mentioned here are also recognized by individuals who are not Roman Catholics, but who are members of the Orthodox Churches or of the Churches of the Anglican Communion.
The section on Terminology and Explanation is little changed from the terminology section of Heaven Help Us. Specifically, we will examine some of the pertinent terminology (saint, canonization, Communion of Saints, intercession, patron saint), and we will then identify, by name and pictorial representation saints the Roman Catholic Church designates as patron saints of those suffering from particular diseases or conditions. In general, these are less well known that are the patron saints of medical or paramedical providers.

A Partial List of Patrons of Those Suffering from Particular Illnesses, Infirmitities, or Health Crises

<table>
<thead>
<tr>
<th>Illness</th>
<th>Patron</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>St. Peregrine Laziosi</td>
</tr>
<tr>
<td>alcoholism</td>
<td>St. Monica</td>
</tr>
<tr>
<td>barrenness/infertility</td>
<td>Our Lady of Lourdes</td>
</tr>
<tr>
<td>breast disease</td>
<td>St. Agatha</td>
</tr>
<tr>
<td>cancer</td>
<td>St. Peregrine Laziosi</td>
</tr>
<tr>
<td>the crippled</td>
<td>St. Leopold Mandic</td>
</tr>
<tr>
<td>deafness</td>
<td>St. Frances de Sales</td>
</tr>
<tr>
<td>dental problems</td>
<td>St. Apollonia</td>
</tr>
<tr>
<td>disabled, all</td>
<td>St. Giles</td>
</tr>
<tr>
<td>dog bites</td>
<td>St. Bellinus of Padua</td>
</tr>
<tr>
<td>ear problems</td>
<td>St. Polycarp</td>
</tr>
<tr>
<td>epilepsy</td>
<td>St. Vitus</td>
</tr>
<tr>
<td>Hansen's disease</td>
<td>St. Lazarus</td>
</tr>
<tr>
<td>heart problems</td>
<td>St. John of God</td>
</tr>
<tr>
<td>insanity</td>
<td>St. Dymphna</td>
</tr>
<tr>
<td>kidney disease</td>
<td>St. Benedict</td>
</tr>
<tr>
<td>knee problems</td>
<td>St. Roch</td>
</tr>
<tr>
<td>miscarriage, prevention</td>
<td>St. Catherine of Sweden</td>
</tr>
<tr>
<td>respiratory problems</td>
<td>St. Bernadine of Siena</td>
</tr>
<tr>
<td>rheumatism</td>
<td>St. James</td>
</tr>
</tbody>
</table>

The Operations Security Officer and the Public Affairs Officer, US Army Medical Department and School, Ft. Sam Houston, Texas, have approved this abstract (and poster) for general release. The opinions expressed are those of the authors only and do not necessarily represent official policy of the Army-Baylor University Graduate Program in Health and Business Administration, the Army Medical Department Center and School, the Department of the Army, or the Department of Defense.
The Book Club:  A New, Medical Humanities Course in the Army-Baylor Graduate Program in Health and Business Administration

Probably 10 years ago, trying to answer the question, how do we interest students in ethics, we seized upon the idea of watching and discussing films. Several years later, students asked if we could convert the after-hours film group’s meetings to a for-credit course. After discussion with the Program Director and the Curriculum Committee, this was approved for the following year.

In the United States, bioethics is typically taught through the case (or scenario) method. This is a modification of the method used in law school where written judicial decisions are explored through the Socratic method. In teaching ethics, real or hypothetical scenarios typically replace the written judicial opinions and principlism is used for analysis. This method then becomes (1) identify the issue(s); (2) break it/them down to its/their smallest parts; (3) consider the primary ethical principles; (4) apply an appropriate decision-making model/method; and (5) decide what the reasonable ethical alternatives are.

The principles referred to are those addressed by Thomas Beauchamp and James Childress in Principles of Biomedical Ethics, now in its 7th edition: respect for persons or autonomy – the duty to permit one (or ones surrogate) self-governance; beneficence – the duty to attempt to do good; nonmaleficence – the duty to attempt not to harm; and justice – the duty to attempt to give to each his due or to treat equals equally. The decision-making methods we suggested were the Army-Baylor 7-Step Method for Clinical Decision-Making and the Army-Baylor 7-Step Method Modified for Organizational Decision-Making. Students are, of course, free to use (and teach) others.

We have had rave reviews on the Ethics in Film course and lots of interest in it from other professors, so when students began to ask, "Don't you have anything for those of us who like to read?" I was frankly flabbergasted. These men and women are in a program of at least 60 semester hours in one year; they have reading in every course, and they want more? Really? But the inquiry came at a time when...
National Public Radio had been reviewing some very interesting books dealing with medical ethics and, of course, I had bookshelves full. We put together a list and pilot-tested the course last year. What about a title? Great, Modern Books in Ethics, Primarily Medical Ethics? Good, Modern Books in Ethics? Our other efforts were no better and some were downright funny. We decided on Readings in Ethics, also known as (AKA) The Book Club.

We read five (5) or more books in a 3 credit-hour course, taught across semesters, and discussed them. Often the discussions were continued to a second class meeting. We designed a short form to fill out about each book: a short review, identification of ethical issues, primary and secondary, and a written analysis of several of those issues. Personal reflection and the discussions are where the learning takes place; the form was designed solely to fulfill the curriculum committee's desire for a gradable deliverable.

Available books have included—

The Voice (Thomas Quastoff, 2008) - a memoir by Thomas Quastoff, a Thalidomide baby, who is widely recognized as one of the world's greatest bass-baritones.

Being Mortal (Atul Gawande, 2014) – surely medicine can do better at giving people what matters at the end of life; depressing or inspiring, depending upon the reader.

As Nature Made Him (John Colapinto, 2000) - after a young, married woman in Canada gave birth to twins, one of the boys was severely injured during circumcision, leaving his parents to decide what to do. What do ethical people do when they really have no idea what is right? These parents listened to John Money, a Johns Hopkins psychologist, who advocated sexual reassignment. It did not end well.

Five Days at Memorial (Sheri Fink, 2013) – life and death in a hospital in New Orleans during and after Hurricane Katrina; ethical dilemmas of nurses, doctors, and administrators.


Approved for general release by the Public Affairs Officer and the Security Operations Officer of the Army Medical Department Center and School, Ft. Sam Houston, TX. The views expressed on this poster are those of the author only and do not necessarily represent official policy of the Army-Baylor University Graduate Program in Health and Business Administration, the Army Medical Department Center and School, the Department of the Army, the Department of the Navy, The Department of Defense, or the U.S. Government.
MERT N. AKSU, DDS, JD, MHSA

Mert N. Aksu was named Dean of the University of Detroit Mercy School of Dentistry in July 2008. Dean Aksu has served as a faculty member and administrator at the School of Dentistry since 1993. Dean Aksu earned a B.S. in Biological Sciences and Psychology from the University of Michigan Dearborn, a Masters in Health Services Administration from the University of Michigan School of Public Health, a D.D.S. from the University of Michigan School of Dentistry, a J.D. from Wayne State University, and a certificate specializing in Public Health from Case Western Reserve University and is currently board eligible. 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, American College of Dentists, International College of Dentists, Academy of General Dentistry, and Pierre Fauchard Academy. Dean Aksu has held numerous administrative positions at the school, including associate dean for clinic administration and executive associate dean. Through his leadership, he began a number of activities to further the mission of Detroit Mercy 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.

MONIQUE A. ANAWIS, MD, JD, FCLM

Dr. Anawis is the Medical Director and an Assistant Attorney General for the Office of the Illinois Attorney General Lisa Madigan and serves a Technical Advisor to the Illinois Prescription Monitoring Program. Dr. Anawis is a practicing board-certified ophthalmologist, a fellow of the American Academy of Ophthalmology, a fellow of the Institute of Medicine, and the Secretary, a fellow and a member of the Board of Governors of the American College of Legal Medicine (ACLM). She is an Assistant Professor of Clinical Ophthalmology at Northwestern University Feinberg School of Medicine. As an attending physician, Dr. Anawis has held the positions of vice-president of the medical staff, co-chair of the medical executive board, and member of the hospital peer review and credentials committees. Dr. Anawis graduated magna cum laude from Brown University and earned her medical degree with honors from Brown University School of Medicine. She served as the Secretary and as a member 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 continues to teach and collaborate with physicians in the U.S., Europe, Australia, and Mongolia. Dr. Anawis is the current Vice Chair of Membership and past Vice-Chair of Programming for the Physicians’ Issues Interest Group of the American Bar Association’s Health Law Section. She has served as the Chair of the Health Care Section Council of the Illinois State Bar Association (ISBA), chaired its health care legislation subcommittee and continues to be a section council member. Dr. Anawis was appointed the Secretary for the ISBA’s new Privacy and Security Law Section Council. She serves on the ACLM’s Ethics, Education and National Health Law Moot Court Committees. Dr. Anawis has worked as an Adjunct Professor of Health Law at John Marshall Law School in Chicago. She earned her law degree with honors and a Certificate of Health Law from DePaul University College of Law. The key goals of Dr. Anawis’s dual careers in law and medicine are to communicate and clarify the complexities of healthcare to her fellow physicians, attorneys and the public. She is a trained mediator and lectures nationally and internationally on health policy, regulatory matters, medical malpractice and ethics.

OREN ASMAN, LL.D. ESQ.

Senior Academic staff member at the Tel Aviv University, Nursing Department, School of Health Professions, Sackler Faculty of Medicine. His research and publications focus on bioethics, clinical ethics, nursing law and ethics, mental health ethics and neuro-ethics. http://orcid.org/0000-0003-2439-6997. Works as a bioethicist, legal consultant and an attorney. Executive Vice President of the World Association for Medical Law (2016-2018) and Chairperson of the Scientific program of the 24th World Congress on Medical Law and Ethics, to be held in Tel Aviv, September 2-5 2018 (www.wcml2018.com)

LEON AUSSPRUNG MD, JD, LL.M

Leon Aussprung M.D., J.D., LL.M. is an experienced trial attorney and a pediatrician. He practices law in the areas of medical malpractice, catastrophic personal injury, and product liability, as well as representing qui tam Relators (whistleblowers). Dr. Aussprung obtained his bachelor’s degree from the University of Virginia, his medical degree from Jefferson Medical College, and then completed a residency program in pediatrics at the duPont Hospital for Children. Dr. Aussprung earned his law degree from the University of Pennsylvania Law School and an LL.M. in Trial Advocacy from the Temple University Beasley School of Law. Dr. Aussprung’s personal interests include training as a black belt in Tang Soo Do, stamp collecting, and being a private pilot.

ELI N. AVILA, MD, JD, MPH, FCLM, DABLM

Dr. Eli N. Avila is currently the 9th confirmed Commissioner of Health for Orange County, NY, the 26th Secretary of Health for the Commonwealth of Pennsylvania and the former Chief Deputy Commissioner of Health Services of Suffolk County, NY. Dr. Avila is an experienced Public Health Executive, Physician, Surgeon and Attorney. He has trained in Internal Medicine, Ophthalmology, Occupational Medicine and Environmental Medicine. He is a Fellow of the New York Academy of Medicine. Additionally, he holds Fellow status and sits on the Board of Governors of the American College of Legal Medicine. He has co-authored and sponsored over 18 health related laws. During the 2017 legislative session, he advised and collaborated in a bipartisan manner with both the New York Senate and Assembly on two pending bills. The first creates and designates a Tactical Emergency Medical Support Officer as a peace officer class, to increase survival in an active shooter scenario. The second is based on a law he co-authored at the request of the Pennsylvania District Attorney’s Association during his tenure in Pennsylvania. It establishes expedited scheduling of designer drug homologues to assist drug prosecutions, which is crucial to combat the current drug epidemic. 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 to further his Meta-leadership during a national pandemic or terrorist event. 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 Sc.B in Biology from Brown University, an M.D. from the Brown Medical School, a J.D. with Cum Laude honors from the St. John’s University School of Law, and an M.P.H. with highest honors from the Mount Sinai School of Medicine. Dr. Avila is a Distinguished Visiting Professor in the Institute of Public Health of the School of Health Sciences and Practice, New York Medical College, Valhalla, NY.
F. Lee Bailey, JD

F. Lee Bailey tried his first case in July, 1954, while serving as a Marine jet fighter pilot. Since then he has handled cases in 49 states, given 4,000 lectures, written 20 books, and flown 25,000 hours. He is currently busy working on 2 more books, and is (with Dr. Cyril Wecht) organizing a high-level school for trial lawyers.

David M. Benjamin, PhD

David M. Benjamin is a Ph.D. - trained Clinical Pharmacologist & Forensic Toxicologist, a trained arbitrator and a mediator. David is a prolific author with more than 200 presentations and publications focusing on Medication Error Reduction, Risk Management and opioid pharmacology. Dr. Benjamin has been teaching Legal Medicine and Forensic Pharmacology in the Tufts Medical School Sr. Clinical Pharmacology elective for approximately 20 years. Although he is not an attorney, Dr. Benjamin regularly teaches Scientific Evidence in Professor James Starrs’ Forensic Science course at George Washington University Law School in Washington, DC and Stetson Law School in Gulfport, FL. Dr. Benjamin is an acknowledged expert in opioid pharmacology and was a member of an ACLM panel at the World Association of Medical Law, LA, CA, Aug. 11, 2016, where he spoke on Heroin, the Opioid Crisis, and Latrogenic Addiction. David is in great demand as a forensic expert in opioid-related cases, and regularly reviews both civil and criminal cases involving wrongful deaths, criminal possession, and possession w/intent. David has been a member of the ACLM since the early 1990s, and was the first person to become a Fellow of the College who holds neither the MD nor the JD degree. He now serves as a member of the Editorial Board of the Journal of Legal Medicine, and has been a frequent speaker at many ACLM programs. Clinical Pharmacologist; 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.

Ken J. Berger, MD, JD, FCLM

Ken J. Berger is a physician lawyer who is well respected in both fields locally and internationally. After receiving his Doctor of Medicine at the University of Toronto, he did four years of training at McGill University in Family and Community Medicine, Emergency Medicine and Core Surgical training. He developed his Sport Medicine Expertise at that time and became the team physician for Rugby Canada, Soccer Canada, and was a physician at national and international games. He also covered leading actors and entertainers as their trusted physician while they performed concerts in Toronto and the surrounding area, including U2, Rolling Stones and many others. After ten years of a successful medical career, he decided to combine active medical practice with law. He attended Osgoode Hall Law School where he was student-athlete for Varsity Tennis and was a member of a Gold Metal tennis team in intercollegiate athletics. He is a member of the Ontario, New York and United States Supreme Court Bar. He litigates high profile cases in criminal, civil and constitutional law in all levels of court, including a leave application to the Supreme Court of Canada. He has worked as an attorney in Canada, and in the United States in New York. For almost 20 years he has been a member of the World Association for Medical Law and is currently the Secretary-General and on the Executive Committee, as well as a Vice President and Board of Governors of the World Association for Medical Law and has been designated the Scientific Chair of the 2020 WAML meeting in Toronto, Canada. He has been a long serving member on the editorial board of Medicine and Law. He is also a Fellow of the American College of Legal Medicine. Berger has been a sought-after speaker at International Health Law meetings and has published and presented papers or lectured fairly extensively in the field for at least 15 years. He has been qualified as an expert witness by the court and has assisted in approximately 20-25 cases in both civil and criminal law as an expert witness. However, primarily he works as a litigator assisting physicians with hospital privileges matters and regulatory matters with physician, medical students and health care providers, as well as assisting physician and health care providers as their criminal defense attorney, and for patients in high stakes medical malpractice claims involving substantial damages. The majority of his legal practice focuses on Health Law and he is principal at Medicallegaladvocacy.com. He is an Assistant Professor in the Faculty of Medicine University of Toronto, He has taught health law to physician, lawyers, medical students and law students and was Co-Chair of the Health Law Advocacy Project teaching law students at 4 Canadian law schools advocacy skills and currently he co-directs or facilitates a course entitled Critical Perspectives in Health Policy and Law at the Institute of Health Policy, Management & Evaluation at the University of Toronto to graduate students, physicians, lawyers and hospital administrators. He is the most responsible physician as a hospitalist at a tertiary care teaching hospital, Sinai Health System in Toronto therefore he is able to bridge Health Law with contemporary medical practice and be on the leading edge of both professions particularly where law and medicine intersect.

Robert Bitonte, MD, JD, FCLM

A physiatrist in Los Angeles, California and is affiliated with Kaiser Permanente San Diego Medical Center. He received his medical degree from University of Miami Miller School of Medicine and has been in practice for more than 20 years. He is one of 2 doctors at Kaiser Permanente San Diego Medical Center who specialize in Physical Medicine & Rehabilitation.

François Blaudeau, MD, JD, FACHE, FCLM

François Blaudeau is of counsel with Hening Garrison Davis, LLC., and serves a leadership role in the firm’s pharma and medical device mass torts litigation. François has a nationally established plaintiff practice in medical negligence cases. Dr. Blaudeau filed the first cases and led national litigation against Intuitive Surgical and served as lead counsel in a complex two-year mediation that resolved over three thousand cases. François also played a key role in the national morcellator litigation serving in the leadership of the Ethicon Morcellator MDL leading to a successful settlement of the litigation. François has litigated complex cases in Federal and State Courts across the country leading motion practice and oral argument in wrongful death, pharma, and medical device litigation and maintains a busy trial calendar. Dr. Blaudeau served six years on the Governing Board of the American College of Legal Medicine and has been a Brief-scoring Judge in the National Healthcare Moot Court Law School Competition for ten years. He received his medical degree from the University of Alabama and completed his residency in Gynecology at Tulane University and Charity Hospital in New Orleans in 1991. He then decided to attend Law School and received his J.D. in 1998 from the Birmingham School of Law. François then joined the plaintiff trial firm of Riley Jackson PC and spent fifteen years in personal injury litigation. Later evolving into national medical device and pharma litigation François joined Hening Garrison Davis in 2014 and has worked on multiple mass tort and class action litigation. François remains a national leader in minimally invasive Gynecological Surgery and has mentored and taught hundreds of surgeons who have traveled to Alabama to learn advanced minimally invasive surgical techniques.
PAUL BLAYLOCK, MD, JD, FACLM
Graduated Valedictorian and Student Gov. President U.of Tenn., 1968; Graduated UT Medical School (Top 5 Alpha Omega Alpha), 1972; Emergency Medicine / Legal Medical Trial Lawyer Practice : Portland, Oregon; ACLM HONORS: Served on Board of Governors, Winner “President’s Award” for Community Service/Red Cross Disaster Service and “Jefferson Cup”; Past Adjunct Professor: Northwestern Law School at Lewis & Clark and Clark College Instructor Emergency Medicine Oregon Health Sciences Center; Outstanding Alumnus UT, Served on Alumni Board of Governors both UTennessee and UT Medical School (UTHSC) in Memphis, Tenn.; Oct., 2017: Named one of the “100 Greatest Graduates” U. of Tennessee” (Founded 1796); Sept., 2018: Will be honored by UT Medical School as “Outstanding Medical Alumnus”; Provides “Paul Blaylock MD JD Legacy Scholarships” to UT Medical Students; Outline of Lecture “America Gone to Pot: The Medical Legal Impact of Recreational Marijuana Legalization”; Driving Accident/Fatality Statistics: Colorado, Washington, and Oregon; Collateral Medical/Legal Impact of Legalization on Children, Teenagers; Medical Physiological Neurological Impairment of Chronic Marijuana Users.

MICHAEL L. BROOKS, MD, JD, FCLM
Dr. Brooks is a graduate of Hahnemann Medical College (now Drexel University College of Medicine) who completed a Diagnostic Radiology residency at Mercy Catholic Medical Center, in Darby, PA. Following residency, he completed a Neuroradiology fellowship at the Harvard Medical School/Brigham and Women’s Hospital and worked as an Instructor at Harvard Medical School and Staff Neuroradiologist at Brigham and Women’s Hospital before returning to Philadelphia in 1988. From 1988 to 1998, Dr. Brooks was Associate Director of the Graduate Hospital Imaging Center and Neuroradiologist for The Graduate Hospital in Philadelphia. Since 1998 Dr. Brooks has been the Neuroradiology Section leader for Mercy Medical Imaging, now Mercy Diagnostic Imaging, where he is involved on a daily basis teaching Radiology residents, Medical residents, Nurses and medical students at Mercy Fitzgerald Hospital and Mercy Hospital of Philadelphia. In 2006, Dr. Brooks received his JD from the Temple University, Beasley School of Law and was admitted to the Bar in Pennsylvania in 2007. In addition to teaching Medical and Nursing professionals, Dr. Brooks, teaches Medical Ethics and Medical topics to attorneys. Dr. Brooks is a member of the Board of Directors of Mercy Health System, Co-Chair of the MFH Ethics committee, Chairman of the MCMC By-Laws Committee and participates in committees at the Hospital and Health System Board level.

ROBERT W. BUCKMAN, PHD, FCLM
Dr Buckman is a practicing Clinical Pharmacologist who has served the State of Illinois as the Chair/Director of the Drug Formulary for the Department of Public Aid for a period of almost 25 years. During that time, he served as a Senior Consultant for the Illinois State Medical Society Drug and Therapeutics Committee. Beyond academic medicine he served, in his career, as Senior Vice President, Director of Medical Affairs Worldwide, for the Interpublic Advertising Group of Companies. He is the Founder and Chief Executive Officer of Medical Scientific Information Resources, Inc. He is a graduate of the Graduate School of Loyola University of Chicago and the Clinical Pharmacology Program of Loyola’s Stritch School of Medicine. He was privileged to be one of the U S Navy’s first Medical Scholars named under the Health Professions Scholarship program whereby he was able to complete his Graduate, Clinical and Fellowship training in Clinical Pharmacology. During active duty, Dr Buckman was on the adjunct faculty of the Naval Academy with an adjunct clinical appointment to the National Naval Medical Center, Bethesda, MD, as he served as the Clinical Pharmacologist for the 3rd and 7th Naval Fleets, Pacific. Dr Buckman is an adjunct faculty member of the University of Wisconsin and lectures in the area of pharmacological therapeutics and legal medicine. He holds memberships in numerous medical/scientific societies. Currently he is celebrating his company’s 37th 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, with substantial jury trial experience, spans a period of 28+ 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, is certified by and a Diplomate of the American Board of Legal Medicine, is 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 ACLM. Dr Buckman has been awarded the highest life time achievement award of the College, The Gold Medal, for his professional achievements and his service to the College and his colleagues of the American Bar Association and American Medical Association.

JOHN BUSOWSKI, MD, JD
John Busowski, MD, JD is an Associate Professor in the Department of Obstetrics and Gynecology at the University of Central Florida College of Medicine and Florida State University College of Medicine. Dr. Busowski is currently Director of the High Risk Obstetric Clinic at Winnie Palmer Hospital for Women and Babies in Orlando, Florida. He practices high risk obstetrics in Orlando, Florida. He has served as Chairman of the Department of Obstetrics and Gynecology at Winnie Palmer Hospital. He is former Academic Chair and Residency Program Director and Director of Research in the Department of Obstetrics and Gynecology at Winnie Palmer Hospital (Orlando Health). He has served on Patient Safety and Quality committees for over 20 years. He is a member of the American Board of Legal Medicine.

JOHN P. CONOMY, MD, JD
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 during the Viet Nam era, 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 specialist in Neurology and Legal 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 at the Cleveland Clinic Foundation 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 and is the past Editor-in-Chief of the Journal of Legal Medicine. Dr. Conomy has held numerous research and clinical investigative grants and awards in the fields of cardiovascular diseases, diabetes, epilepsy, brain injury 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 widely 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 USA 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, a college student. Dr. Conomy is married to Dr. Jill Mushkat Conomy, a Psychologist and a specialist in the field of chronic pain management. Dr. Conomy has served upon the Governing Board of the Cleveland Medical Library Association in the 1980’s, and again since 2014. He is an avid bibliophile (having haunted the Allen Memorial Library since the age of 16 years), traveler, cyclist, skier, music lover and photographer, and has a notably low threshold for breaking into Irish Songs, occasionally in the Irish language.

DALE COWAN, MD, JD, FACP, FCLM, FAHLA
Dale Cowan, MD, JD, FACP, FCLM, FAHLA is a graduate of Harvard College, Harvard Medical School, and Case Western Reserve University School of Law. He is Board-Certified in Internal Medicine, Hematology, and Medical Oncology and is licensed to practice medicine in California, Florida, and Ohio. Additionally, he is a member of the Ohio State Bar. Dr. Cowan has served on the faculty of the Schools of Medicine and Law at Case Western Reserve University and was also a member of the staff of the Cleveland Clinic. He is a past-president of the Ohio/ West Virginia Oncology Society, the Academy of Medicine of Cleveland and Northeast Ohio, the Medical Staff of University Hospitals Parma Medical Center, and the American College of Legal Medicine. He is a Fellow of the American College of Physicians, the American College of Legal Medicine, and the American Health Lawyers Association. Dr. Cowan’s interests are in the organization of medical practice, medical staff management, alternative health care delivery systems, utilization and peer review, quality assurance, ethical-legal issues of medical research, palliative and end of life care, and alternative dispute resolution. Dr. Cowan is a recipient of the David J. Greenburg Service Award from the American Health Lawyers Association, the Outstanding Community Service Award from the Cleveland Clinic Division of Regional Medical Practice, and the Special Honors Award from the Academy of Medicine of Cleveland and Northeast Ohio. In 2010 he was named Clinician of the Year by the Academy of Medicine of Cleveland and Northeast Ohio.

JONATHAN DAVIES, JD, LLM
Jonathan Davies, JD, LLM is an experienced trial attorney practicing mainly in the field of medical malpractice, holding law offices in both Jerusalem & Tel Aviv. His main focus is on representing plaintiffs in personal injury cases. He was chairperson of Council for Presidents for World Association of Medical Law (WAML) for 6 years (2008-2014) and Editor-in-Chief, of the periodical “Medicine and Law” (Hebrew) for 15 years (2000- 2015) He is a member of the board of directors, of the Society for Medicine and Law in Israel. He is a member of the Unesco forum for Medicine, Law and Ethics in Haifa University. He is a member of the Helsinki Committee in HMO medical services (GCP). He is also a fellow of the ACLM - American College of Legal Medicine and the RSM - The British Royal Society of Medicine. Jonathan has published many articles and books in the field of Medicine & Law. He is a graduate of law from Tel Aviv University law school (LLB) and also of commercial law (LL.M magna cum laude) from TAU in collaboration with Berkeley University of California. He has been a member of the Israel Bar Association since 1984.

DAVID DONNERSBERGER, MD, JD, MA, FACP
David Donnersberger MD JD MA FACP is the current President-Elect of the ACLM. He is an assistant clinical professor of medicine at the University of Chicago Pritzker School of Medicine and a senior attending at Evanston Hospital in Evanston, IL where he serves as chief ethics officer for the four-hospital system. He practices internal medicine in Winnetka, IL with his wife and two other internists.

Cavan Doyle, JD, LL.M
Cavan Doyle, JD, LL.M is an Assistant Professor at the Neiswanger Institute for Bioethics at Loyola University Chicago’s Stritch School of Medicine. Ms. Doyle received her JD and Certificate in Health Law from Loyola University Chicago School of Law. Ms. Doyle also has an LL.M in Medical Law and Ethics from the University of Kent at Canterbury, England. Prior to joining the Neiswanger Institute, Ms. Doyle practiced health care law in Chicago for several years, representing a broad spectrum of clinical Dr. Friedland providers and health facility clients in regulatory and compliance matters. Ms. Doyle currently serves as outside regulatory counsel for a health care technology company, advising on matters pertaining to employee assistance and behavioral health services. In 2014, Ms. Doyle left the full time practice of law to pursue a Fellowship in Clinical Medical Ethics at the MacLean Center at the University of Chicago, where she received formal training in principles of clinical ethics and clinical ethics consultation. Ms. Doyle is a current member of the Institutional Ethics Committee of NorthShore University Health System, where she performs ethics consultations and is involved in hospital ethics policy development. Her current research examines issues at the intersection of clinical ethics and law with a particular emphasis on state legal mechanisms governing surrogate decision making for incapacitated patients.

MARJORIE ESKAY-AUERBACH, MD, JD, FCLM
Marjorie Eskay-Auerbach, MD, JD, FCLM [SpineCare and Forensic Medicine, PLLC; Board of Directors, International Academy of Independent Medical Evaluators] is an orthopedic surgeon with Fellowship training in Spine Surgery. She is an attorney, medical-legal consultant with a special interest in spine care, author and frequent lecturer nationally. Dr. Eskay-Auerbach earned both her undergraduate and medical degrees at the University of Michigan, where she was a student in the combined Six Year Integrated Premedical-Medical Program (Inteflex). She completed her residency training in Orthopaedic Surgery at the University of Pittsburgh Health Sciences Center and her fellowship under Dr. Leon Wiltse and Long Beach Memorial Hospital in Long Beach, CA. Attorney Eskay-Auerbach received her JD from...
University of Arizona. Dr. Eskay-Auerbach is board-certified by the American Board of Orthopedic Surgeons and the American College of Spine Surgery. She is an active member of the North American Spine Society and served as a member of the Board of Directors. She is an active educator for the AMA on the most recent edition of the AMA Guides to the Evaluation of Permanent Impairment and was a contributing editor for the AMA Guides to Evaluation of Permanent Impairment, Sixth Edition musculoskeletal chapters, and co-author of Transition to the AMA Guides Sixth and a number of workbooks related to use of the Guides. She has contributed chapters to a number of AMA publications including Guides the Evaluation of Disease and Injury Causation, 2nd Edition and AMA Guides to the Evaluation Work Ability and Return to Work. She has taught multiple Continuing Legal Education courses, including a course entitled, “Orthopedics for Lawyers,” and currently trains physicians in performing Independent Medical Examination and providing expert testimony. Dr. Eskay-Auerbach has over 30 years of clinical experience. Her current clinical practice in Tucson, AZ is in occupational orthopedics, and she practiced spine surgery and non-operative care of back and neck injuries in Phoenix previously. She performs medical-legal consultations, independent medical evaluations, review of impairment ratings and record reviews, and provides expert opinions and testimony. She holds medical licenses in AZ, CA, NM and OK.

RANDI ETTNER, PHD
Randi Ettner PhD is a clinical and forensic psychologist. She is the Secretary of WPATH and executive board member, an author of the Standards of Care, and Chair of the Committee for Institutionalized Persons. Dr. Ettner has written four books on transgender issues, including a medical and surgical text, numerous peer-reviewed articles and research, and was an internationally syndicated columnist. She was the lead expert in the lawsuit that overturned Medicare’s exclusion of surgery, has been instrumental in the passage of anti-discrimination laws, provided testimony that helped establish legal precedent for the rights of transgendered individuals in the workplace and appropriate treatment for prisoners, including the first case to provide surgery to an incarcerated transwoman. She is a member of the Screen Actors Guild, and has appeared on hundreds of television and radio shows, including Oprah, regarding transgender issues. She was chief psychologist at the Chicago Gender Center, and is the president of New Health Foundation Worldwide. She is the honoree of Randi and Fred Ettner Transgender Health Fellowship, at The University of Minnesota Program in Human Sexuality and a member of the University of Minnesota’s Leadership Program. Dr. Ettner serves as a consultant to corporations, including, Walgreen’s and Tawain Enterprises, to facilitate gender affirmation in the workplace.

BERNARD FRIEDLAND, DDS, JD, FCLM
Dr. Friedland graduated from the Univ. of Stellenbosch and from the Univ. of Toronto where he trained in oral and maxillofacial radiology. He has been on the faculty at Harvard School of Dental Medicine for 28 years. His area of expertise is oral & maxillofacial radiology. In addition to teaching radiology, Dr. Friedland is responsible for teaching ethics and jurisprudence. He publishes in the medicolegal, ethics 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
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 (NYSDA) Attorney Referral Panel and District Chair of the NYSDA Professional Liability Claims Committee, which reviews dental malpractice claims. 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 New York State Dental Journal, Reviewing Editor of the Journal of the American Dental Association, fellow of the American College of Legal Medicine and American College of Dentists, and member of the Lambda Lambda Chapter of Omicron Kappa Upsilon, and the Erie County, New York and Florida Bar Associations.

JOSEPH GRASKEMPER DDS, JD, FCLM, DABLM
Dr. Graskemper currently practices full-time in Bellport, New York. 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, California 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, U.S. 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, American College of Legal Medicine, and American College of Dentists. Recently, Dr Graskemper became a Diplomat in the American Board of Legal Medicine. Besides practicing dentistry full-time, he also is an Associate Clinical Professor in the 4th year General Practice Program at Stony Brook School of Dental Medicine, and teaches the Professionalism and Ethics in Dentistry course for residents and Dental Law at the 2nd, 3rd,

MARVIN FIRESTONE, MD, JD, DLFAPA
MARVIN FIRESTONE, MD, JD holds a medical degree from Temple University (1964) and a law degree from the University of Colorado (1980). He is Board Certified in Legal Medicine (1982), Psychiatry (1971) and Forensic Psychiatry (1985). He is PastPresident of the American College of Legal Medicine and the Northern California Psychiatric Society, and serves as Chair of its Ethics Committee. He is on the Board of Trustees of the Board of Legal Medicine, the Psychiatric Foundation of Northern California, and Vice Chair of California Public Protection and Physician Health, Inc. He formerly held the Hirsh Chair at the George Washington University in Washington, D.C., where he was Professor at its Medical and Law Schools and School of Health Services Administration. A frequent lecturer at national law and medicine conferences, Dr. Firestone has authored journal articles in his fields of expertise and chapters in The Medical Malpractice Survival Handbook (Mosby); Legal Medicine (Mosby); Textbook of Forensic Psychiatry (APPI), and Head and Neck Injury Handbook (Shepard’s McGraw Hill). He is Editor-in-Chief Emeritus of Legal Medicine Questions and Answers; on the Editorial Board of the Journal of Legal Medicine and a Reviewer for Psychiatric Services, a journal of the American Psychiatric Association. He is the Deputy Editor of Legal Medicine, The Medical Malpractice Survival Handbook, and Medical Ethics and Legal Medicine. His primary offices are in the San Francisco Bay area. Dr. Firestone provides medical/legal consultation and his legal practice primarily involves representation of physicians in cases involving hospital staff privilege disputes, licensure, medical practice contractual issues, and medical malpractice. He is a certified mediator and a member of the Bar in several state and federal jurisdictions, including California, Colorado, the District of Columbia, the U.S. Claims Court and the U.S. Supreme Court.
JAMISON GREEN, PHD
Dr. Jamison Green (Ph.D., Equalities Law) is an author, educator, public speaker, independent legal scholar, consulting expert in transgender health, employment discrimination litigation, diversity trainer and policy consultant for business, educational, and governmental institutions, former corporate publications director, and immediate past-president of the World Professional Association for Transgender Health (WPATH).

VICTORIA L. GREEN, MD, MHSA, MBA, JD
Dr. Green earned her Bachelor of Science and Medical Doctorate Degrees from Northwestern University in the Honors Program in Medical Education. She completed her residency in obstetrics and gynecology at Henry Ford Hospital in Detroit, Michigan. She was awarded a Master’s Degree from the School of Public Health at the University of Michigan in Health Management and Policy and later completed her Masters in Business Administration. She graduated from the Georgia State University College of Law with a Juris Doctorate (JD). She is a Professor in the Department of Gynecology and Obstetrics at Emory University School of Medicine and the Medical Director of the Women’s Health Ambulatory Care/Satellite Clinics. She has direct responsibility for residency and medical student training as the director of the Gynecology Comprehensive Breast Clinic, which is a division of the Avon Breast Clinic in the Georgia Cancer Center of Excellence, Winship Cancer Institute. Additionally, she conducts trainings on the business, legal and quality improvement aspects of medicine and was also the previous Director of the Medical Student Clerkship. Dr. Green is board certified in obstetrics and gynecology and a Fellow of both the American College of Obstetricians and Gynecologists and the American College of Legal Medicine. She currently serves as the Chair of the Georgia section of ACOG, and is a Past President of the American College of Legal Medicine and a Past Chair of the OB/GYN section of the National Medical Association. She has been appointed to numerous hospital committees including the Executive Risk Management Committee, Conflict of Interest Committee, the Committee on the Status of Women, the Ethics Committee and the Community Health Coalition. She has also served on several regional and national committees including the Professional Liability Committee and Committee for Underserved Women of the American College of Obstetrics and Gynecology, the Dekalb County Task Force on Domestic Violence and the Georgia Breast Cancer Coalition. In addition, Dr. Green serves on the Executive Committee/Board of Directors of the Georgia Obstetrical and Gynecological Society and the National Medical Association. She has previously served on the Board of Governors of the American College of Legal Medicine. Additionally, she is a member of the State Bar of Georgia, American Bar Association and American Health Lawyers Association. Dr. Green has served on the editorial board of several major publications including Contemporary OB/GYN, Medical/Legal Studies and as the deputy editor of Legal Medicine Perspectives. Dr. Green has received specialized credentialing as an International Board Certified Lactation Consultant (IBCLC) and a North American Menopause Society (NAMS) Certified Menopause Practitioner (NCMP). Dr. Green has been published several times and is both previously and currently very active in a number of research projects focusing on the Alliance for Innovation in Maternal Health (AIM) patient safety bundles, breastfeeding rates in underserved populations, risk assessment and BRCa testing in the breast clinic population, applicability and clinical relevance of current risk assessment models and educational tools for patients at high risk for breast cancer, domestic violence issues in the minority population, barriers to HPV vaccination among minority women and the impact of the Medicaid revisions on pregnancy outcomes. She has won the Emory teaching award, APGO Solvay Scholar Award, the CALI Excellence Award, the NMA service and teaching Award, the ACLM Gold Medal and the APGO Excellence in Teaching Award. She lectures extensively, both regionally and nationally, on general gynecology, menopause, breastfeeding acculturation, breast disease and risk assessment, domestic violence, patient safety, quality assessment/ improvement and a comprehensive list of medicolegal issues including federal regulations, practitioner credentialing, malpractice, ethics and contract law. Dr. Green has lectured for both physicians and attorneys at leading conferences sponsored by the Institute for Continuing Legal Education, the American College of Obstetrics and Gynecology, the Association of Professors of Obstetrics and Gynecology (APOG), the Managed Care Institute at Morehouse School of Medicine and Contraceptive Technology. In addition, Dr. Green has functioned as a consultant for the Emory Regional Training Center, the LIFE Residency Wellness Curriculum Board and the State of Georgia, Department of Human Resources/ Women’s Health Division.

RICHARD S. HAROLD, DMD, JD, FCLM
Dr. Richard S. Harold is an Associate Clinical Professor and Practice Coordinator in the Department of Comprehensive Care, Tufts University, School of Dental Medicine. Dr. Harold received his B.S. degree from Massachusetts College of Pharmacy and his D.M.D. degree from Tufts University School of Dental Medicine. Dr. Harold owned and operated a dental practice in the Boston area for many years prior to joining the faculty at Tufts. Dr. Harold is an attorney and received his J.D. degree from New England School of Law. He is a member of the Massachusetts Bar and has a specific interest in dental-legal issues including the management of acute dental pain and the prescription opioid epidemic. He is a consultant in the areas of dental record keeping, documentation, treatment planning, prescription writing, regulatory issues, dental negligence and standards of care. He has lectured both locally and nationally and has published several dental-legal journal articles.
ROBERT R. HARRISON, M.H.A., J.D. LL.M.

Robert R. Harrison, M.H.A., J.D. LL.M., is a partner at Kimball, Stilling & Harrison in Salt Lake City, Utah, where his practice focuses on health care regulatory compliance and ethics. Prior to entering the practice of law, Mr. Harrison served in a variety of academic and administrative capacities in university medical centers and community hospitals, including seven years as an Assistant Professor at the Medical College of Virginia School of Medicine. Following undergraduate education at the University of Richmond, he earned a Master of Health Administration degree from Virginia Commonwealth University, and graduated from the Saint Louis University School of Law with an Honors Certificate in Health Law from the Center for Health Law Studies. He was also a Fellow at the Beazley Institute for Health Law and Policy at Loyola University Chicago, where he earned a Master of Laws in Health Law with a concentration in regulatory compliance. He is the author of more than two dozen publications on issues in health care and health law, including book chapters, journal articles and professional association publications. An active ACLM member, he serves on the Editorial Board of Legal Medicine Perspectives and was recently appointed to the Ethics Committee.

WELDON (DON) HAVINS, M.D., J.D., L.L.M. (HEALTH LAW)

Weldon (Don) Havins attended the Coronado, California primary school system, then San Diego State University where he received a B.A. with high honors. Graduating from Wake Forest University School of Medicine with an M.D. in 1970, he interned in surgery at the Washington Hospital Center in Washington, D.C. Following two years with the U.S. Navy (one year as a medical officer on the USS Daniel Webster SSBN-626 nuclear submarine, one year at the Long Beach Regional Naval Medical Center), he completed an ophthalmology residency at the Jules Stein Eye Institute at UCLA in 1976, and later, a fellowship in Ophthalmic Plastic and Reconstructive Surgery at the University of Texas, Houston, in 1981. He earned a Master’s degree in Management from the Claremont Graduate University while practicing Ophthalmology in Upland, California. From 1982 to 1995, Don practiced Ophthalmology and Oculoplastic Surgery in Las Vegas, Nevada. Returning to San Diego in 1995, he attended law school at the University of San Diego where he graduated cum laude, was an editor of the law review, and selected to Order of the Coif. Remaining at the University of San Diego School of Law for an additional year, Don earned a Master of Laws degree, cum laude, in Health Law. Returning to Las Vegas in 1999, Don served as a law clerk for a District Court Judge while practicing medicine part-time. From 2001 to 2008, he worked as the executive director and legal counsel for the Clark County Medical Society. Following a stint as Executive Director of the Nevada Board of Osteopathic Medicine, Don received a full-time appointment to the faculty of Touro University College of Osteopathic Medicine, where he currently serves as an Associate Dean, Professor and Director Medical Jurisprudence, Professor of Ophthalmology, In-House Counsel, and Title IX Coordinator while practicing General Ophthalmology part-time. Don is a member of the Nevada Bar. He is certified by the American Board of Ophthalmology and the American Board of Legal Medicine. He serves as a member of the Board of Governors of the American College of Legal Medicine and the American Board of Legal Medicine. Don is currently a Board Member of the Nevada State Board of Medical Examiners, and a Board Member of the Governor’s Office of Economic Development. He is a fellow of the American College of Surgeons, the American Society of Ophthalmic Plastic and Reconstructive Surgeons, and the American College of Legal Medicine. He is immediate past-president of the Nevada State Medical Association. Don has numerous publications in medical journals and law reviews. He enjoys aviation and has earned Airline Transport Pilot ratings in both single and multi-engine aircraft. Don has earned ratings as a certified flight instructor in single and multi-engine aircraft, and as an instrument flight instructor. Don and his wife Kelly enjoy time with son Bradley, a U.S. Army Major in the Army Medical Corps (Family Medicine), daughter Laura who is an R.N. working in a surgical intensive care unit while completing her Masters Degree as a Nurse Practitioner (UNLV), and daughter Anna who teaches English in Kochi, Japan.

MARGARET HILL, DMD

Educated at the University of Eastern Kentucky University (undergraduate) with a B.S. in Biology with a minor in Chemistry. Dr. Hill subsequently attended the University of Louisville School of Dentistry, earning DMD in 1987. She then earned a certificate in General Practice Residency at the University of Louisville School of Dentistry in 1988. At the University of Kentucky, Dr. Hill completed her residency program in Periodontics in 1990.

BILL HINNANT, MD, JD, FCLM

Bill Hinnant, Principal in the firm Hinnant Medical and Law Offices, LLC, is a Urologist and Health Care Attorney admitted to the trial and appellate courts in the State of South Carolina, the Fourth Circuit Court of Appeals and the U.S. Supreme Court. His legal practice focuses on medical malpractice, qui tam litigation, administrative health law, white collar crime, drug matters, insurance law, healthcare business and transactions, workers compensation and social security disability. His medical interests include infertility, reproductive endocrinology, oncology, voiding dysfunction, renovascular disease and general urology. He is a long-term member of his state’s Federal Criminal Justice Act Attorney Panel and completes annual CLE addressing the Federal Sentencing Guidelines. Bill serves as President and General Counsel of the American College of Legal Medicine. He has authored amicus briefs for national medical organizations, including for the College, as well as regulatory comments for medical associations and national medical organizations. He has advised or represented over 200 physicians in peer review and credentialing matters. He is active in assisting physicians and attorneys with substance abuse and addiction. He is also Membership Chair for the World Association for Medical Law. Bill and his wife, Virginia, have four grown children and enjoy travel, sports, food and wine, theater and are self-professed politics and news junkies. They participate annually in Renaissance Weekend, one of the oldest idea festivals in the country, originally organized by Bill and Hillary Clinton.

DR. ALEXANDER HOLDEN, BDS, MDPH, LLM

Dr Alexander Holden qualified as a dentist from the University of Sheffield in the UK. Alongside working in public and private practice, Alexander gained postgraduate qualifications in law and dental public health. He now holds an academic appointment at the University of Sydney in Australia where he teaches ethics, law and professionalism at the Faculty of Dentistry. Alexander’s research interests include examining society’s relationship with the dental profession and digital professionalism.

LAURANCE JERROLD, DDS, JD, ABO

Laurance Jerrold is the Chair and Orthodontic Residency Program Director at NYU Langone Hospital – Brooklyn. His background includes 25 years in the private practice of both orthodontics and law, and over 15 years in full time academia teaching orthodontics, clinical bioethics, and engaging in post-doctoral educational administration. He has also served the profession at all levels of organized dentistry. Dr. Jerrold has presented or written well over 400 lectures, articles, textbook chapters, and multi-media presentations dealing with orthodontic practice, risk management, and clinical ethics. In addition, he is the Legal Editor for the American Journal of Orthodontics and Dentofacial Orthopedics.
and is an Associate Editor and reviewer for several other orthodontic journals. Lastly, Dr. Jerrold is the President of Orthodontic Consulting Group, a dental think tank that has written several White Papers for various DSO’s and also specializes in providing comprehensive risk, practice, and clinical management ideas and services for interested parties within the orthodontic community.

MICHAEL KANER, DMD, JD
Michael Kaner, DMD, JD, graduated from the University of Rochester and Tufts University School of Dentistry in 1985. After completing a GPR in Allentown, PA., he assumed the practice of a retiring dentist in Feasterville/Trevose, PA., where he has practiced since 1986. In 2003 he earned a JD degree from Concord Law School and is a member of both the State Bar of California and the District of Columbia. A Fellow of the Academy of General Dentistry and past President of the Pennsylvania AGD, he has authored several articles on Forensic Dentistry, Bite Marks, Oral Cancer, Emergency Preparedness, Sexual Harassment, HIPAA Compliance, and Going Green in Dentistry. He is a past member of the Pennsylvania Dental Association’s (PDA) Environmental Impact Committee helping to set standards and policies that will protect the environment. Dr. Kaner is a trained forensic dentist and is on staff at the Bucks County Coroner’s Office and DMORT, the federal disaster response team. He was part of the team that helped identify those killed on 9/11 in both Somerset County, PA., where Flight 93 crashed and at the Medical Examiner’s Office in New York City. In addition, he spent two weeks in Mississippi after Hurricane Katrina to help identify the victims. Dr. Kaner lives in Bucks County with his wife Barbara and has two adult sons and a golden retriever.

ALEX KARYDI, LMFT, CSAC, CAC
Dr. Alex Karydi, LMFT, CSAC, CAC, is a certified drug and alcohol counselor that has researched the impact of minority stress. She has a Masters in Clinical Psychology, Ph.D. in Clinical Sexology, and a Ph.D. in Marriage and Family Therapy (ABD). She has served for Richland 2 School District as a therapist and with the Department of Juvenile Justice (DJJ) as an evaluating psychologist with the designation of the Lesbian, Gay, Bisexual, Transgender (LGBT) youth coordinator. She is currently the Program Director for the SC Youth Suicide Prevention Initiative a community movement to end suicide in children and young adults. She has been working with kids and their families throughout her travels since 2000.

RICHARD KELLY, MD, JD, MPH, FCLM
Dr Richard Kelly is a member of the medical faculty at the University of California in Irvine. As an undergraduate at Harvard University, Dr. Kelly studied theology and biochemistry. After graduation, he was awarded a full scholarship to study public health at the University of California in Berkeley. He then moved to Stanford University where he pursued dual professional degrees in Law and Medicine. He completed his anesthesiology medical training (internship, residency, fellowship) at the University of California in San Francisco (UCSF) and after several years in private practice Dr. Kelly returned to academics. He teaches cardiothoracic anesthesiology at the university medical center and teaches a course in public policy for graduate students at the Health Policy Research Institute. His clinical interests focus on the anesthetic management of surgical patients with complex cardiothoracic diseases and his public policy research interests include the societal consequences of the Patient Protection and Affordable Care Act (“Obamacare”); the ethical and legal implications of physician fatigue; medical professionalism; opioid tolerance and addiction; and national trends in medical malpractice awards. He actively participates in the American College of Legal Medicine and the World Association for Medical Law.

RAYMUND KING, MD, JD, FCLM
Raymund King, MD, JD, FCLM, is the principal and founder of the Law Offices of Raymund C. King, MD, JD, PLLC, in Plano, Texas. Dr. King worked his way through college as a professional magician, receiving his undergraduate degree from the University of Dallas. He then obtained his medical degree from the University of Texas Medical School in Houston, Texas, and received his residency training in Otolaryngology/Head & Neck Surgery at the University of Oklahoma Health Sciences Center prior to going into private practice. Dr. King was one of the physicians that treated victims of the Oklahoma City Bombing in 1995, and he actually applied to law school the week after the 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 in 1999. Dr. King’s law firm focuses on healthcare corporate transactional and corporate entertainment law. He represents physicians, dentists, ambulatory surgery centers, and other healthcare entities and corporations. He also represents producers, directors, actors, and entertainment companies. In either sector, Dr. King’s forte is designing successful corporate exit strategies for his clients. Interestingly, Dr. King has produced seven films in the past four years, and he has also acted in eight films.

AMY T. KULB, ESQ.
Ms. Kulb received her B.A. cum laude from Barnard College in 1976 and her J.D. from St. John’s University School of Law in 1979. She was admitted to the practice of law in New York in January, 1980. Ms. Kulb served as a prosecutor for the Office of Professional Discipline until she joined the firm of Jacobson Goldberg & Kulb, LLP in 1986. She concentrates her practice on the representation of dentists and other health professionals in the defense of professional discipline matters, Medicaid matters and audits, as well as other law enforcement and regulatory matters. The firm represents dentists in the purchase, sale and credentialing of dental practices.

Ms. Kulb is a Risk Management instructor and Ethics and Jurisprudence instructor for the NYS Dental Association and frequently lectures to a variety of dental groups and other health professional groups on current legal topics affecting the professions.

THEODORE R. LEBLANG, JD, FCLM
Mr. LeBlang is Emeritus Professor of Law and Medicine at Southern Illinois University Schools of Medicine and Law. Previously, he served as professor and chair of the Department of Medical Humanities. A graduate of Pennsylvania State University and the University of Illinois College of Law, Mr. LeBlang is Past President of the American College of Legal Medicine (ACLM). He is also a recipient of the ACLM Gold Medal Award, in recognition of his important contributions to the field of legal medicine. Mr. LeBlang is Editor Emeritus of the Journal of Legal Medicine and a former Editor-in-Chief of the Illinois Bar Journal. He has served on numerous journal editorial boards and is a former co-annotator of the Code of Medical Ethics: Current Opinions with Annotations, published by the American Medical Association. Mr. LeBlang has written and spoken extensively on various issues in legal medicine and is co-author of The Law of Medical Practice in Illinois (2d ed.), published by Thomson/West.

ROBERT W. LILES, JD, MBA, MS
Mr. Liles’ background is somewhat unique. In addition to a law degree, he holds both an M.B.A. and an M.S. in Health Care Administration. Robert has worked on the provider side, as a federal prosecutor and now represents physician practices and other health care providers around the country in connection with Medicare / Medicaid / Private Payor audits, state board of licensure actions, and False Claims
IRVING MCKENZIE, DDS
Dr. Irving McKenzie received his medical degree, with a specialty in Stomatology, from the I. P. Pavlov Medical University, St. Petersburg, Russia, and his MSc degree in Orthodontics and Dentofacial orthopedics from St. Petersburg Academy for postdoctoral studies. He is Chief Dental Surgeon for Jamaica and an advisor to Minister of Health and to other Ministers of Government on ‘Dental and Oral Health’ matter. Dr. McKenzie is an Adjunct Professor of Dental Surgery and founding Dean of the College of Oral Health Sciences, University of Technology, Jamaica, a Master of the American Academy of Implant Prosthodontics and a Diplomate in the International Congress of Oral Implantologists. He has published and lectured nationally and internationally on ‘infection control procedures’, dental public health, orthodontics & dentofacial orthopedics, and forensic stomatology. Dr. McKenzie is Secretary of the Caribbean Council of Chief Dental Officers. Dr McKenzie is Fellow in the International College of Dentist, the Academy of Dentistry International and the Pierre Fauchard Academy. Dr. McKenzie is also a member of the Board of Directors of the American Board of Dental Examiners and a member of Commission on Dental Competency Assessment (ADEX-CDC). Dr. McKenzie

MARK S MONASKY, MD, JD, CFP®, AEP®, EPLS, FACS, FAANS, FCLM
Dr. Monasky is a graduate of the Columbia University College of Physicians and Surgeons in New York City and underwent neurosurgery training at Mayo Clinic and the University of Maryland followed by a pediatric neurosurgery fellowship at Southwestern Medical School in Dallas, Texas. He is board certified by the American Board of Neurological Surgery and is the only physician in the country board certified in estate planning by the Estate Planning Law Specialist Board (EPLS), which is accredited by the American Bar Association. Dr. Monasky passed a comprehensive national examination designed for actively practicing estate planning attorneys to acquire this designation. He maintains active practices in both law and neurosurgery, and recently earned the Certified Financial Planner (CFP®) designation. Dr. Monasky has practiced neurosurgery for 26 years and law for 10 years. He spends half his time practicing neurosurgery at Sanford Medical Center in Sioux Falls, SD and Rapid City Regional Hospital in Rapid City, SD, and the other half practicing law with a special concentration on asset protection, estate, tax, and business planning. His virtual practice focuses on drafting trusts and creating business entities utilizing highly favorable South Dakota asset protection, trust, and business laws. He has many physicians, particularly surgeons, and other high net worth individuals as clients. Dr. Monasky has drafted hundreds of complex trusts and formed numerous business entities to achieve his clients’ desires. He lectures frequently to physician groups. He was a partner in a local law firm in North Dakota when the oil boom took off practicing estate and asset protection and business planning. He recently founded MD Wealth Protector, LLC, a niche, virtual law firm catering to business owners, physicians, surgeons, and other high net worth individuals. Mark is passionate about helping his fellow physicians and attorneys navigate the complex estate, tax, and business planning world. He is licensed to practice both medicine and law in North and South Dakota. He is a fellow of the American College of Surgeons (FACS), the American Association of Neurological Surgeons (FAANS), and the American College of Legal Medicine (FCLM). He is an active member of the Congress of Neurological Surgeons, Christian Medical and Dental Association, North and South Dakota State Medical Associations, American Bar Association, State Bar Association of North Dakota and State Bar of South Dakota. He is a member of the Asset Protection Council of the Real Property, Trust, and Estate Law section of the American Bar Association. Additionally, he is the only physician member of Wealth Counsel, a National Association of 4,000 estate planning attorneys. He has earned the accredited estate planner (AEP®) designation by the National Association of Estate Planning Councils. He belongs to the Financial Planning Association and is an affiliate member of the Chartered Financial Analyst Institute. Dr. Monasky has been married to Judy for 36 years. They are the proud parents of Mark Jr., a commercial pilot based in New York City, and Heather, an attorney in Los Angeles. Dr. Monasky can be reached at mmonasky@mdwealthprotector.com.

ROGER (REGAN) L. MOORE, DDS, MSD
Roger (Regan) L. Moore, DDS, MSD, President, Institute for the Advancement of Sports Dentistry, LLC; Academic Institution: Retired Faculty in Periodontology, University of Louisville School of Dentistry, Louisville, KY E-mail: teamdentist@aol.com Phone: (502)418-1833; Session Title: Legal Issues/Sports Dentistry. Dr. Roger (Regan) Moore Biosketch: Cincinnati Ohio native. Princeton H.S. (1961); Manchester College, N.Manchester Indiana (BS 1964 ); Ohio State Univ, DDS (1968); US Army Dental, Bamberg Germany (1968-1972); Private General Practice dentistry, Wilmington Ohio (1972-83); Certificate in Periodontics (85) and Masters of Science in Dentistry (86), University of Kentucky; Full time Periodontics faculty, University of Louisville School of Dentistry (1985-2015), Retired USLD in 2015. Published in periodontal surgery, patient IV sedation, sports dentistry. Member: ADA, AAP, ASD and affiliates. President, KY Society of Periodontists 1988 and 2010. Inducted in Fellowship of America College of Dentists 2006. Editorial Board, Journal of Dental Traumatology until retirement in 2015. Served as President, Academy for Sports Dentistry 2007-08. Have worked with athletes of all ages including high school college, professional, adult amateur club and Olympic elite. Teach periodontic, pediatric, endodontic and general practice residents in knowledge, skills and practice of sports dentistry.

LILLIAN OBUCINA, DDS, JD, FCLM
Dr. Lillian Obucina is an Assistant Professor at Midwestern University College of Dental Medicine, Downers Grove, Illinois, where she teaches removable prosthodontics and practice management. She also owns and operates a dental, and a law practice, in the Chicago Loop. Dr. Obucina is a 1988 graduate of Northwestern University Dental School, and she completed post-graduate dental training at Northwestern by obtaining a Certificate in Prosthodontics in 1990. In 2002, Dr. Obucina graduated from The John Marshall Law School. Her legal practice is dedicated to healthcare law. She has lectured independently, and on behalf of the ADA, on risk management, ethics, oral health literacy and practice management. In her spare time, Dr. Obucina enjoys travel, photography and walking.

KALU UGWA EMMANUEL OGBUREKE
BDS, MSC, DMSC, JD, FDSRCS, FDSRCS, FRCPATH
Kalu U. E. Ogbureke is a tenured 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 Augusta University (AU) Dental College of Georgia and the College of Graduate Studies in Augusta Georgia. Professor Ogbureke holds several visiting professorship at institutions in the United States and abroad. Professor Ogbureke 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, Molecular/Oral Biology) from Harvard University, and a juris doctorate (JD, Law) 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 (FDSRCPSc), and the Royal College of Surgeons of Edinburgh (FDSRCS). Professor Ogbugure also earned a graduate certificate in the Business of Medicine from Johns Hopkins University. He completed a 2½-year clinical research fellowship at the National Institutes of Health (NIH), Bethesda, Maryland. Professor Ogbugure 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 the American Board of Legal Medicine (ABLM), 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 Ogbugure has been inducted into the fellowship of the American College of Dentists (FACD). Professor Ogbugure 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 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 Ogbugure 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 Ogbugure is an attorney and admitted to practice law in three United States Jurisdictions (Georgia, Massachusetts, District of Columbia) and the United States Supreme Court. His interest is in Health Law and Policy, and Forensic odontology, and 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 Ogbugure received three (3) separate Commendation Letters from AU 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 2010. In 2012, Professor Ogbugure 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 “Angel-Togba” homicide case in Monrovia, Liberia in 2008. Professor Ogbugure 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 the International Association for Dental Research (IADR). Professor Ogbugure is a recipient of The University of Texas School of Dentistry at Houston, Dean’s Excellence (Scholarship of Discovery) Award (2015). He is a 2016 King James IV Professor, Royal College of Surgeons of Edinburgh (RCSEd; 2016), and the first African to receive this prestigious award. Professor Ogbugure was recently named the 2017 Harry W. Bruce Jr. Legislative Fellow by the American Dental Education Association (ADEA) and will be assisting with advocacy and legislative activities relevant to Oral Health during the summer of 2017. In June 2002, Dr. Ogbugure was invited as a Discussant on the subject of “NOMA in Nigeria” by the National Public Radio/ BBC, “The World Today” program (AUDIO available) hosted by Lisa Mullin. In 2010, he was profiled by the Augusta Chronicle in a full-length article titled: “Professor Stays Too Busy to Count his Degrees” (Available online at: http://chronicle.augusta.com/news/metro/2010-02-21/professor-stays-too-busy-count-his-degrees), and quoted in an Augusta Chronicle article discussing research report on “Coffee and tea intake and risk of head and neck cancer: pooled analysis in the international head and neck cancer epidemiology consortium.” The article by Galeone et al. (2010) discussed the effects of coffee consumption on the risk of developing head and neck cancers, including oral cancers. (Available online at: http://chronicle.augusta.com/news/health/2010-06-21/coffee-could-greatly-cut-cancer-risk-research-says?ver=1277170906). The same year (2010) Professor Ogbugure’s research was highlighted in the Augusta Chronicles in a full-length article titled: “GHSU wants to increase research, federal funding” (Available also online at: http://chronicle.augusta.com/news/education/2011-11-09/ghsu-wants-increase-research-federal-funding). Professor Ogbugure 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 titled Oral Cancer.

OLIVIA CALHOUN PALMER, DMD, JD

Dr. Palmer is a native of Charleston, SC. She graduated from the Medical University of South Carolina’s College of Dental Medicine in 1982 and entered private practice. In 1999 she completed the Medical College of Georgia’s dental implant residency program. Dr. Palmer is an Honored Fellow of the American Academy of Implant Dentistry and a Diplomate of the American Board of Oral Implantology. Dr. Palmer served 32 years in the care and treatment of infants born with cleft lip and palate, and was a co-producer of a video about that care that won an international health sciences award. It was presented at the American College of Surgeons meeting in 1985. Dr. Palmer has
presented to dental groups all over the US and South Africa. In 2010 she entered the Charleston School of Law’s evening program and completed the four year curriculum in three years, while practicing dentistry full time. After passing the SC Bar examination, she sold her private practice and formed Palmer Law Firm, LLC. She is a plaintiff’s attorney and focuses on dental malpractice. She also has a consulting company, Palmer Consulting, LLC that offers expert witness services and risk management to attorneys and dentists around the country. Always the educator, she maintains a faculty appointment at the Medical University of South Carolina’s Department of Stomatology where she teaches dental practice and risk management.

NICHOLAS E. PANOMITROS, DDS, JD, FCLM
Nicholas E. Panomitros is a practicing dentist and licensed attorney. He received his Doctor of Dental Surgery from the University of Illinois College of Dentistry and also holds a Juris Doctor as well as an LLM. Dr. Panomitros currently has faculty appointments at Loyola University’s, Medical School, General Practice Dental Residency Program and University of Illinois, Schools of Public Health and College of Dentistry. Panomitros has been a dental board examiner for CDCA, CRDTS, WREB, SRTA and CITA. On his legal side, Dr. Panomitros has also taught at Loyola School of Law and was previously an Administrative Law Judge for the State of Illinois.

ANABEL PELHAM, PH.D.
Dr. Pelham is president of the National Association for Professional Gerontologists, emerita professor of Gerontology, and executive director of the Center for Age-Friendly Excellence. She is a member of the board of directors of the Los Altos Community Foundation and international expert and thought leader in aging. She recently guided the successful and first time 15-city Age-Friendly Silicon Valley initiative and is now working with other cities in the West.

JOSEPH D. PIORKOWSKI JR., MD, JD, FCLM
Joe Piorkowski has served as the leader of national expert witness teams for the defense of Norplant, Sulzer hip and knee implant, Baycol, and YAZ/Yasmin litigations. He has experience representing scientists, physicians, other health care providers, hospitals, and other product manufacturers in a wide range of litigation, including toxic tort/products liability cases, medical malpractice actions, peer review proceedings, and FDA matters. Joe was selected as one of Washington, DC’s 2017 “Superlawyers” for Personal Injury Products (Defense) and he has been repeatedly listed by Washingtonian magazine as one of the “Best Lawyers in Washington.” Joe is a physician as well as an attorney and is board certified in three areas, including family practice. He served as a flight surgeon in the U.S. Naval Reserve Medical Corps for over 25 years until his retirement with the rank of Captain in 2005. He continues to teach other doctors and health care providers as an Instructor in Advanced Trauma Life Support and Advanced Cardiac Life Support. Joe has served as an Adjunct Professor of Law at Georgetown University Law Center since 1992, where he has taught courses including “Trial Practice: Working with Medical Experts” and “Causality in Science and Law Seminar.” He also served as Clinical Assistant Professor in the Department of Surgery (General) at the Georgetown University of Medical Center from 1995 to 2004. Joe is the author of “Medical Testimony and the Expert Witness” Legal Medicine: Medical Dynamics of Legal Encounters (3d. ed. 1995, 4th ed. 1998, 5th ed. 2001, 6th ed. 2004, 7th ed. 2007, 8th ed. 2010, 9th ed. 2015); Note, Between a Rock and a Hard Place: AIDS and the Conflicting Physician’s Duties of Preventing Disease Transmission and Safeguarding Confidentiality 76 Georgetown Law Journal 169 (1987); and Note, Professional Conduct and the Preparation of Witnesses for Trial: Defining the Acceptable Limitations of “Coaching” 1 Georgetown Journal of Law Ethics 389 (1987). He is also a frequent lecturer and presenter on various legal and medical topics. Joe is a Fellow of the American College of Preventive Medicine and the American College of Legal Medicine. He is a member of the International Association of Defense Counsel (IADC), Regulatory Affairs Professional Society, International Society for Pharmacoepidemiology, and the American Bar Association’s Litigation section. Joe is admitted to practice before the state courts of Maryland, Texas and the District of Columbia; and numerous United States District Courts and Courts of Appeals as well as the United States Supreme Court. Joe is licensed to practice medicine in the District of Columbia and Maryland.

ERIC PLOUMIS, DMD, JD
Dr. Eric Ploumis is an attorney, an orthodontist, and an associate clinical professor of orthodontics at New York University. He maintains a practice in orthodontics and in law in New York City.

DAVE PREBLE, DDS, JD, CAE
Dave Preble Vice President, Practice Institute, American Dental Association leads an operating agency responsible to grow the value of ADA membership through the delivery of programs, products and services related to the business of operating a dental practice of any size and to promoting the interests of the dental profession in issues related to health care finance, health outcomes and quality, informatics and standards, and public health. Dr. Preble has a nicely diverse background and experience base as he has practiced dentistry for over 20 years in both private and public health settings, holds a law degree, is a Certified Association Executive, is a Kellogg Executive Scholar in Non-Profit Management and is a Fellow of both the American College of Dentists and the American College of Legal Medicine.

FRANK RECKER,DDS, JD, FCLM
Dr. Frank Recker obtained his D.D.S. from the Ohio State University College of Dentistry, and his J.D. from Northern Kentucky University Chase College of Law. Before entering the full time practice of law, he practiced as a general dentist in Cincinnati and served on the Ohio State Dental Board. As a Life member of the American Association of Dental Boards, he monitors dental board activities and trends throughout the U.S. In addition to having represented dentists in disciplinary and malpractice proceedings in over 25 states, he has successfully litigated First Amendment/advertising cases against dental boards in several states. Dr. Recker has lectured to dental groups throughout the country on a multitude of risk management issues, including high-risk patients, clinical issues, staffing and employment protocols, and dental board matters. He is licensed to practice dentistry in Ohio and Florida, and admitted to the practice of law in Ohio, Kentucky, Florida, and multiple federal appellate courts and the US Supreme Court.

FRANK J. RICCIO, DMD, JD, FCLM
Attorney Riccio has maintained a private law practice in Braintree, Massachusetts 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 AAI; 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 and FINRA Arbitrator. 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.

JOSEPH P. RILEY JR., JD
FORMER MAYOR OF CHARLESTON, SOUTH CAROLINA

Joe Riley is widely considered one of the most visionary and highly effective governmental leaders in America. He served ten terms as Mayor of the City of Charleston from 1975 to 2016. He graduated from The Citadel in 1964 and the University of South Carolina Law School in 1967, and served in the S.C. House of Representatives from 1968 to 1974. In his time as Mayor, Charleston transformed from a decaying urban center to a top cultural destination. He is known for his innovative redevelopment projects, carefully crafted to add to the overall quality of life in the city. He diffused racial tensions by working closely with the African American community. The crisis leadership that he demonstrated after Hurricane Hugo in 1989 gained national praise for getting the city quickly cleaned up and running. Today, Riley is professor of American Government and Public Policy at The Citadel and Executive in Residence at the Joseph P. Riley, Jr. Center for Livable Communities at the College of Charleston. He is a Distinguished Fellow of the Pew Charitable Trusts, working on smart solutions for flood-prone communities and the national government, and the first Distinguished Visiting Fellow at the Urban Land Institute. Riley is also currently working to build the International African-American Museum, a $75 million project scheduled to break ground in 2018. Under his leadership, Charleston increased its commitment to racial harmony and progress, achieved a substantial decrease in crime, experienced a remarkable revitalization of its historic downtown business district, supported the creation and growth of Spoleto Festival USA, added significantly to the City’s park system including the highly celebrated Waterfront Park, developed nationally acclaimed affordable housing, and experienced unprecedented growth in Charleston’s size and population. Mayor Riley led a city government with an impressive record of innovation in public safety, housing, arts and culture, children’s issues, and economic revitalization and development. The City of Charleston is recognized as one of the most livable and progressive cities in the United States. Riley has held numerous national leadership positions and received many awards and distinctions. President Barack Obama presented him with the 2009 National Medal of the Arts for cultivating Charleston’s historic and cultural resources to enhance public spaces, and for revitalizing urban centers throughout the U.S. as the founder of the Mayors’ Institute on City Design. The American Architectural Foundation and the U.S. Conference of Mayors in 2010 created the Joseph P. Riley, Jr. Award for Leadership in City Design in his honor. He received the American Society of Landscape Architects’ 2004 Olmsted Medal; Governing Magazine named him their Public Official of the Year in 2003 for “leveraging the power of urban design and civic space.” The American Architectural Foundation honored him in 2002 with the Keystone Award for exemplary leadership to those who use architecture to transform their communities. He was named one of the 2004 Giants of Design by House Beautiful Magazine and received the first U.S. Conference of Mayors President’s Award in 2000 for outstanding leadership. In 2000, he was honored as the first recipient of the Urban Land Institute’s J. C. Nichols Prize for Visionary Urban Development, and also in 2000, was honored with the Arthur J. Clement Award in Race Relations for his battle to remove the confederate flag from the S.C. Statehouse. Riley received the 1994 Thomas Jefferson Award for “his exceptional leadership and ‘Jeffersonian’ vision in redefining the promise and, ultimate the future, of our nation and its cities.” He has received the Seaside Prize from the Seaside Institute for exemplary leadership and contributions to high-quality urban design throughout America. He received the Outstanding Mayors Award from the National Urban Coalition, the Distinguished Citizen Award by the National Association of Realtors. He served as President of the U.S. Conference of Mayors in 1986-87 and has received honorary degrees from ten colleges and universities.

S. SANDY SANBAR, MD, PHD, JD
BACHELOR OF SCIENCE (With Distinction) in Biology; DOCTOR OF MEDICINE (With Distinction), American University of Beirut, Lebanon; DOCTOR OF PHILOSOPHY (in Biochemistry), University of Oklahoma; JURIS DOCTOR, Oklahoma City University. Military Service in the U.S. Army Medical Corps: 1969 - CAPTAIN, promoted to MAJOR, at Fitzsimmons General Hospital, Denver, Colorado; 1970 - LT. COLONEL U.S. Army Medical Corps, U.S. Army Hospital, Danang, Vietnam; 1970 - Bronze Star Medal Award in Vietnam prior; Honorably Discharged July 4, 1970. Since 1970’s, he has practiced in Oklahoma City both as an Attorney at Law and Internal Medicine and Cardiology. Sanbar is a Past President of the American College of Legal Medicine (1989-1990) and he has received numerous Awards, including Gold Medal Award (2000), Distinguished Service Award (2007) of the American College of Legal Medicine. From 2007-2012, he served as the Chairman of the American Board of Legal Medicine (ABLM). He is a Diplomat of the ABLM. He is an Adjunct Professor of Medical Education, Univ. Of Oklahoma Health Sciences Center, Oklahoma City, OK; and Adjunct Professor of Medical Jurisprudence, Touro University Nevada College of Osteopathic Medicine. Sanbar is a prolific author of over 200 articles, and author or editor of eleven Books. His books include Hyperlipidemia & Hyperlipoproteinemia; Medical and Hospital Law; Editor, LEGAL MEDICINE, seven Editions from 1987-2007; Editor, MEDICAL MALPRACTICE SURVIVAL HANDBOOK, 2007; and Editor, ABLM BOARD REVIEW EXAM & STUDY GUIDE, 2007 & 2012, and LEGAL MEDICINE & MEDICAL ETHICS, 2010 and 2015.

BRUCE H. SEIDBERG
DDS, MSCD, JD, DABLM, FACD, FCLM, FAAHD, FPFA

Dr. Bruce Seidberg received his DDS from SUNY Buffalo, Masters (MScD) degree in Endodontics from the Boston University School of Graduate and his JD from Kensington University. He is a Diplomat of the American Board of Endodontics and the American Board of Legal Medicine, a Fellow of the American College of Dentists, the American Association of Hospital Dentistry, the Pierre Fauchard Academy and the American College of Legal Medicine. He is a member of the American Dental Association, American Association of Endodontists, American Association of Dental Editors, New York State Endodontic Association and other local dental societies. A former Associate Professor of Endodontics at SUNY at Buffalo and Director of a General Dentistry Residency Program at the St. Joseph’s Hospital Health Center in Syracuse, he is currently Chief of Dentistry at Crouse Hospital in Syracuse, NY, serves on the American Board of Legal Medicine and is Secretary of the American College of Legal Medicine Foundation. Dr. Seidberg has contributed many articles to the dental literature, a chapter in the dental text Dentistry for the Special Patient, legal text Legal Medicine and the 6th Edition of Ingle’s Endodontics. Dr. Seidberg served as Associate Editor of the Fifth District Dental Society Bulletin (NYS), Editor of the Boston University School of Graduate Dentistry Endodontic publications (Quarterly, Newsletter and Journal) for twenty five years, on the Scientific Advisory Panel for the Journal of Endodontics, Managing Editor of the ACLM Communiciqué and Editor-in-Chief of the AAE District II Endodontic Forum; and he served a four year term on the American Dental Association Council on Communications. He has lectured at national and international meetings about the
fields of dentistry and law. He is a past chair of the Pierre Fauchard Academy and has served two terms on the AAE Foundation Board including a term as secretary-treasurer, vice-chair of the American Dental Association Council on Communications, two terms each on the Board of Governors of the American College of Legal Medicine and the Board of Directors of the American Association of Endodontics. He was awarded the President’s Award from the AAE in 2001, being the second individual to receive the honor in the 54 year history of the organization. He was also presented with a President’s Award for Service from ACLM in 1992, 1993 and 1994 and the Gold Medal in 2013 for excellence and participation on behalf of dentistry and law. He has completed two terms as President of the New York State Association of Endodontists, and represented the State Endodontists on the New York State Dental Association Board of Governors. Dr. Seidberg is a Past President of the Cayuga County and the Onondaga County Dental Societies. He was the 48th President of the American College of Legal Medicine, the first dentist to serve in that capacity. He is currently in his second term as Chairman of the New York State Board for Dentistry. Dr. Seidberg is a Board Certified Endodontist with a private practice in Liverpool (Syracuse), New York and consultant for dental malpractice cases and can be reached at: Advanced Endodontics, PC; Dental-Legal Consultant, Plaza at North Medical Center 5112 West Taft Road; Suite “R”, Liverpool (Syracuse), New York 13088 Tel.: 315-453-3636 Fax: 315-466-3636 - E-mail: bseidberg@me.com

ERIC E. SHORE, DO, JD, MBA, FCLM

Dr. Shore practiced Internal Medicine in the Philadelphia area for more than 28 years and Health Care Law for 14 years. He received his DO degree from the Philadelphia College of Osteopathic Medicine and pursued a residency in Internal Medicine at Philadelphia General Hospital. He received his JD degree from Rutgers University School of Law, and his MBA in Medical and Healthcare Management from Saint Joseph’s University. He is a Fellow of that American College of Utilization Review Physicians (FACURP) and certified in Quality Assurance and Utilization Review, a Fellow of the American Academy of Family Physicians (FAAFP) and the American College of Legal Medicine (FCLM). He is currently Chair of the Pennsylvania Bar Association Medical Marijuana and Hemp Subcommittee on Workers Compensation and his law practice includes most healthcare related issues as well as appeals to reverse payment denials to hospitals.

JACK SNYDER, BS, MD, JD, PHD, MFS, MPH-MBA-MSIS

Dr. Jack Snyder, BS, MD (Northwestern), JD (Georgetown), PhD (MCV), MFS (GeoWash), MPH-MBA-MSIS (Johns Hopkins) currently serves as managing director for the Washington office of CATO Research Ltd, a global clinical research organization, and also as a member of the Board of Directors of the American Board of Toxicology. Dr. Snyder is Board-Certified in Medical Toxicology, General Toxicology, Clinical Informatics, Occupational Medicine, General Preventive Medicine, Pathology (Anatomic, Clinical & Chemical), Chemistry (Toxicological & Clinical), Quality Assurance & Utilization Review, Legal Medicine, Public Health, and Regulatory Affairs (US, Europe, Canada, Global). Jack is also certified as a Project Management Professional, Physician Investigator, Physician Executive, and Medical Review Officer, and maintains a New York Certificate of Qualification to direct clinical laboratories. He has directed & inspected clinical & research projects & laboratories; served as managing director, chief medical officer, and medical examiner; taught law, medicine, forensics, and regulatory science at Thomas Jefferson, George Washington, and Johns Hopkins Universities; served on non-profit boards; authored/edited textbooks, regulatory documents, study reports, and clinical trial protocols; authored >120 manuscripts in medical, legal, and scientific publications; and presented hundreds of papers at national and international meetings. Finally, Dr. Snyder is past president of ACLM, past Secretary of ABLM, and fellow of the American College of Medical Toxicology, American Academy of Clinical Toxicology, Association of Clinical Scientists, American Society of Clinical Pathologists, College of American Pathologists, Academy of Physicians in Clinical Research, National Academy of Clinical Biochemistry, American Board of Quality Assurance & Utilization Review, and the American College of Legal Medicine.

JENNIFER UNIS SULLIVAN, DMD, JD, FCLM

Jennifer Unis Sullivan was born and raised in the Pittsburgh area. She attended the University of Pittsburgh for undergraduate studies earning a B.S. degree prior to attending Temple University School of Dentistry (Kornberg School of Dentistry) in Philadelphia, Pennsylvania where she earned a D.M.D. degree. Upon graduation from dental school in 1986, Dr. Jennifer was hired by the Director of Clinics at Temple University School of Dentistry to evaluate patients for treatment in the dental school. She also maintained a limited general dental practice in the School of Dentistry, treating patients referred from Temple Dental School and Temple University Hospital. Dr. Jennifer left her position at Temple Dental School to practice as an associate dentist in a private general dental practice in Havertown, PA. In 1990, she moved back to the Pittsburgh area and founded Unis Dental Associates along with her brother, Nicholas J. Unis, D.M.D. who graduated from Temple University School of Dentistry in 1989. She continues to practice general and cosmetic dentistry, bringing over 30 years of experience to her patients. Dr. Jennifer also attended Duquesne University Law School in the evening while maintaining a very busy General Dental practice during the day, graduating in 1994 with a J.D. degree. She is the first female dentist in the Commonwealth of Pennsylvania to earn a law degree, and to pass the Pennsylvania Bar. She has maintained a Law license for over 20 years, has experience with a myriad of legal topics including dental/legal issues and employment law. Dr. Jennifer has been involved in organized dentistry and law with memberships in the American Dental Association, the American Bar Association, the Pennsylvania Dental Association, and has served as President of the Beaver Valley Dental Society. She is a Fellow of the American College of Legal Medicine. She has been named several times as one of Pittsburgh’s “Top Dentists” in Pittsburgh Magazine. Dr. Jennifer lives outside of Pittsburgh with her husband William, and her sons William Jr., and Bradley.

VELING W. TSAI, MD, JD, FCLM

Veling W. Tsai, MD, JD, FCLM, 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, California. Additionally, Dr. Tsai is in private practice, and Chief of Staff at Alhambra Hospital in Alhambra, California. 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 continues to be actively involved in scholarly research by serving on the editorial board for the Journal of Legal Medicine. Dr. Tsai is the current Treasurer of ACLM.
MARY WALL, MD, JD, FCLM
Dr. Mary Wall is a board-certified radiologist by the American Board of Radiology. She earned her Bachelor of Arts in Chemistry at Washington and Jefferson College in Washington, PA. After attending medical school at Drexel University, she completed her residency in Diagnostic radiology at Monmouth Medical Center in Long Branch, NJ where she served as Chief Resident. She went on to complete a Magnetic Resonance Imaging fellowship, also at Monmouth Medical Center. In 1999, Dr. Wall graduated from Case Western Reserve University School of Law where she received the degree Juris Doctor. She is a member of the American Bar Association and the Ohio Bar Association. Dr. Wall is the immediate Past President of the Ohio State Medical Association and a member of Governor Kasich Ohio Committee on Medical Pay Reform. In addition, she is a member of the Ohio Veteran’s Court Information Group, Past Chairperson of the Executive Compensation Committee for the Ohio State Medical Association, Past President of the OSMA, and a fellow of the American College of Legal Medicine. Dr. Wall was born in Pittsburgh, PA and currently resides in Bellevue, Ohio. She joined Mercy Radiology Group in June, 2016, which transitioned to Columbus Radiology Corporation division of Radiology Partners, Incorporated in March, 2017. She serves as lead Nuclear Physician for the Northwest Ohio division of Mercy Health.

CYRIL H. WECHT, MD, JD
Cyril R Wecht received his M.D. degree from the University of Pittsburgh and his J.D. Degree from the University of Maryland. He is certified by the American Board of Pathology, the American Board of Disaster Medicine, and the American Board of Legal Medicine. Dr. Wecht is actively involved as a medical-legal and forensic science consultant, author, and lecturer, and was the elected Coroner of Allegheny County for 20 years. He has performed approximately 20,000 autopsies, and reviewed or been consulted on approximately 40,000 additional post-mortem examinations, including cases in several foreign countries. Dr. Wecht holds several professorial faculty positions at the University of Pittsburgh, Duquesne and Carlow Universities. He is the author or co-author of more than 600 professional publications, and editor or coeditor of 46 books. Dr. Wecht has appeared as a frequent gnef on numerous national TV and radio shows, discussing famous cases, rp.any of which are discussed in his books, Cause of Death. Grave Secrets, Who Killed JonBenet Ramsey? Mortal Evidence, Tales from the Morgue, From Crime Scene to Courtroom, A Question of Murder, and Final Exam.

RICHARD S. WILBUR, MD, JD, FCLM, FACP, FACPE, FRSM
Richard S. Wilbur MD JD FCLM FACP FACPE FRSM is a Stanford trained Board Certified Internist and Gastroenterologist physician-executive. Currently, Board Chairman of the American Medical Foundation for Peer Review and Education working on patient safety. Member of the National Academy of Medicine. Former ACLM President.

MICHAEL WILLIAMS, JD
Michael Williams was born and raised in the capital city of Jamaica and was educated both in Jamaica and in the Union of Soviet Socialist Republics (USSR) as it then was. Michael was called to the Russian (Moscow) Bar in 1992 and briefly practiced there. He was called to the Jamaican Bar in 2014 and has practiced there since. Michael has distinguished himself by representing the people of West Kingston in the recently concluded public enquiry (West Kingston Commission of Enquiry) into the death of 74 persons in an internal security operation in in the said West Kingston in May 2010. Largely due to Michael's trenchant and fearless advocacy, the Commissioners of the Enquiry recommended that the estates of those killed in suspected cases of extra judicial killings, those who lost properties and those whose properties were damaged to be compensated. The Government of Jamaica is slated to pay out some Two Hundred Million Dollars in compensation. In addition to running a very busy general law practice, Michael lectures and tutors Law & Ethics at the College of Oral Health, University of Technology, Jamaica (UTech). Michael was Jamaica’s Consumer Representative to the American Board of Dental Examiners (ADEX) for three years ending August of 2017 when ADEX retired the Consumer Representative posts in its House of Representatives.

SAMUEL WOLFMAN, LLB, PHD
Dr. Samuel Wolfman teaches Psychiatry and Law at the Law Faculty of Haifa University Israel and at the medical school and has lectured, as a visiting professor, on psychiatry and law, medical law and bioethics, in universities in Europe and the US. Dr. Wolfman is a member of UNESCO teaching professors in bioethics, he participates in many international forums and congresses on forensic psychiatry, medical law and bioethics. He has attended and lectured in ACLM meetings since 2002. Dr. Wolfman serves as chairman of statutory tribunals in Israel for involuntary detaintments of mental patients so that his presentation is bases on academic as well as on practical experience.

PAMELA ZARKOWSKI, MPH
Professor Pamela Zarkowski is currently Provost and Vice President for Academic Affairs at the University of Detroit Mercy. She earned a Bachelor of Science, a Masters of Public Health in Dental Public Health and a Teaching Certificate in Community Dentistry from the University of Michigan and a Juris Doctor from Wayne State University. An educator for 38 years, she has served in various administrative roles and continues to teach predoctoral, graduate and dental hygiene students. She has held various leadership roles in national organizations, provided workshops and published in the area of legal and ethical issues for dental and health professionals.

KARIN WAUGH ZUCKER, MA, JD, LLM, FCLM
Karin Waugh Zucker, MA, JD, LLM, FCLM, is a Professor of Health Care Administration, Baylor University, and a Consultant in Bioethics to Brooke Army Medical Center. She teaches, or has taught, health care law, managed care law, health care contracting, health politics and policy, negotiations, international health, human resources management, and ethics —introduction to medical ethics, clinical ethics, organizational ethics, and the law and ethics of war and terrorism. Professor Zucker received her BA. in political science from Quincy College in Quincy, Illinois; her MA in philosophy from Boston College in Chestnut Hill, Massachusetts; her JD from the University of Missouri at Kansas City, Missouri; and her MFS and LLM from George Washington University, Washington, DC. Among her assignments while on active duty with the Judge Advocate General’s Corps, US Army, were tours as the Command Judge Advocate for the U.S. Army Medical Command Europe (7th Medical Command) and as the Legal Counsel for the Armed Forces Institute of Pathology and the Collaborative Center for the Investigation of AIDS. While in the Army, she also held academic appointments at the University of Maryland, the University of Texas Health Science Center - Houston, Texas Wesleyan University, and Tulane University. She is now a Department of the Army civilian employee with the Army - Baylor University Graduate Program in Health and Business Administration at the Army Medical Department Center and School. Professor Zucker is a Fellow of the American College of Legal Medicine and a member of the Association of Professional and Practical Ethics. She has lectured widely on legal medicine and bioethics and, since 2007, has been a member of the faculty of the European Summer University on Medical Ethics and Law in Toulouse, France.
GENERAL SESSION I: Update on Recent Developments in Legal Medicine
Moderator: Ted LeBlang, JD, FCLM, ACLM Past President
- 8:00 AM - 8:30 AM Federal and State Legislative Update Veling Tsai, MD, JD, FCLM
- 8:30 AM - 9:00 AM Federal and State Case Law Update Mary Wall, MD, JD, FCLM
- 9:00 AM - 9:30 AM Federal and State Regulatory Update Robert Harrison, MHA, JD, LLM
- 9:30 AM - 9:50 AM Q&A General Session I

SANDY SANBAR LECTURE
The Tragedy, Politics, and Public Policy of the Charleston Church Shooting (Ethics credit)
Invited Presenter: The Honorable Joseph P. Riley, Jr., JD, Former Mayor of Charleston, South Carolina

PINCKNEY
DENTAL SESSION I
Moderator: Joseph Graskemper, DDS, JD, FCLM, DABLM
- 10:00 AM - 10:30 AM Protecting Your Dental License and Privileges Amy Kulb, JD
- 10:30 AM - 11:00 AM Ethical & Legal Issues with Real Life Scenarios (Ethics credit) Bernard Friedland, DDS, JD, FCLM
- 11:00 AM - 11:30 AM Emerging Technologies, Emerging Risks: Legal and Ethical Considerations when Utilizing New Technology in the Dental Office Eric Ploumis, DMD, JD
- 11:30 AM - 12:00 PM Comparison of Legal & Professional Positions Towards Tooth Whitening Alexander Holden, BDS, MDPH, LLM

COLONIAL BALLROOM | 8:00 am - 9:50 am
GENERAL SESSION I: Update on Recent Developments in Legal Medicine
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COLONIAL BALLROOM | 11:00 am - 12:00 pm
STEWARD REUTER LECTURE
Alternative Decision Makers for Incapacitated Patients: Ethical Substituted Judgment (Ethics credit)
Invited Presenter: Cavan Doyle JD, LLM
Moderator: Robert W. Buckman, PhD, FCLM

COLONIAL BALLROOM | 1:00 pm - 2:45 pm
BREAKOUT SESSION I: LAWYERS, DOCTORS, HOSPITALS AND PATIENTS
Moderator: David Donnersberger, MD, JD, FCLM
- 1:00 PM - 1:20 PM Legal & Medical Aspects of “Observation” Admitting Status Eric Shore, DO, JD, FCLM
- 1:20 PM - 1:40 PM Patient Safety & Medical Error Richard Wilbur, MD, JD, FCLM
- 1:40 PM - 2:05 PM Patient Privilege & Law on Defense Counsel Contact with Treating Physicians Joe Piorkowski, MD, JD, FCLM
- 2:05 PM - 2:30 PM Ethical, Legal and Medical Staff Consequences of Physician Employment (Ethics credit) Dale Cowan, MD, JD, FCLM
- 2:30 PM - 2:45 PM Q & A Breakout Session I

COLONIAL BALLROOM | 3:00 pm - 5:00 pm
BREAKOUT SESSION II: Current Issues in Transgender Development, Health, Civil Rights and the Law
Moderator: Eli Avila, MD, JD, FCLM
This presentation made available through support from the World Professional Association for Transgender Health (WPATH)
- 3:00 PM - 3:30 PM Transgender Issues in Children and Adolescents Alexandra Karydi, PhD
- 3:30 PM - 4:00 PM Transitioning: Bathrooms are Only the Beginning Randi Ettnner, PhD
- 4:00 PM - 4:30 PM Transgender Civil Rights in the Workplace, in Healthcare and Beyond Jamison Green, PhD
- 4:30 PM - 5:00 PM Q&A Breakout Session II

PICKNEY | 3:00 pm - 5:00 pm
DENTAL SESSION III
Moderator: Daniel Orr, DDS, MD, JD, FCLM, DABE, ACLM, Past President
- 3:00 PM - 3:30 PM Tort Liability and the Mini Dental Implant Olivia Palmer, DMD, JD
- 3:30 PM - 4:00 PM The First Amendment and Dentistry: The Revolution Frank Recker, DDS, JD, FCLM
- 4:00 PM - 4:30 PM Dental Ethics in a Small Island Nation (Ethics credit) Michael Williams, JD
- 4:30 PM - 5:00 PM Update on E-Mailing Patient Records Joseph Graskemper, DDS, JD, FCLM, DABLM

PICKNEY | 5:00 pm - 5:15 pm
Distribution of Proposed Bylaws Changes and Brief Q & A
Leon Aussprung, MD, JD, FCLM
FRIDAY, FEBRUARY 23

COLONIAL BALLROOM  |  8:00 am - 9:50 am

GENERAL SESSION I: Update on Recent Developments in Legal Medicine
Moderator: Ted LeBlang, JD, FCLM, ACLM Past President

- 8:00 AM - 8:30 AM  Federal and State Legislative Update  Veling Tsai, MD, JD, FCLM
- 8:30 AM - 9:00 AM  Federal and State Case Law Update  Mary Wall, MD, JD, FCLM
- 9:00 AM - 9:30 AM  Federal and State Regulatory Update  Robert Harrison, MHA, JD, LLM
- 9:30 AM - 9:50 AM  Q & A General Session I
FEDERAL AND STATE LEGISLATIVE UPDATE
2017-2018

Veling Tsai, MD, JD, FCLM
Charleston, South Carolina
Feb. 23, 2018

WHAT HAPPENED IN THE LAST YEAR?

115 CONGRESS (2017-2019)

- Introduced 913 bills
- 20 bills passed

2017 FEDERAL LEGISLATION - ENACTED

- Public Law No: 115-80 — National Clinical Care Commission Act
- Public Law No: 115-71 — Early Hearing Detection and Intervention Act of 2017
- Public Law No: 115-83 — Protecting Patient Access to Emergency Medications Act of 2017
- Public Law No: 115-52 — FDA Reauthorization Act of 2017
- Public Law No: 115-92 — To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes.
- Public Law No: 115-23 — Providing for congressional disapproval under chapter 6, of title 5, United States Code, of the final rule submitted by the Secretary of Health and Human Services relating to compliance with Title X requirements.

WELCOME TO CHARLESTON!

- America's first museum, The Charleston Museum, was founded here in 1773.
- The official beginning of the Civil War happened here at Fort Sumter in 1860.
FDA REAUTHORIZATION ACT OF 2017

- Reauthorizes so-called “user fees” to the Food and Drug Administration for 5 years. These fees are paid for by medical device and drug manufacturers with every new product application and will continue to be paid every 5 years.
- Requires the FDA speed up approval process for many types of generic drugs usually cost about 80 to 85 percent less than their name-brand drugs. The sped-up process would be invoked if a similar medication is being sold at an estimated sixths of Americans with hearing loss don't get hearing aids, in large part because the devices are so expensive. The provision passed over the opposition from an unlikely source: gun rights groups, which claimed the provision could allow the devices to be used as a gun trigger.
- Allows certain types of hearing aids to be sold over the counter. An estimated five-sixths of Americans with hearing loss don't get hearing aids, in large part because the devices are so expensive. The provision passed over the opposition from an unlikely source: gun rights groups, which claimed the provision could allow the devices to be used as a gun trigger.
- Requires the FDA to regularize approval devices often used by patients. It would likely increase costs and reduce innovation.
- Reauthorizes so-called “user fees” to the Food and Drug Administration for five years. These fees are paid for by medical drug and device manufacturers with every new product application, and will account for $8 billion over the next five years, or about a quarter of the FDA’s total budget. President Trump actually wanted the FDA funded 100 percent by user fees, as a way of keeping the agency funded while slashing the expensive programs. But this plan was rejected by Congress for reauthorization.

STATE LAWS ON PRESCRIPTIONS

- 194 enacted state laws on prescription medications in 46 states ranging from establishing a controlled substance database to insurance coverage of specific medications.

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.
- 493 healthcare related legislations introduced in 52 states and territories in 2017
- 372 bills enacted in 30 states in 2017

STATE BY STATE BREAKDOWN

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- **STATE BY STATE BREAKDOWN**
ALASKA

- Act no. 2017-17 - Requires the board to adopt regulations in relation to the prescription and use of pharmaceutical agents for the treatment of eye disease and to develop uniform standards for the practice of optometry.

ARIZONA

- Act No. 117 - Authorizes a licensed pharmacist to dispense prescriptions for an emergency refill, for oral fluoride varnish, and for tobacco cessation, provides requirements for such prescriptions, requires the pharmacy to maintain a record of all prescriptions dispensed.
- Act No. 42 - Allowing drug retailers to promote and market drugs off-label if the information consists of "truthful promotion" of a drug, biological product or device. Prohibits the state or any medical board or subdivision from enforcing any federal or state restriction on manufacturers, health-care institutions or a physician from such "truthful promotion."

ARKANSAS

- Act No. 1096 - Amends the requirements for health insurance coverage for medically necessary foods used in the treatment of inborn errors of metabolism, defines medical disorder requiring specialized nutrients or formulas, exempts benefits provided under the state Medicaid Program and certain limited benefits health insurance policies from these requirements.
- Act No. 438 - Amends the Arkansas medical marijuana amendment of 2016, prohibits telemedicine as the method by which a qualifying patient obtains a written certification from a physician.

ARKANSAS

- Act No. 141 - Amends the definitions of the Gross Receipts Tax Act to include the definition of candy and soft drinks, imposes the full gross receipts tax and compensating tax on the sale of candy and soft drinks.
- Twenty and six-tenths cents (20.6¢) per gallon for each gallon of bottled soft drinks sold or offered for sale in the State of Arkansas;
- When a package or container of powder or other base product other than a syrup or simple sugar is sold or offered for sale in Arkansas, and the powder is for the purpose of producing a liquid soft drink, then the tax on the sale of each package or container shall be equal to twenty and six-tenths (20.6¢) for each gallon of soft drink which may be produced from each package or container by following the manufacturer's directions.

CALIFORNIA

- Act No. 2017-611 - Prohibits a person who manufactures a prescription drug from offering any discount coupon, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses, including a copayment, coinsurance, or deductible, for any prescription drug if a lower-cost generic drug is covered under the individual's health insurance, health care service plan, or other health coverage.

COLORADO

- Act No. 147 - Prohibits a carrier from setting fees for a dental service that is not paid for by the carrier.
- Act No. 296 - Prohibition against a carrier requiring a covered person to undergo step therapy, and, in connection therewith, requiring coverage for a prescribed medication that is part of the carrier's medication formulary.
CONNECTICUT

- Act No 17-6 - Requires health care providers to order serological tests for pregnant women in the state who they are providing prenatal care to and when the tests shall be ordered.
- Act 17-55 - Requires health insurance coverage for fertility preservation for insureds diagnosed with cancer. Insurers "shall provide coverage for the medically necessary expenses of the diagnosis and treatment of infertility, including, but not limited to, ovulation induction, intrauterine insemination, in-vitro fertilization, embryo transfer, gestation intra-fallopian transfer, and low tubal ovum transfer.

DELAWARE

- Act No 29 - Requires carriers to provide coverage for medically necessary inpatient treatment of alcohol and drug dependencies and prohibits carriers from imposing precertification, prior authorization, pre-admission screening, or referral requirements for the diagnosis and treatment, including in-patient treatment, of drug and alcohol dependencies, makes technical corrections to conform existing law.

HAWAII

- Act No. 67 - Authorizes pharmacists to prescribe and dispense self-administered hormonal contraceptive supplies to patients, regardless of a previous prescription from an authorized prescriber, specifies requirements pharmacists must meet prior to prescribing and dispensing contraceptive supplies.
- Act No. 68 - Authorizes pharmacists to prescribe and administer the human papillomavirus, Tdap, meningococcal, or influenza vaccine to persons between specified ages, specifies requirements pharmacists must meet prior to administering the vaccines.
- Act No. 66 - Requires execution of an opioid therapy informed consent process agreement between a patient and a prescriber of opioids in circumstances that may carry an elevated risk of causing dependency, limits initial prescriptions for opioids and narcotic analgesics to a maximum of seven consecutive days, except for treatment of specified conditions.

IDAHO

- Act No. 23 - Provides that prescribing tuberculin purified protein derivative products is within the practice of pharmacy, provides that a pharmacist may prescribe and administer a tuberculin purified protein derivative product under certain circumstances.
- Act No. 25 - Prescribing tobacco cessation products is within the practice of pharmacy, pharmacists may prescribe tobacco cessation products under certain circumstances.
- Act No. 242 - Removes language providing that a physician has examined in person the woman to whom the abortifacient is administered to determine the medical appropriateness of such administration and has determined that the abortifacient is sufficiently safe for use in the gestational age at which it will be administered; removed language providing that no drug may be prescribed through telehealth services for the purposes of causing an abortion.

ILLINOIS

- Act No. 395 - Requires insurers to cover an MRI of an entire breast or breasts if a mammogram demonstrates dense breast tissue.
- Act No. 305 - Provides coverage for treatment of serious mental illness and substance use disorders, including eating disorders, expands the definition as including, but not limited to, anorexia nervosa, bulimia nervosa, and binge eating disorder.
- Act No. 317 - Provides that a health care professional treating a patient located in the State through telehealth must be licensed in Illinois; this does not apply to a health care professional who is a resident of Illinois and is licensed in his or her respective licensing Act consistent with the standards of care for in-person services.

KENTUCKY

- Act No. 49 - Require insurance coverage for United States Food and Drug Administration-approved tobacco cessation medicines and services recommended by the United States Preventive Services Task Force, specifies restrictions and limits of coverage; requires Medicaid coverage for United States Food and Drug Administration-approved tobacco cessation medication and services recommended by the United States Preventive Services Task Force.
<table>
<thead>
<tr>
<th>State</th>
<th>Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Louisiana</td>
<td>Act No. 82 - Provides for a seven-day limit on first time opiate prescriptions, provides for exceptions to the limitation, authorizes a prescription to be filled for a lesser quantity than the maximum prescribed amount.</td>
</tr>
</tbody>
</table>
| Maryland   | Act No. 677 - Establishes that a mandate or coverage requirement that applies to insurers, nonprofit health service plans, and HMOs includes coverage for breast cancer-related digital tomosynthesis under certain circumstances, prohibits insurers, nonprofit health service plans, and HMOs from imposing a copayment or coinsurance requirement for digital tomosynthesis that is greater than any requirement for other breast cancer screenings.  
Act No. 678 - Prohibits a specified insurer, nonprofit health service plan, or health maintenance organization from imposing a step therapy or fail-first protocol on an insured or an enrollee for a specified prescription drug used in the treatment of a specified cancer underspecified circumstances. |
| Nevada     | Act No. 319 - Requires certain employers to provide reasonable accommodations to female employees and applicants for employment for a condition relating to pregnancy, childbirth or a related medical condition, except in certain circumstances, prohibits certain other discriminatory practices by employers relating to pregnancy, childbirth or a related medical condition, authorizes the equal rights commission to investigate complaints of unlawful employment practices.  
Act No. 221 - Prohibits a person from knowingly selling or offering to sell a material, compound, mixture or preparation containing dextromethorphan to a minor, prohibits a minor from knowingly purchasing any material, compound, mixture or preparation containing dextromethorphan under certain circumstances, provides penalties. |
| Oklahoma   | Act No. 234 - authorizes pharmacist to prescribe naloxone, provides that no dispensing protocol shall be required, authorizes pharmacists to exercise professional judgment in dispensing refill medications in certain circumstances, excludes certain medications, provides quantity limitations. |
| Oregon     | Act No. 289 - allows pharmacists to prescribe and administer injectable hormonal contraceptives and prescribe and dispense self-administered hormonal contraceptives, defines “injectable hormonal contraceptive” and “self-administered hormonal contraceptive”, requires prescription drug benefit programs and prescription drug benefits offered under health benefit plans to provide coverage for pharmacist consultations.  
Act No. 701 - prohibiting the selling of tobacco products or inhalant delivery systems, increasing the minimum age from under 18 to persons under 21 years of age, to include sales clerks, managers and owners. |
| Rhode Island| Act No. 2017-132 - mandates insurance coverage for medically necessary expenses for standard fertility preservation services when a medical treatment may directly or indirectly cause iatrogenic infertility, defines iatrogenic infertility as an impairment of fertility as a result of surgery, radiation, chemotherapy or other medical treatment affecting the reproductive organs or processes. |
VIRGINIA

Act No. 429 - Requires a prescription for any controlled substance containing an opiate to be issued as an electronic prescription, prohibits a pharmacist from dispensing a controlled substance that contains an opiate unless the prescription is issued as an electronic prescription, relates to a written prescription that is generated on an electronic application and transmitted to a pharmacy as an electronic data file.

WHAT IS AHEAD?

- MIPS
- MOC
- Opiates
- Gene therapy
- Marijuana use
- Lack of individual mandate

MOC DEBATE

- At least 21 states now have passed or considered bills to protect physicians who choose not to fulfill American Board of Medical Specialties requirements for Maintenance of Certification (MOC) from losing their hospital privileges, insurance eligibility and/or state licensure.
- Georgia, Maryland, Missouri, North Carolina, Oklahoma, Texas laws prohibit MOC as a part of licensure requirements, staff privileges, employment in certain facilities, reimbursement, or malpractice insurance coverage.
- Kentucky and Arizona also passed laws last year. They limit the ability of state agencies to deny licensing based on MOC or board certification status.

UNTIL NEXT YEAR... LOS ANGELES!!

ENJOY THE MEETING!!

- Thank you for your attention and enjoy the rest of the meeting!
Important Legal Decision Making and Events

Healthcare In 2017

Mary J. Wall, MD, JD, FCLM

Overview

Mergers
- Healthcare Systems/Hospitals
- Health Insurers
- Healthcare contracting/Arbitration
- ERISA Exemptions
- Medical Patients/Infringement
- EMR/Electronic Patient Information/Identity
- VA Issues
- Opioids/Liability/Corporate Responsibility

Mergers

• Federal Trade Commission
  - Less Activity

Anthem and Cigna
Anthem/Humana

U.S. v. ANTHEM 16-CV-1493 DC DCI
U.S. v. ANTHEM 16-CV-1494 USD DC

Healthcare Contracting/Arbitration

• Kindred Nursing Centers LP dba Winchester Center for Health and Rehabilitation et. al v. Janis E Clark et. al.

Healthcare Contracting/Arbitration

Appeal of Kentucky decision
KY 478 S.W. 3d, at 313

POA clauses – do they permit signing away grantors right to litigation.
ERISA
CHARITY
EXEMPTIONS

Advocate Healthcare Network
v. Stapleton

• USC 16-74
• 817 F 3d 517 (7th Cir. 2016)
• Ascension Health
  Underfunded plan by 134.5 M

St. Peters v. Kaplan

810 F 3d 517 (3d cir., 2015)

Dignity v. Rollins

830 F 3d 900 (9th Cir. 2016)

Medical Patients/Infringements

• Genentech v. Pfizer
  12-Cv-1672 US DCI(Del)
  Sandoz v. Amgen
  Amgen v. Sandoz
  193 ct. 15-1039, decided 7/14/17
  B Braun Melsungen AG v. Becton Dickenson et.al
  2016 CV 0041 Doc 126 (D. Del 2017)

Genentech v. Pfizer

• Biosimilar Herceptin
Sandoz v. Amgen

- Biosimilar Neupogen
- 9-0 decision
- Involves ACA
- 12p Subchapter of 906 page ACA
- Biologics Price Competition
- Innovation Act

B Braun Melsungen AG v. Becton Dickinson et. Al

- Germany then US Suit
- 10 Patents
- 1 V Catheter Safety

Freddie H Mathis v. David J Shulkin

- US 16-677 (2017)
- SCI VA (2017)

EMR/Electronic Patient Information/Identity

- Attias v. Care First Inc.
- 865 F.3d, 620 (2017), DC Ct Appeals
- -risk of harm
- -data breach
- -medical data/PHI theft

Opioid Oversight/Corporate Responsibility

McKesson
- Steinberg v. Bryant
- Del. Ct Chancery
Ohio v. Purdue, Endo, Teva, Johnson and Johnson et. Al
- Cherokee Nation v. McKesson, Cardinal Health, CVS, Walgreen, Walmart
- CV-17-203
Steinberg v. Bryant

McKesson – directors
Poor oversight after fine
Corporate v. Public policy responsibility

Ohio v. Purdue et. al

Mike Dewine, Attorney General
Regulatory Developments Update

A New Broom Sweeps Clean:
Reducing Regulation and Controlling Regulatory Costs,
Executive Order 13771
January 30, 2017

Regulatory Freeze Pending Review,
Memorandum for the Heads of Executive Departments and Agencies, Reince Preibus, Chief of Staff
January 20, 2017

Regulatory Developments Update

1. MACRA – MIPS
2. Expansion of Exclusion Authorities
3. Appeals Process Final Rule
4. Fraud and Abuse Enforcement
5. FDA Regulatory Initiatives

MACRA-MIPS
Medicare Access and CHIP Reauthorization Act of 2015
Passed with bipartisan support (remember that?)
Two goals addressed:
- Eliminate annual MPFS payment cuts due to SGR
- Lower cost through VBP and other APMs
Final Rule November 2016, Effective January 1, 2017

MACRA-MIPS
Repealed Medicare Sustainable Growth methodology
Replaced with Medicare Quality Payment Program
Either participate or face Part B reductions
Two ways to participate in QPP:
- Merit Based Payment Incentive System (MIPS) or
- Alternative Payment Model arrangements (APMs)

Merit Based Incentive Payment System
The default option (applies unless opt-in to APM)
Four performance measures
- Quality
- Resource Use (cost)
- Practice improvement activities
- Advancing care information (EHR utilization)

Replaces programs that MACRA ends on December 31, 2018
Physician Quality Reporting System
Value-Based Payment Modifier program
EHR Incentive Program (Meaningful Use)
Alternative Payment Model Arrangements

Two-tiered model

I. QPP APMs are focused on changing delivery and payment (i.e., Medicare Shared Savings Program)

I. MACRA Advanced APM
   Additional financial rewards
   At-risk arrangements (such as):
   - Track 2 and 3 ACOs
   - CPC Plus Medical Home Model
   - Oncology Care Model

Substantial financial bonuses:
- 2017 – 2022, bonuses in addition to APM gains or losses
- 5% of Medicare professional service billings
- 7.5% MPFFS update rather than .25% for MIPS

Office of the Inspector General on QPP

If clinicians do not receive sufficient information and assistance, they may struggle to succeed under the QPP or choose not to participate. This is of particular concern for small practices and clinicians in rural or medically underserved areas, who may lack the resources to fully engage in the QPP without customized technical assistance to meet practice-specific needs.

Report: http://oig.hhs.gov/oei/reports/oei-12-17-00350.asp

CMS has conducted minimal planning with regard to program integrity. Further, although CMS has designated executive leadership for other aspects of the QPP, it has not designated an executive lead on QPP program integrity. Without a comprehensive plan for program integrity, the QPP will be at heightened risk of fraud and improper payments, particularly related to MIPS payment adjustments.

Report: http://oig.hhs.gov/oei/reports/oei-12-17-00350.asp

MedPAC Recommends Repeal of MIPS

June 17, 2017: Report to Congress
October 3, 2017: Recommendation to repeal announced

- Unlikely to succeed in helping beneficiaries choose clinicians
- Unlikely to help clinicians change practice patterns to improve value
- Unlikely to help Medicare reward clinicians based on value

MedPAC Recommends Repeal of MIPS

- Considerable reporting burdens
- Imbalance in financial incentives
- Selective clinician choice of process measures
- Self-selected clinician attestations
- Too few cases per clinician for measurement reliability

June 2017 Report to the Congress: Medicare and the Health Care Delivery System, available at:
http://medpac.gov/-documents-/reports
Haymarket Provider Survey on QPP

Survey released January 19, 2018

71% “not very comfortable” or “not comfortable at all.”
62% find measures “not very important” or “not important at all.”
76% say their staff doesn’t understand QPP.
60% “not very prepared” or “not prepared at all” for QPP.

[available at] www.haymarketmedicaleducation.com

Expanded CMS Exclusion Authorities

• Expanded definition of “indirectly” to include items and services provided by individuals who do not request or receive payment from Federal programs.
• Added ten-year limitations period to align with FCA
• Increased financial loss aggravating factors
  • last update was 20 years ago
  • $1,500 and $5,000 to $15,000 and $50,000
  • “realistic marker for determining whether someone is untrustworthy”

Medicare Appeals Procedures Final Rule

American Hospital Association et al v. Burwell

• District Court found that, absent intervention, appeals backlog would reach almost 2,000,000 by the end of 2020.
• Required aggressive actions by CMS.
• This rulemaking is one result of the CMS response.
Medicare Appeals Procedures Final Rule

Four key changes:
- Grant precedential authority to certain DAB and MAC decisions.
- Provide for attorney adjudicators at the ALJ level.
- Revise rules for introduction of evidence.
- Revise CMS contractor participation in hearings.

CMS Low-Volume Appeals Initiative

- Administered by CMS rather than OMHA
- Substance has no bearing – no coverage criteria review
- 62% of net approved amount
- Part A & B providers with fewer than 500 pending appeals
- Across all NPIs for the provider
- $9,000 individual claim limit

CMS Low-Volume Appeals Initiative

- LVA opt-in is “all or nothing” option – no carve-outs
- Excludes providers seeking or in bankruptcy
- Excludes providers with pending fraud and abuse actions
- Claims must be pending as of November 3, 2017
- For NPI numbers ending in even numbers, March 9
- For NPI numbers ending in odd numbers, April 11

Fraud and Abuse Enforcement 2017

The False Claims Act takes center stage:
- 32 FCA settlements involving liability for individual providers.
- Significant increase prior years:
  - 2016 = 8
  - 2015 = 6
  - 2014 = 5
- Three-fold increase in settlements with physicians, dentists and podiatrists.

Fraud and Abuse Enforcement 2017

Stark predicate:
- South Carolina, September 11, 2017
- Dr. Serbin, FMC Clinics, incentive compensation for referrals to laboratory services
- FMC paid $1.56 million
- Dr. Serbin paid $443,000
New DOJ Policy on FCA Dismissal

Background:
- 600 new qui tam cases each year
- Rate of intervention has not increased
- Non-intervened cases impose substantial cost
- 700 cases dismissed by relators after declination since Jan. 1, 2012
- Dismissal Authority under 31 U.S.C. § 3730(c)(2)(A)

"If the cases lack substantial merit, they can generate adverse decisions that affect the government’s ability to enforce the FCA. Thus, when evaluating a recommendation to decline intervention . . . attorneys should also consider whether the government’s interests are served, in addition, by seeking dismissal."

Department of Justice, Commercial Litigation Branch
Memorandum to Assistant U.S. Attorneys Handling FCA Cases
January 10, 2018

Seven Non-Exclusive Factors:
1. Curbing Meritless Qui Tam Actions
2. Preventing Parasitic or Opportunistic Qui Tam Actions
3. Preventing Interference with Agency Policies and Programs
4. Controlling Litigation Brought on Behalf of the United States
5. Safeguarding Classified Information and National Security Interests
6. Preserving Government Resources
7. Addressing Egregious Procedural Errors

Other Considerations:
- Standard of Review
- Alternative Grounds for Dismissal
- Partial Dismissal
- Dismissal at a Later Stage Post-Declination

FDA REGULATORY ACTIONS IN 2017
- Human Drug Compounding Progress Report (January)
- Digital Health Innovation Action Plan (July)
- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices (August)
- FDA Reauthorization Act of 2017 (August)
- Breakthrough Devices Program Draft Guidance (October)
- Technical Considerations for Additive Manufactured Medical Devices (December)
- Clinical and Patient Decision Support Software Draft Guidance (December)
- Good ANDA Assessment MAPP (January, 2018)
FRIDAY, FEBRUARY 23

PINCKNEY | 10:00 am - 12:00 pm

DENTAL SESSION I

Moderator: Joseph Graskemper, DDS, JD, FCLM, DABLM

• 10:00 AM - 10:30 AM  Protecting Your Dental License and Privileges Amy Kulb, JD

• 10:30 AM - 11:00 AM  Ethical & Legal Issues with Real Life Scenarios (Ethics credit) Bernard Friedland, DDS, JD, FCLM

• 11:00 AM - 11:30 AM  Emerging Technologies, Emerging Risks: Legal and Ethical Considerations when Utilizing New Technology in the Dental Office Eric Ploumis, DMD, JD

• 11:30 AM - 12:00 PM  Comparison of Legal & Professional Positions Towards Tooth Whitening Alexander Holden, BDS, MDPH, LLM
Scenario 1
An oral & maxillofacial radiologist has among his referring doctors dentists who do dental implant surgery. These dentists request an “implant CT scan” that they use to plan the implant surgery. On occasion one of the referring dentists refers a patient with a note that he (the dentist) will pay for the CT scan. The radiologist bills the dentist and he pays the bill. The treatment plan is legitimate and he is not recommending treatment that is excessive or unnecessary. The referring dentist’s motives are not entirely altruistic – these patients often balk at going ahead with the treatment when they learn that the CT scan is not included in his fee. When this happens he tells patients that he will cover the cost of the scan, thus removing the financial obstacle of the CT scan, making patients more likely to accept the treatment plan. Unbeknownst to the patients the dentist builds the cost of his out-of-pocket expense into the fee that he quotes the patient. Recently the radiologist accidentally found out from one of the dentist’s staff that when he pays for the scan he increases the fee for his treatment to cover the cost of the scan. He does not list the fee for a CT scan as a separate item, but rather adds to his fee for other line items, e.g., he might add $50 to the cost of each implant. Patients are not aware of this.

QUESTION
Does the radiologist, with his newfound knowledge of the state of affairs, have an ethical, moral or legal obligation to tell patients about the referring dentist’s “sleight of hand”?

Scenario 2
The patient was a 51-year-old African American female. She had moved from one area of the city to a different area and sought care from a new dentist only because it was too far and difficult for her to take public transportation to her old dentist, who she stated was a nice man who had always treated her well. Based on his intra-oral examination the new dentist took a full-mouth series. Some of the images are presented in the next slide.

Scenario 2
What is the second dentist’s ethical and legal responsibility?

Scenario 3
The purpose of the Oral Diagnosis Clinic at at Harvard School of Dental Medicine is to assess the patient’s medical condition as well as to assess generally what the patient’s primary dental needs are and what level of practitioner would be competent to provide the necessary treatment within the standard of care, e.g. a dental student, a student in one of the specialty programs.

The standard practice at the oral diagnosis clinic is for a student on an oral diagnosis rotation to greet a patient in the waiting room and escort him/her to the clinic. The student then takes the patient’s medical and dental history and conducts a limited clinical examination. Thereafter student calls the covering faculty member and describes his/her findings to that faculty member. This discussion takes place in the presence of the patient. The faculty member then examines the patient and consults with the student regarding what x-rays should be taken. Only after the x-rays are taken and reviewed is a decision made as to whether the patient will be treated at HSDM, and if so, in which clinic and by whom.

Index Patient

Cemento-osseous dysplasia/Periapical cemental dysplasia

Scenario 3

Ethical & Legal Issues with Real Life Scenarios (Ethics credit) Bernard Friedland, DDS, JD, FCLM
Ms. K presented to the Oral Diagnosis Clinic. She was greeted by a student in the waiting room and escorted to the oral diagnosis clinic. The student took the medical history but then, instead of proceeding with the clinical examination, called the faculty member overseeing the clinic. The faculty member and the student went over Ms. K’s allergy list and spoke to Ms. K about her allergies. Ms. K has multiple allergies (the list ran to almost a full page of a notebook size page), including to some medications that are commonly used in dentistry. In particular, Ms. K informed them that for anesthesia, only topical medication could be used. It was because of the patient’s multiple allergies that the student called the faculty member before proceeding with the clinical examination. The student did not think that the patient could be treated as safely in the student clinic as she could be treated at a facility more accustomed to dealing with potentially severe allergic reactions. In addition, the inability to work under local anesthesia would be difficult at best for a student.

The faculty member agreed, exercised his professional judgment and decided in good faith that based on Ms. K’s numerous allergies, HSDM was not an appropriate facility for her dental treatment, and that she should receive her dental treatment at a fully equipped hospital facility, of which there are a few in Boston. The faculty member explained and discussed his reasoning with the student. The faculty member explained to Ms. K that due to her multiple allergies, it would be in her best interest to be treated at a hospital. It was at this point that Ms. K became aggressive. She insisted that she would be treated at HSDM and stated she would not leave the dental chair she was seated in. The faculty member continued to try to explain to Ms. K why a hospital would be more appropriate for her treatment, but he could barely get a word in over her remonstrations. She continued to insist she would be treated at HSDM, and also continued to refuse to leave the chair in the oral diagnosis clinic room. After several minutes of the faculty member trying to speak with Ms. K and her refusal to leave the chair, there was a backlog of patients forming because the oral diagnosis room could not be used to see other patients. The faculty member spoke to the Teaching Practices Manager about the situation. The Teaching Practices Manager called the University Police. The Teaching Practices Manager, in the presence of two University Police officers told Ms. K HSDM was not an appropriate facility for her care and that she would need to leave. Ms. K continued to refuse to leave. One of the police officers then told Ms. K that she to leave the clinic and he escorted her out of the building.

The faculty member’s good faith refusal to accept Ms. K as a patient in the student clinic was, as he explained to the student, based on her long list of allergies to commonly used medications. Prior to the patient’s outburst he had conveyed to the student that this was the reason for not accepting her as a patient. Even while making this decision the faculty member was cognizant of the fact that Ms. K could allege discrimination based on her medical condition, whether or not it formally qualified as a disability. Following her outburst, and before the student had begun writing the note in the patient’s chart, he considered changing the reason for his refusal to accept Ms. K as a patient, stating instead that it was because of her aggressive behavior. Unlike individuals with a disability, aggressive & unreasonable people are not a protected class and this reason for dismissing her would in all likelihood be less problematic.

ISSUES
Would it have been ethically, morally and legally permissible to change the purported reason for refusing to accept Ms. K as a patient? What would be the implications/benefits/downsides of such a decision?
Emerging Technologies, Emerging Risks: Legal and Ethical Considerations when Utilizing New Technology in the Dental Office

Eric Ploumis, DMD, JD

Presentation Objectives:
- Understand the nexus of emerging technology and evolving law
- Evaluate the risk-management issues that accompany implementing new technology in your office
- Implement protocols to reduce liability exposure to a tolerable level
- Explore the ethical issues involved in utilizing new technology in your dental office

Presentation Objectives:
- Recognize the legal and ethical perils when embracing emerging technology
- Define and evaluate the “standard of care” as it relates to new technology
- Analyze what type of informed consent is required when using new technology

Presentation Objectives:
- Theoretical: Provide you with a conceptual framework to evaluate the suitability of any new technology for your office
- Practical: Help you to decide if the new technology you are considering is right for your practice

Technology vs. Jurisprudence
- auto
- telephone
- facsimile
- computer
- e-mail
- Google, Facebook
- drones
- genomic and reproductive issues
What is it?
Typically: \( \text{H}_2\text{O}_2 \)
- Hydrogen peroxide
- Carbamide peroxide

Is it safe?
- Lower doses equally effective (6% vs 35%) (Martín, Vildósola, Berczio et al. 2015)
- 6%-10% limited effects on pulpal stem cell viability. Full recovery 3 days post-exposure. (Soares, Basso, Hebling et al. 2015)
- 648g of hydrogen peroxide created daily by body. 2 trays of whitening gel around 3.5g. (Li, 2003)
- Most reviews conclude safe provided manufacturer’s guidance followed. (Carey 2014; Li and Greenwall 2013)

1. United Kingdom

UK Framework
- Enforced by UK Trading Standards.
- General Dental Council (UK) responsible for the illegal practice of dentistry.

Permitted Usage
The regulations:
- Limit the concentration available to the public to concentrations less than 0.1%
- Dentists may use concentrations between 0.1% and 6%
- No-one may use concentrations above 6% (equivalent to 16% carbamide peroxide). To do so is a criminal offence.
- Prohibit the supply to anyone under the age of 18.

Comparative Legal and Professional Positions
1. United Kingdom
2. Australia
3. New Zealand
Does cost factor into determining the Standard of Care?

The Cost of Care vs the Standard of Care

When does the cost of care help define the standard of care?

What are the ethical considerations of utilizing (or not utilizing) a particular technology.

Standard of Care

If we don’t help establish the standard of care, the lawyers will do it for us.

ADA Clinical Practice Guidelines

Evidence-based clinical practice guidelines are intended to provide guidance and should be integrated with a practitioner’s professional judgment and a patient’s needs and preferences. They are not standards of care, requirements, or regulations. They represent the best judgment of a team of experienced clinicians, researchers and methodologists interpreting the scientific evidence on a particular topic.

AAO’s Clinical Practice Guidelines

Clinical Practice Guidelines for Orthodontics and Dentofacial Orthopedics
AAO on the Standard of Care:
The AAO recognizes that these guidelines may be used by insurance carriers and other payers, attorneys in malpractice litigation, and various entities with an interest in orthodontics. The Association encourages all interested persons to become familiar with the Guidelines. This document was not developed to establish standards of care or to be used for reimbursement or litigation purposes. The AAO cautions that these uses involve considerations that are beyond the scope of the Guidelines.

Proving a Malpractice Case
In order to demonstrate a breach of the standard of care the plaintiff must prove these four essential elements:
- Duty (doctor/patient relationship)
- Breach
- Causation
- Damages

Questions we will explore:
- When should you utilize new technology?
- Is there any disclaimer that can reduce your liability?
- What type of informed consent is appropriate?
- Can you ignore emerging technology?
- What are the ethical issues associated with the utilization of new technology?

Implementing Technology in Your Office
When should you implement new technology?
When will implementing any new technology become the standard of care?

Answer:
- When the average, prudent dentist would utilize that type of technology.
- When the benefits outweigh the risks.
- When there is a favorable cost/benefit ratio.
- When it is ethically improper not to utilize the technology.

Standard of Care as it relates to malpractice
The dental malpractice plaintiff must establish the appropriate standard of care and demonstrate that the standard of care has been breached.
**Example: Utilizing CBCT**

- Is the cone beam the "standard of care?"
- Should you read your own scan of is having a radiologist read a CBCT the standard of care?

- Would the average, prudent dentist utilize a CBCT in a similar situation?
- Would the average, prudent dentist have sent the CBCT to a radiologist to interpret under the same or similar circumstances?

**Is there any disclaimer that can reduce your liability?**

- Professionals cannot "disclaim" their way out of the standard of care.
- Courts have not recognized disclaimers as an effective shield against an allegation of malpractice.

**Informed Refusal**

- Patients must be informed of what might happen if they do *not* follow your advice
- Document this as you would informed consent

**Informed Consent: CBCT**

- Radiation concerns
- Diagnostic concerns
- Treatment concerns

**What type of Informed Consent is appropriate when you utilize new technology?**

Consent is appropriate when a reasonably prudent person in the patient’s position would have undergone and accepted the procedure if he or she had been fully informed of the risks, benefits, and costs.
Informed Consent: Radiation Concerns

- Are you informing the patient of the increased radiation a CBCT provides?
- Is your cbct "ALARA" (as low as reasonably achievable)?
- What do you do about an older machine that is not ALARA?

Informed Consent: Diagnostic Concerns

- Are you offering the patient the option to have the CBCT read by a radiologist?
- Are you reading the scan yourself?
- Are you sure you aren’t missing any pathology?
- Are you attempting to “disclaim” responsibility for reading a scan?
- Are you utilizing this technology as a risk-management tool or for the patient’s best interest?

AAO Insurance’s position

“CBCT scans can show information beyond that which we, as orthodontists, are trained to interpret. However, legally you may be presumed to know all that is shown. Involving a radiologist relative to the reading of CBCT scans is therefore advisable.”

The New York Times

Radiation Worries for Children in Dentists’ Chairs

“Children are vulnerable to radiation, but dentists use technology that emits high levels of it.”

Pathology analogy

When you do a biopsy of a suspicious lesion, do you diagnose the tissue yourself or do you send it to a pathologist?

Oral and Maxillofacial Radiology Executive Position Paper

- “Standard of Care: Dentists using CBCT should be held to the same standards as board certified radiologists.”
- “There may be a misconception on the part of some practitioners that the user has no responsibility for radiologic findings beyond those needed for a specific task (e.g., implant treatment planning). This assumption is erroneous.”
Informed Consent: Treatment Concerns

- Once you pick up pathology, are you presenting all treatment options?
- Are you documenting all of your findings and suggestions?
- Are you providing Informed Refusal?

Conclusions:

- CBCT is a new technology that has outpaced the ability of the law to guide us.
- Some of us will be the ones who make new law.
- The “reasonable doctor” standard is the appropriate analysis.
- The benefit to the patient is paramount.

Conclusions:

- CBCT should be read by someone “qualified” to interpret them.
- If you feel qualified, that could be you.
- If you have any doubt, send the scans to a radiologist.

Conclusions:

- You have a duty to refer if you don’t understand something.
- You have a duty to inform the patient of what might happen if they don’t seek an outside opinion.

Other Technology Issues

- cone beam radiography (CBCT)
- implants and tad’s
- sleep apnea
- distraction osteogenesis
- accelerated tooth movement
- telemedicine
- salivary diagnostics and genomics

Teledmedicine

*Telehealth: means the use of electronic information and communication technologies by telehealth providers to deliver health care treatment, education, care management and/or self-management of a patient.

To the extent it involves providing professional services in a jurisdiction other than the one in which the practitioner is physically located, telepractice raises the issue of the jurisdiction or jurisdictions in which the practitioner must be licensed. In New York State, a practitioner must hold a New York license, or be otherwise authorized to practice, when providing professional services to a patient located in New York or when the practitioner is located in New York.
SMILE DIRECT CLUB

"It's easy to get started on your new smile. You can make an appointment for a digital scan in one of our SmileShops™ (select cities), or you can complete an online photo assessment through our SMILECHECK™ system, and we’ll send you an easy to use at-home impression kit. We’ll submit your information to a state-licensed dental professional in our network for review and set-up, and you’ll be one step closer to your new smile."

SmileDirectClub makes straighter and whiter teeth more affordable by delivering invisible aligners direct to you.

Salivary Diagnostics and Genomics

Excerpts from that article:

- "With relatively inexpensive, fast and highly accurate technology, whole-genome sequencing reveals the entire gene content for an individual patient within hours."
- "As these tools become available, are we, as oral health professionals gaining competency to include these new innovations in our diagnostic and prognostic toolbox?"
- "If our scope of practice is expanded, are we prepared to engage in genomics to identify patients at risk as an integral part of the inter-professional health care team?"

Scope of Practice

Q. Do salivary diagnostics and genomics even fall within our legally permitted duties as dentists?

Salivary Diagnostics

GUEST EDITORIAL
Revising the scope of practice for oral health professionals: Enter genomics
Harold C. Slavkin
JADA March 2014 145(3): 228-230
Definition of Dentistry (NY § 6601 Education Law)

The practice of the profession of dentistry is defined as diagnosing, treating, operating, or prescribing for any disease, pain, injury, deformity, or physical condition of the oral and maxillofacial area related to restoring and maintaining dental health. The practice of dentistry may include performing physical evaluations in conjunction with the provision of dental treatment.

Definition of Dentistry in NC

A person shall be deemed to be practicing dentistry in this State who does, undertakes or attempts to do, or claims the ability to do any one or more of the following acts or things which, for the purposes of this Article, constitute the practice of dentistry:

1. Diagnoses, treats, operates, or prescribes for any disease, disorder, pain, deformity, injury, deficiency, defect, or other physical condition of the human teeth, gums, alveolar process, jaws, maxilla, mandible, or adjacent tissues or structures of the oral cavity.

Malpractice Policy Considerations

- Does your policy cover salivary diagnostics and genetic testing?
- Do you need a rider?
- Get it in writing from your carrier!

David Wong, UCLA Dental Salivary Diagnostics

“Imagine a world where a visit to the dentist saves your life. Imagine a world where doctors don’t have to draw your blood to test if you’re sick. Imagine a world where procedures save countless lives and save billions of dollars. The goal of the Salivary Diagnostics laboratory is to make this dream a reality. We are pioneering research in the usage of saliva as a diagnostic medium.”

Crash and Burn Technology: theranos

“Theranos was poised to revolutionize the blood testing industry by using only a few drops of blood in inexpensive tests. But now, federal regulators say they will bar the company’s dynamic founder and CEO Elizabeth Holmes from owning or operating a lab for at least two years.”

“Theranos story is now viewed as a cautionary tale, and questions are being raised about whether applying hardware and software business culture to biotechnology is dangerous.”

HIPAA issues related to technology

- File transfer protocol for e-mailing patient-related data
- Are you using a secure transmission?
- HIPAA (Health Insurance Portability and Accountability Act)
- HITECH (Health Information Technology for Economic and Clinical Health)
HIPAA

- AOL, Yahoo, Dropbox: not HIPAA compliant
- Google is if you have a paid account and sign a Business Associate Agreement

Electronic Medical Records Issue

- Do you have a way to encrypt and share your files with other health care providers?
  - Standardized FTP (file transfer protocol)
  - DICOM: (digital imaging and communication in medicine) is the ADA standard
  - EMHR (electronic medical health records)

Is your software compliant?

Dear Dr. _________ :

This is our notification that [Software Name] is in compliance with the HIPAA Security Rule, HIPAA privacy rule, and HITECH with regard to the functions our systems performs for electronic Patient Health Information (ePHI).

Business Associate Agreement

- Mandatory under HITECH as of 9/2014
- Who: persons and entities that perform or assist providers in any activity of function that involves the use of protected health information
- Anyone who receives or handles protected health information (eg: lab, software vendor)

Sailing in Ireland

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Emerging Technologies, Emerging Risks: legal and ethical considerations in utilizing new technology in the dental office

Eric J. Ploumis, D.M.D., J.D.
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New York, NY 10010
ericploumis@aol.com
dentallawyers.com
Objectives

- To understand the nature of tooth whitening and understand the safety considerations
- To explore the legal and regulatory position of tooth whitening in the UK, Australia and New Zealand.
- To examine the effect of this on professionalism and professional dominance.

An Artificial Distinction

- An artificial differentiation made by the dental profession between:
  - Tooth whitening – The act of cosmetically whitening a tooth to improve the cosmetics.
  - Tooth bleaching – The act of “therapeutically” whitening a tooth to improve aesthetics.
- What about internal bleaching?

History

- Gum disease used to be treated by mouthwashing with a weak solution of hydrogen peroxide.
- Dental professionals began to notice that whilst the gum disease didn’t necessarily get better, the teeth got whiter.
- Introduction of tooth whitening gels and different methodologies for whitening teeth.

Y Li and L Greenwall, ‘Safety issues of tooth whitening using peroxide-based materials’ (2013) 215 British Dental Journal 29-34
What is it?

Typically:

- Hydrogen peroxide
- Carbamide peroxide

Is it safe?

- Lower doses equally effective (6% v 35%) (Martín, Vildósola, Bersezio et al. 2015)
- 8%-10% limited effects on pulpal stem cell viability. Full recovery 3 days post-exposure. (Soares, Basso, Hebling et al. 2015)
- 648g of hydrogen peroxide created daily by body. 2 trays of whitening gel around 3.5g. (Li, 2003)
- Most reviews conclude safe provided manufacturer’s guidance followed. (Carey 2014; Li and Greenwall 2013)

UK Framework

- Enforced by UK Trading Standards.
- General Dental Council (UK) responsible for the illegal practice of dentistry.

Permitted Usage

The regulations:

- Limit the concentration available to the public to concentrations less than 0.1%
- Dentists may use concentrations between 0.1% and 6%
- No-one may use concentrations above 6% (equivalent to 16% carbamide peroxide). To do so is a criminal offence.
- Prohibit the supply to anyone under the age of 18.
Role of the General Dental Council

FOI request shows between 2012 and April 2017, the GDC have prosecuted 89 cases relating to the illegal practice of dentistry involving tooth whitening.

GDC Attitude Towards Registrant Use

“Concentrations exceeding 6% of hydrogen peroxide present or released in oral products, including tooth whitening or bleaching products, remain prohibited unless wholly for the purpose of the treatment or prevention of disease.”

Is tooth whitening a therapeutic activity?

– “Darker teeth may be less attractive than sparkling white teeth but it does not seem to me that they constitute a “handicap” within the meaning of this Medical Devices Directive.” Lord Slynn (Optident Limited and Another v Secretary of State for Trade and Industry and Another [2001] UKHL 32)

– What is the purpose of dentistry?

However...

“It is a criminal offence to act in breach of the Regulations...The GDC does not bring criminal prosecutions of breaches of the regulations as this role is undertaken by Trading Standards. However, the GDC is concerned with the fitness to practise of its members. The Council takes the view that if a practitioner has committed a criminal offence, that must be relevant to any assessment of that practitioner’s fitness to practise irrespective of whether there has been a prosecution. Therefore, if we receive information or a complaint that a registrant is using a product for cosmetic purposes in excess of the 6% they may face fitness to practise proceedings and can expect to have the matter referred to the relevant Trading Standards department.”

Maximum penalty for a breach in the regulations?

6 months imprisonment

2. Australia
**Australian Legal Framework**

Poisons Standard (SUSMP) states:
- Products containing between 3% - 6% hydrogen peroxide (or 9% - 18% carbamide peroxide) may be sold as general sale items. Schedule 5 (Caution)
- Products containing above 6% hydrogen peroxide (or 18% carbamide peroxide) may only be sold by a dental practitioner. Schedule 10 (“Substances of such danger to health as to warrant prohibition of sale, supply and use”)

**TGA**
- Does not classify “dental bleaches and dental whiteners” as goods that are therapeutic goods.
- “A person must not include any reference to a poison included in Schedule 9 or Schedule 10...of this Standard in any advertisement”

**National Law**

Section 121 (2)(a) – Restricted Dental Acts
- “performing any irreversible procedure on the human teeth or jaw or associated structures”
- Was the Dental Board of Australia suggesting all tooth whitening should be restricted to professional use and supply only?

**ACCC**
- Takes an interest in tooth whitening.
  Reports that Poison Centres across Australia reported 63 cases of harm resultant from tooth whitening between 2011 and 2014
- The ACCC has the ability to recall tooth whitening products it considers to be a public safety risk under the Competition and Consumer Act and has done so on several occasions

**DBA Position now clarified (2017):**
- “A restricted dental act includes performing any irreversible procedure on the human teeth or jaw or associated structures such as the use of teeth whitening substances identified under schedule 10 of the Poisons Standard (containing more than 18 per cent carbamide peroxide or more than six per cent hydrogen peroxide).”
- Therefore the DBA no longer insinuates that all tooth whitening is the professional remit of dentistry

**The Dental Board of Australia**

“Teeth whitening/bleaching, is an irreversible procedure on the human teeth and any tooth whitening/bleaching products containing more than 6% concentration of the active whitening/bleaching agent, should only be used by a registered dental practitioner with education, training and competence in teeth whitening/bleaching.”

**Uncontroversial?**


**Dental Practice Board of Victoria v Suong Van Thi (2009)**
- Van Thi applied 6% hydrogen peroxide and was alleged to have caused ulceration and burns to the victim’s throat and gums. Also reported marbling of her teeth.
- “Irreversible and invasive”
- Fined $2000
- Cause much concern in Australia. Many beauty salons offering closed or stopped offering.
- No subsequent cases. Now common and widespread again.

- Not subtle!
- States the TGA needs to classify as dental therapeutics
- Also states that the maximum available to the public should be 3% hydrogen peroxide not 6%

Australian Dental Association Inc. - Policy Statement 2.2.8 – Community Oral Health Promotion: Teeth Whitening (Bleaching) By Persons Other Than Dental Practitioners, August 17/18th

### Legal Framework

- Enforced by the NZ Environmental Protection Authority.

<table>
<thead>
<tr>
<th>Professional Group</th>
<th>Dentist</th>
<th>Oral Health Practitioner</th>
<th>Non-Registered Tooth-Whitening Practitioner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Role of hydrogen peroxide releasing products</td>
<td>May sell all concentrations of hydrogen peroxide releasing product</td>
<td>• 7% - 12% autonomously • Above 12% under supervision from a dentist</td>
<td>9% - 12% under the supervision of a dentist</td>
</tr>
<tr>
<td>Application of hydrogen peroxide releasing products</td>
<td>May apply all concentrations of hydrogen peroxide releasing product</td>
<td>• Less than 12% autonomously • Above 12% under supervision from a dentist</td>
<td>• Less than 12% autonomously • Above 12% under supervision from a dentist</td>
</tr>
</tbody>
</table>

### 3. New Zealand

**Health Practitioners Competence Assurance Act 2003**

**Restricted Dental Acts**

a) Surgical or operative procedures below the gingival margin or the surface of the skin, mucous membranes or teeth.

b) Clinical procedures involved in the insertion and maintenance of fixed and removable orthodontic or oral and maxillofacial prosthetic appliances.

**Dental Council of New Zealand Guidance**

- “To the extent that bleaching/whitening is performed on the surface of a healthy tooth it is unlikely to fall within the category of a restricted activity”
- “Where the integrity of the surface of the tooth is broken, there is a risk that caustic oxidising agents used in bleaching products could enter the dentine below the surface of the tooth and severely damage or result in pulp necrosis”
- “If such harm were to occur in practice the Council would consider that a restricted activity has in fact been undertaken”

Non-registered tooth-whitening practitioners
- Referred to in the Dental Group Standards
- Only jurisdiction of those examined to make reference to a separate, non-dental group distinct from the public

Part of Dentistry?
WHO definition of Oral Health; “Oral health is essential to general health and quality of life. It is a state of being free from mouth and facial pain, oral and throat cancer, oral infection and sores, periodontal (gum) disease, tooth decay, tooth loss, and other diseases and disorders that limit an individual’s capacity in biting, chewing, smiling, speaking, and psychosocial wellbeing.”

Summary
Food for thought

Which Position is Correct?
- The evidence base is reasonably clear; tooth whitening is safe as long as it is used properly.
- What is the justification for the levels set in each jurisdiction?
- UK would be disparaging of the Australian position and both would be horrified at the NZ situation.
- Evidence is not hugely supportive of anything being terribly wrong in NZ.

Professional Domination
“Ordinary monopolies corner the market; radical monopolies disable people from doing or making things on their own.”

FDI Definition of Oral Health; “Oral health is multi-faceted and includes the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence and without pain, discomfort and disease of the craniofacial complex.”

WHO definition of Oral Health; “Oral health is essential to general health and quality of life. It is a state of being free from mouth and facial pain, oral and throat cancer, oral infection and sores, periodontal (gum) disease, tooth decay, tooth loss, and other diseases and disorders that limit an individual’s capacity in biting, chewing, smiling, speaking, and psychosocial wellbeing.”
What does a “White, Bright Smile” mean?

- Bedos et al. 2009
  - Qualitative interviews with those on social assistance.
  - Challenged the long-assumed notion that the poor don’t care about dental appearance.
  - Noted low self-esteem, feelings of helplessness and damage to employability and social relationships.
- Moeller et al. 2015
  - Poor oral health is very visible
  - You can’t see diabetes — but you can see tooth decay and tooth loss!
  - Highlighted the link between poor oral health and negative social perception.

Social Equity

- Does having a brighter, whiter smile effect opportunity?
- We accept that in Western society, there is a social prerogative to have a smile like this.
- Could restricting access to such a service be responsible for widening inequity and opportunity?

Conclusions

- Tooth whitening is a cosmetic intervention — boundaries of cosmesis?
- The dental profession would seem to desire it to be otherwise categorised as a therapeutic intervention.
- Legal position is incongruent with the professional position.
- Social justice issue.

Conclusions (Cont.)

- Public safety justification to lay-thresholds on concentration.
- However, low concentrations are as effective as high concentrations.
- Home systems relatively easy and safe to use.
- Tooth whitening should not form part of the legitimate professional monopoly of dentistry.

Social Equity

- Does having a brighter, whiter smile effect opportunity?
- We accept that in Western society, there is a social prerogative to have a smile like this.
- Could restricting access to such a service be responsible for widening inequity and opportunity?

Acknowledgement

- Travel grant from the Faculty of Dentistry, University of Sydney that has allowed me to be here today and present to you.

Any Questions?

- Twitter: @TheHonestTooth
  Email: alexander.holden@sydney.edu.au
FRIDAY, FEBRUARY 23

COLONIAL BALLROOM  |  11:00 am - 12:00 pm

STEWART REUTER LECTURE
Alternative Decision Makers for Incapacitated Patients: Ethical Substituted Judgment (Ethics credit)

Invited Presenter: Cavan Doyle JD, LLM
Moderator: Robert W. Buckman, PhD, FCLM
Disclosures
No financial or other conflicts of interest to report.

Ethical Decision-Making for Incapacitated Patients
- Legal Framework
- State Statutes
- Ethical Principles
- Case Study
- Challenges and Conclusions

Incapacitated Patients
- Distinct patient population
  - Unable to make medical decisions
  - Primarily in hospitals
  - No advance directives (POA, living will) or other written evidence of care wishes
  - Often at end-of-life

Incapacitated Patients
- By some estimates, the prevalence of decisional incapacity approaches 40% of adult medical inpatients and residential hospice patients
- May be as high as 90% among adults in ICUs
- Rate of completion of advance directives in the general U.S. population hovers around 20-30%
  - Creates uncertainty about who will fill the alternate decision-maker role for many patients
Legal Landscape

- Each state has its own statutory approach to decision-making for patients who do not have a durable POA for health care, written advance directive, or living will.
- State statutes vary in the mechanism for appointment and responsibilities of “default surrogates” to make decisions for these patients.

State Statute: Florida

State Statutes

- Research group examined surrogate health care decision statutes in all 50 states and the District of Columbia.
- Only concerned with statutes addressing “default surrogates.”

State Statutes

- Discovered startling heterogeneity in default surrogate laws.
  - Ranging from silence to meticulously regulated.
  - Judicial and extra-judicial appeal mechanisms.
  - “Ladders” or “Chains.”
  - Preservation of first three “rungs.”
  - Wide variation in subsequent classes listed.
  - Diversity of titles given to surrogates.
  - Characteristics of appropriate surrogate.

Legal Landscape

- Both providers and patients are more mobile than ever.
- About 20% of U.S. physicians maintain medical licenses in multiple states.
- Patients cross state lines to receive care.
- Variability in state statutes means that patients and medical decisions may be treated differently in different jurisdictions.
Ethical Principles

- How should we make medical treatment decisions on behalf of people who cannot make those decisions for themselves?

- Distinct groups
  1. People who were never competent
  2. People who were once competent, but no longer are
     A. Evidence of treatment preferences
     B. No evidence of treatment preferences

Attributes of Appropriate Surrogates

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult</td>
<td>98% (54)</td>
</tr>
<tr>
<td>Decisively capable</td>
<td>59% (16)</td>
</tr>
<tr>
<td>Willing to act</td>
<td>73% (16)</td>
</tr>
<tr>
<td>Reasonably available</td>
<td>8% (4)</td>
</tr>
<tr>
<td>Familiar with beliefs/values</td>
<td>47% (24)</td>
</tr>
<tr>
<td>Exhibits special care and concern*</td>
<td>15% (18)</td>
</tr>
<tr>
<td>Restriction on health providers as ACM</td>
<td>67% (15)</td>
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Substituted Judgment

- Substituted judgment is when a surrogate relies on known preferences of the patient to reach a conclusion about medical treatment.

- Applies in two situations:
  1. Where the patient has previously expressed his or her preferences explicitly; or
  2. Where the surrogate can reasonably infer the patient's preferences from past statements or actions.

- What evidence is available about what decision the patient himself would make if he were able?
Substituted Judgment

- Patient has previously expressed preferences concerning course of action she would desire in current circumstances.
  - Surrogate should follow the patient’s preferences as closely as possible.
  - Surrogate is not making decisions for the patient, but rather giving effect to decisions the patient would make for herself.
  - Courts typically apply this standard where the patient’s wishes are known.

- Patient has not specifically stated what she would want, but there is some evidence of values and beliefs
  - Surrogate should base his decision on familiarity with the patient’s values and beliefs.
  - Surrogates must be careful not to inject their own values and beliefs into the decision-making process.

Substituted Judgment

- Strengths
  - Supports and respects the patient’s autonomy
  - Reduces moral distress for decision-maker

- Challenges
  - Individual preferences regarding treatment change over time
  - Surrogates cannot always accurately predict what patient would want in particular circumstances
  - Patients don’t always want their prior wishes to be the sole basis for decisions made on their behalf
  - Even when surrogates have evidence of patients’ wishes, they don’t always follow them

Best Interests

- Under the “best interests” standard, the surrogate makes a decision based on what best promotes the individual’s welfare
- Best interests is used when substituted judgment is not possible because there is no evidence or insufficient evidence to determine what decision the patient would have made

- Sometimes best interests is the only available option because there is no evidence about patient’s wishes, beliefs or values
  - Patient who was never able to express opinion about medical care (severely disabled)
  - Unbefriended/unrepresented patients
Before asking patients what they would want in a particular future scenario (thereby implicitly privileging substituted judgment), better to begin advance care planning by asking patients how they would like decisions to be made on their behalf. Focus on decision-making process, rather than specific treatment decisions.
**Substituted Judgment**
- Respect for autonomy is the central tenet of the substituted judgment standard
- “At a minimum, personal autonomy encompasses self-rule that is free from both controlling interference by others and limitations that prevent meaningful choice, such as inadequate understanding... a person of diminished autonomy is in some material respect controlled by others or incapable of deliberating or acting on the basis of her desires or plans.”

**Best Interests**
- Best interests asks: What offers the patient the highest probable net benefit among the available options?
- Quality of Life
  - Diminished QOL v. death

**Hybrid Approach**
- Combine what evidence we do have about Mairin’s wishes with a best interests analysis
- At least some evidence suggests that Mairin probably would not want to continue living in the state she is in, unable to interact with her family and friends
- Could also reasonably argue that it is not in her best interests to remain on life-sustaining treatment with a highly diminished quality of life

**Conclusion**
- Making treatment decisions for patients who have lost the capacity to make their own decisions poses one of the most difficult ethical challenges in clinical medicine.
FRIDAY, FEBRUARY 23

COLONIAL BALLROOM | 1:00 pm - 2:45 pm

BREAKOUT SESSION I: Lawyers, Doctors, Hospitals and Patients
Moderator: David Donnersberger, MD, JD, FCLM

• 1:00 PM - 1:20 PM Legal & Medical Aspects of “Observation” Admitting Status
  Eric Shore, DO, JD, FCLM

• 1:20 PM - 1:40 PM Patient Safety & Medical Error
  Richard Wilbur, MD, JD, FCLM

• 1:40 PM - 2:05 PM Patient Privilege & Law on Defense Counsel Contact with Treating Physicians
  Joe Piorkowski, MD, JD, FCLM

• 2:05 PM - 2:30 PM Ethical, Legal and Medical Staff Consequences of Physician Employment (Ethics credit)
  Dale Cowan, MD, JD, FCLM

• 2:30 PM - 2:45 PM Q & A Breakout Session I
OBSERVATION STATUS

A REVIEW OF CURRENT STATUS AND THE LEGAL ISSUES WHICH FOLLOW

Eric E. Shore, DO, JD, MBA, FCLM
Shore Legal Group, LLC

History of Observation

- Began as 23 hour “Observation” used when we did not know if a patient actually needed to be admitted.
- Converted to a Payment Convention by CMS and States
  - Observation
  - Observation Status
  - Observation Services
- Discussion limited to Medicare and Medicaid
- Two-Midnight Rule
  - Adopted by Medicare in December 2014
  - Not mandatory for Medicaid but may be persuasive

DEFINITIONS

- DEFINITIONS FROM CMS POLICY MANUAL
  - INPATIENT: a person who has been admitted to hospital for bed occupancy for purposes of receiving inpatient hospital services. Policy Manual, Ch. 1 § 10.
  - OBSERVATION: a well-defined set of clinically appropriate services which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Id., Ch. 6 § 20.6(A)
  - NB: The “well-defined” set of services is never defined!

Observation and the Courts

- Seminal Case: Barrows v Burwell, 777 F.3d 104 (2d Cir. 2015)
  - Appellants contended that they had been in a hospital for longer than the necessary three days, following which they could be considered for payment for Rehab services by Medicare but that the initial day(s) were classified as Observation and thus they did not meet the criteria for payment. They, therefore, believed that their ultimate inpatient status should be extended retroactively to their first day of admission and that they had a “property interest” in such extension.
  - The Court stated that since it (and neither the appellants nor the Respondents) could produce any accepted definition of Observation, the only generally accepted definition was that of Inpatient which, in the CMS Policy Manual, stated:
  - INPATIENT: a person who has been admitted to hospital for bed occupancy for purposes of receiving inpatient hospital services.
  - OBSERVATION SERVICES: a well-defined set of clinically appropriate services which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital.
  - The decision whether to admit a Medicare beneficiary as an inpatient belongs to the “physician or other practitioner responsible for a patients care at the hospital” and the decision to admit a patient is a complex medical judgment. Policy Manual, Ch. 1 § 10.
  - OBSERVATION AND THE COURTS
  - Based upon these definitions, the court held against the Appellants stating that a patient is an inpatient when, and only when a physician orders the patient admitted as an inpatient and not before.
  - In other words: one is not an inpatient until the admitting physician actually writes the order.
  - This has not yet been tested.
  - Barrows is cited by many cases following its basic approach, but a review of such cases is too lengthy for this presentation.
ADDITIONAL LEGAL ISSUES

- Observation appears to be contrary to the intent of federal law
  - All insurance is based upon a Risk Pool
    - The DRG system was established by Medicare in 1983 on the premise that if a hospital were paid a flat fee, on a prospective payment basis based upon an average for a particular diagnosis
      - This was a Risk-Sharing concept
    - A more efficient hospital would be able to get patients out sooner and keep the "extra" money they keep on the flat payment, would offset the costs for sicker patients who stayed longer
    - By removing the lower end of that pool, it has undermined the intent and altered the outcome of federal law, placing more risk on the hospital, and is consequently contrary to it.

- Constitution of the United States: Article I Section 9 (4) - Congress shall enact no bill of attainder or ex post facto law
  - SCOTUS: Calder v Bull, 1798 held that the article only applied to criminal laws, but then went on to state that it would prevent "[a] law that takes property from A and gives it to B" (<i>Calder</i>: 388). Thus, the status of this issue remains in question yet today.
  - Retroactively recouping money from hospitals based upon regulations requiring observation that were not present or known at the time a patient was admitted, may constitute an ex post facto law. All money recouped using that technique would then become an unconstitutional taking.

DUE PROCESS

- Since any retrospective determination against the hospital is frequently made past the time allowed for re-billing, there is no remedy for the appellant when an admission is downgraded to observation.
- HEARINGS: When hearings are eventually held, in many cases it is also past the time when the facility could re-bill for observation, thus making the ALJ decision a sham because the hospital cannot even follow the judge’s order (i.e. re-bill as Observation).
- BURDEN OF PROOF: rests with the appellant, even though it is the RAC that retrospectively denies the admission for lack of medical necessity. Not only does the RAC not have to prove that the previously approved admission was wrong, but it would seem impossible to "prove" medical necessity when its relationship to Observation remains undefined.

CONCLUSION

- Cursory review of a complex subject
- Many more cases and issues every day, but few actual answers
- Providers still losing much money each day despite their best efforts at appeal
Patient Satisfaction & Medical Error

Hon. Richard S. Wilbur MD JD
FACP, FCLM, FACPE, FRSM
Chairman
American Medical Foundation for Peer Review and Education

Disclosure:

- This is one presentation to a Medical College in which I can confidently assure you that there will be no scientifically accurate statistics;
- No “p-value” No “95% confidence interval”

Why?

- Most of the statistics are immeasurable -- medical error is not recorded as either a cause of death or an ICD-10 medical diagnosis. "Medical or Surgical Misadventure" is as close as it gets:

- ICD-10-CM Range Y62-Y69
- Misadventures to patients during surgical and medical care
- ICD-10-CM Diagnosis Code Y63
- Failure in dosage during surgical and medical care
- accidental overdose of drug or wrong drug given in error (T36-T50)
- ICD-10-CM Diagnosis Code Y65.8
- Other specified misadventures during surgical and medical care
- ICD-10-CM Diagnosis Code Y69
- Unspecified misadventure during surgical and medical care
- ICD-10-CM Diagnosis Code Y65
- Other misadventures during surgical and medical care

Some diagnoses are carefully delineated:

- Caterpillars Venomous Accidental T63.431
- Caterpillars Venomous Intentional Self-harm T63.432
- Caterpillars Venomous Assault T63.433
- Caterpillars Venomous Undetermined T63.434

But not Medical Error

Medical Error and Patient Satisfaction:

- Where Medicine, Law and Medical Ethics need to join together.

ACLM: Where Medicine, Law, and Medical Ethics do join together. Ideal Organization to address it.

Size of Medical Error Problem:

Huge, although immeasurable accurately

Medical Error Death estimates in the US:

- Nov 1999: We at the IOM, in the report “To Err is Human” said; “Experts estimate that as many as 98,000 people die in any given year from medical errors that occur in hospitals”
- September 2013: John James in the Journal of Patient Safety estimated that there were between 210,000 and 440,000 preventable hospital deaths.
- April 2016: The Leapfrog Group estimated 206,201 avoidable deaths in hospitals.
- May 2016: The report by Makary and Daniel from Johns Hopkins University estimated the deaths at greater than 250,000. May 3 2016 BMJ 2016;353:i2139
Patient Satisfaction & Medical Error

All Medical Error Events:

- "voluntary reporting and the Agency for Healthcare Research and Quality's Patient Safety Indicators—fared very poorly compared to other methods and missed 90 percent of the adverse events. The Institute for Healthcare Improvement’s Global Trigger Tool found at least ten times more confirmed, serious events than these other methods. Overall, adverse events occurred in one-third of hospital admissions." [HTTPS://DOI.ORG/10.1377/HLTHAFF.2011.0190]

It is also a Global Problem:

- "Patient safety is a serious global public health issue. Estimates show that in developed countries as many as one in 10 patients is harmed while receiving hospital care.
- Of every hundred (100) hospitalized patients at any given time, 7 in developed and 10 in developing countries will acquire health care-associated infections. Hundreds of millions of patients are affected by this worldwide each year."
  - WHO, June 2014:

Causes of Error:

- System Flaws:
  - Ever increasing complexity of current Medicine
  - Diseases and Treatments which have arisen since MD finished training
  - Specialization = Failure to know all about the patient: Allergies, Medications, Comorbidities, etc.
  - Handoffs of critical care patients
- Caregiver Flaws:
  - Lack of skills or knowledge,
  - Loss of skills, ROH, Drugs, Senility, Psychiatric problems, Fatigue, etc.

Whatever the cause of the error, the Correction and Prevention of Future Error is Fundamental to Patient Safety.

Here is where the three elements of ACLM come into the picture:

- Law, Medicine, and Ethics.
- What can be done for Patient Satisfaction in Law, Medicine and Ethics?

What Satisfaction does the Patient (or Survivors) Desire and Deserve?:

- Explanation: What happened? Why did it happen? How could it happen here?
- Apology
- Redress
- Assurance: Future safety for self, family, and friends: This won’t happen again.
Patient Satisfaction & Medical Error

- How do Medicine, Law and Ethics Satisfy the Patient?
  - **Medical**:
    - Hospital:
      - External: Inspections: Joint Commission (quasi legal)
      - Internal: Quality Review Committees:
        - Sentinel Events and Root Cause Analysis,
        - Evaluation of and Implementation of Solutions

- External Inspections: Joint Commission (quasi legal)
- Internal Inspections: Quality Review Committees:
  - Sentinel Events and Root Cause Analysis,
  - Evaluation of and Implementation of Solutions

Patient Satisfaction & Medical Error

- Medical Staff Responsibility:
  - Admission to staff: Credential Check
  - Privileging: Evaluate competence by repeated observations over years
  - Confidential Peer Review
  - Patient Safety Organizations (PSOs)
  - Goal: Avoidance of Error

Patient Satisfaction & Medical Error

- Ethical:
  - Medical Ethics has an effective and humane solution:
    - Admission of Error.
    - It is ethical, legally recognized and protected and medically essential. Medically essential because correction of medical error can only occur if there is first an admission that an error actually occurred. Admission leads to investigation of the cause(s) and implementation of necessary corrections. If there is denial or attempt to cover up to protect against adverse publicity or lawsuit, then the cause of the error will not be corrected and it will recur causing further patient injury.

For the admission to be successful ethically and legally, it should be prompt, understandable to the patient and/or the family and accompanied by manifest regret and apology.

If the error generates added expense, this should be borne or forgiven by the individual or institution in which the error occurred.

Patient Satisfaction & Medical Error

- Law:
  - Government Regulation:
    - Federal: Medicare and Medicaid Regulations (AHRQ)
    - Food and Drug Administration (FDA)
    - National Practitioner Data Bank (NPDB)
  - State: Medical Boards of Discipline for Professionals: MDs, RNs, etc.
  - State, City and County: Hospital Regulations

The US Agency for Healthcare Research and Quality (AHRQ) developed an online toolkit to help hospitals and clinicians communicate accurately and openly with patients and their families when something goes wrong with their care.

The toolkit expands use of an AHRQ developed process called Communication and Optimal Resolution, or CANDOR, which helps hospitals and health systems respond immediately when a patient is harmed and promotes candid, empathetic communication and timely resolution for patients and caregivers.
Patient Satisfaction & Medical Error

- Court:
  - Criminal: Not common in English Case Law
  - Usually for drug or patient sexual abuse
- Civil Suits: Torts: (Wrongs)
  - Negligence Malpractice
  - The adversarial tort system is an intimidating, inefficient and inequitable method for attempting to correct medical error. Totally inadequate to assure any satisfaction to most of those harmed.

- Inefficient and expensive:
  - 68% of malpractice premiums goes to those who run the system—Insurance Companies, defense lawyers and plaintiff lawyers.
  - Takes 4-6 years to arrive at a conclusion.
  - Prevents Correction of Error
  - During the years before trial the health care providers deny that there was any error so as to prevent losing the case at trial and, therefore, don't do an analysis or correction, allowing the error to be repeated causing still more injury

- Inadequate System to meet need:
  - Malpractice paid claims:
    - 12,000/year vs. 250,000 deaths and millions injured
    - (68% of claims are dropped and/or result in no payment)
  - 280,368 paid on behalf of physicians in 22 years.
  - Impossible to scale up
    - Crowded Courts: already an average of 5 years to a judgement
    - Incompetent to reach correct results
      - (Expert Witnesses, but Lay Jury)

- The least adequate leg is the Law.
  - Tort Law is a total failure to achieve Patient Satisfaction and cannot be altered to succeed. It is time for us in ACLM to explore other options.
  - New Zealand, Sweden, Denmark and Finland have all instituted forms of administrative compensation for medical error.

- These resemble our Workmen’s Compensation begun over a century ago when those claims overwhelmed our tort system.
  - In them, the appropriate compensation is divorced from the cause of the error, but does not eliminate responsibility for it.
  - The cause of the error should be determined by impartial experts. If there is culpability it should be dealt with separately from compensation.

- In those countries injured patients or their families file claims for compensation without an attorney. Neutral medical experts evaluate these claims without the patients having to prove negligence in order to receive this compensation which is based on the extent of the injury.
  - Data from claims is then available to analyze opportunities for patient safety improvement. The systems have successfully limited liability costs while improving injured patients’ access to compensation.
Patient Safety: The eradication of Medical Error is an elusive goal, difficult to achieve. In the complex and rapidly changing field of medical care, error is almost certain to occur. When it does, the patient, the family and the public look to the elements of ACLM for solutions: The Law, Medicine and Ethics. It is up to us as ACLM Members to help develop and to promulgate those solutions to be sure that they get the answers which they so rightly deserve.

Patient Satisfaction is an ideal ACLM goal. It can be achieved by using our expertise in Law, Medicine, & Ethics.

The success of these countries in developing “no fault” patient satisfaction which is faster, more economical, and fairer to all parties gives us a framework to build on.

We can begin by developing and advocating a better method of redress for injury then our current medieval institution: The Tort System.

Let’s get started
American College of Legal Medicine

Friday, February 23, 2018

Physician-Patient Privilege and the Law on Defense Counsel Contact with Treating Physicians

Joseph D. Piorkowski, Jr.
The Piorkowski Law Firm, PC
Georgetown University Law Center
Washington, DC

Dramatic Variability in State Law

• About half of states allow ex parte contacts with treating physicians, and about half prohibit them.
  – In the states that allow it, some are completely permissive and others enforce restrictions limiting the scope or requiring notice to plaintiff’s counsel
• Similar breakdown in federal district courts
• Choice of law problem in Multi-District Litigation

When States Prohibit Contact

• States that limit ex parte communications often prohibit all substantive communication, not just communications that would be protected by the physician-patient privilege.
• Some jurisdictions even prohibit non-substantive contacts, such as calls to schedule depositions.
• Typically no corresponding restrictions on plaintiffs’ attorneys ex parte communications – often have unfettered access to treating physicians.

Significant Restrictions: E.g., Illinois

• High-water mark of prohibitions on ex parte contact
• Courts point not only to physician-patient privilege, but to a fiduciary duty between a patient and physician.
  – “There is an implied promise, arising when the physician begins treating the patient, that the physician will refrain from engaging in conduct that is inconsistent with the ‘good faith’ required of a fiduciary.” Petrillo v. Syntex Laboratories, 499 N.E.2d 952, 961 (Ill. App. Ct. 1986)
  – Emphasis on AMA Code of Medical Ethics rather than state-created privilege
  – Lawsuit does not destroy confidential relationship.

Minimal to No Restrictions:
  E.g., District of Columbia

• Both federal district court and D.C. Court of Appeals have permitted ex parte interviews with treating physicians.
  – “The privilege was never intended...to be used as a trial tactic by which a party entitled to invoke it may control to his advantage the timing and circumstances of the release of information he must inevitably see revealed at some time.” Id.
• Courts’ reasons to allow include:
  – Less costly than depositions
  – Easier to schedule
  – Encourages greater candor than formal discovery
  – Eliminates non-essential witnesses

Actively Encouraging Ex Parte Communications:
  E.g., Alaska

Private conferences with the attending physicians “are to be encouraged, for they facilitate early evaluation and settlement of cases, with a resulting decrease in litigation costs, and represent further the wise application of judicial resources.” Trans-World Investments v. Drobny, 554 P.2d 1148, 1152 (Alaska 1976).
Effect of Restriction
- Defense counsel are barred from all communications with treating physicians outside of formal discovery (deposition)
- Even communications that would not be implicated by physician-patient privilege
  - General practices of the physician
  - What doctor knew about drug, device, or procedure at the time
  - Sources of information doctor relies upon
  - Doctors awareness of certain risks

Defense Counsel Perspective: An Uneven Playing Field
- Defense counsel is prohibited from all ex parte communications with treating physicians whether specifically related to plaintiff or not
- Meanwhile, plaintiff's counsel enjoys unrestricted access to treating physicians
  - May discuss theory of the case
  - May preview questions for deposition
  - May show physician medical articles or internal company documents that support plaintiff's theory of the case
  - Looming threat of adding treating physician as co-defendant

Rationale: Informal Discovery is Unnecessary
- "No appreciative gain (regarding the evidence to be obtained) can be had through such meetings." Petriilo, 499 N.E.2d at 588.
- Anything that can be obtained through ex parte conferences can be obtained through formal discovery.
- Fairness issue -- Why should this rationale apply only to defense counsel?

Rationale: Physician-Patient Privilege
- Physician-patient privilege
  - "When a treating physician is interviewed ex parte by defense counsel, there are no safeguards against the revelation of matters irrelevant to the lawsuit and personally damaging to the patient, and the potential for breaches in confidentiality can have a chilling effect upon the critically important underlying relationship." Horner v. Rowan Co., 153 F.R.D. 597, 601 (S.D. Tex. 1994).
  - Critical question: Is waiver limited to formal discovery or does it also apply to informal discovery?
    - Petriilo: plaintiff's implicit consent to disclosure is "obviously and necessarily limited" to formal discovery methods. 499 N.E.2d at 599.

Rationale: Duty of Loyalty
- N.D. Ohio: "It cannot be questioned that part of a doctor's duty of total care requires him to offer his medical testimony on behalf of his patient if the patient becomes involved in litigation over the injury or illness which the doctor treated." Hammonds v. Aetna, 243 F. Supp. 793, 799 (N.D. Ohio 1965)
- As if physician were part of plaintiff's legal team
- But see Petriilo: "A plaintiff, like a defendant, has no right to influence the opinion of the treating physician." 499 N.E.2d at 601.

Rationale: Incentive for Bad Behavior
- Courts imply defense counsel will behave badly
  "Such interviews also create situations which invite questionable conduct." Horner, 153 F.R.D. at 601.
Physician-Patient Privilege

- By putting medical condition at issue in litigation, plaintiff waives privilege
  - Question is simply scope of waiver
- *Ex parte* interviews do not necessarily undermine the purpose of the privilege
  - Communications can be limited to those that are outside scope of the physician-privilege
- If presence of a third party destroys privilege, no rational basis to distinguish between defense counsel and plaintiff's counsel.

Duty of Loyalty

- New Jersey: "We disavow any suggestion that a physician, or any witness for that matter, has a duty to support substantively a litigant's claims or defenses." In re Pelvic Mesh/Gynecare Litigation, 43 A.3d 1211, 1222 (N.J. Super. Ct. App. Div. 2012).
- Compare to lay witnesses: "Witnesses, particularly eye witnesses, to a crime are the property of neither the prosecution nor the defense. Both sides have an equal right, and should have an equal opportunity, to interview them." Gregory v. United States, 369 F.2d 185, 188 (D.C. Cir. 1966).

First Amendment Issues

- Petrillo: "[w]here a court restricts the speech of a private person, that restriction can be sustained only if it can be shown that the court's restriction is a precisely drawn means of serving a compelling state interest." 499 N.E.2d at 606-07.
- "the trial court's restriction was precise: [defense counsel] was barred from speaking *ex parte* to the plaintiff's treating physicians regarding the mental or physical condition of the plaintiff."
- Implication is that any restriction beyond what is necessary to protect a compelling state interest would be prohibited by the First Amendment.

No Proprietary Right to Witness's Testimony

- Basic principle acknowledged even in the most restrictive jurisdictions
- "As a general proposition . . . no party to litigation has anything resembling a proprietary right to any witness's evidence. Absent a privilege no party is entitled to restrict an opponent's access to a witness, however partial or important to him, by insisting upon some notion of allegiance." Doe v. Eli Lilly Co., 99 F.R.D. 126, 128 (D.D.C. 1983).
- "No person owns the testimony of another." Petrillo, 499 N.E.2d at 600.

Judicial Trends Towards Leveling the Playing Field

Order: *In re Chantix*

- Limitations on the scope of discussion between plaintiff's counsel and treating physicians when *ex parte* communications with defense counsel are prohibited
Order: In re Chantix

“Although plaintiffs’ counsel is clearly permitted by law to have ex parte communications with their clients’ treating physicians, the court ORDERS such communications are limited to the individual care of the individual plaintiffs, such as the plaintiffs’ treatment, medical records and conversations with their health care providers. Plaintiffs’ counsel shall not discuss defendant’s internal documents with plaintiffs’ health care providers outside of a deposition or other on the record setting…”

Rationale: In re Chantix

• Even without privilege, the court must protect the “time honored doctor-patient confidential relationship.” In re Vioxx Products Liability Litigation, 230 F.R.D. 473, 476 (E.D.La.2005)
• “What both the defendant and plaintiffs seek to obtain through ex parte communications can easily be gotten through depositions of these doctors.” Order at 6.
• Neither party’s counsel is permitted to discuss internal company documents.

Order: Hedrick v. Genetech

• Prohibition on defense counsel’s ex parte communications coupled with significant restriction on allowable scope of plaintiff’s counsel’s ex parte communication

Order: Hedrick v. Genetech

• Plaintiff’s ex parte contact with prescribing physicians limited to “discovering what information the prescribing physician saw and relied on when prescribing Raptiva to the Plaintiff.”
• “None of Defendant’s ‘Confidential’ documents shall be used in connection with these ex parte communications.”
• Besides this limited authorization, “neither side will contact these witnesses other than for scheduling purposes.”

Other Alternative Approaches

Permit ex parte communications with defense counsel, but restrict their scope to relevant topics not protected by physician-privilege
• Distinguishes between privileged information and general fact witness role of treating physician
• Continues to safeguard information protected by physician-patient privilege
• More consistent with First Amendment concerns
Other Alternative Approaches

First Amendment Concerns (Petrillo)
• “where a court restricts the speech of a private person, that restriction can be sustained only if it can be shown that the court’s restriction is a precisely drawn means of serving a compelling state interest.” Petrillo, 499 N.E.2d at 606-07.
• “the trial court’s restriction was precise: [defense counsel] was barred from speaking ex parte to the plaintiff’s treating physicians regarding the mental or physical condition of the plaintiffs.”

In re Pelvic Mesh/Gynecare Litigation
• New Jersey: Treating physicians of individual plaintiffs in a class can serve as experts for the defense regarding the rest of the class, “with appropriate sensitivity to physician-patient confidentiality.” In Re Pelvic Mesh/Gynecare Litigation, 426 N.J. Super. 167, 180 (2012)
• Implicitly recognizes the possibility of conversations with treating physicians that do not threaten privilege – e.g., “issues of product defect or safety,” and “causes of common injuries and conditions of plaintiffs.” Id.

Other Alternative Approaches

Allow both parties to request informal meeting with treating physicians
• Impose requirement that opposing counsel be invited to attend, so in effect, there is no ex parte communication by either party
• Notice must be reasonable
• Ensures that neither side has unfair advantage of establishing relationship with witness
• Ensures that treating physicians hear both sides of either story in context of informal discovery

Conclusions
• If prohibitions on ex parte communications are predicated on the sanctity of the physician-patient privilege, then restrictions on such communications should be limited to the scope of what is necessary to preserve that privilege.
• If informal discovery is not necessary for defense counsel, it is equally unnecessary for plaintiff’s counsel.
• Unequal access to treating physicians can severely disadvantage the party who does not have access, even in the absence of improper conduct; courts have several approaches available for ensuring fairness in the discovery process without depriving any party of their fundamental rights.
ETHICAL, LEGAL, AND MEDICAL CONSEQUENCES OF PHYSICIAN EMPLOYMENT

DALE H. COWAN, MD, JD, FACP, FCLM

OUTLINE

• DATA – PHYSICIAN EMPLOYMENT
• HYPOTHETICAL – ISSUES RAISED
• THE PARTIES IN QUESTION
• RATIONALE FOR PHYSICIAN EMPLOYMENT
• DUTIES OF THE EMPLOYED PHYSICIAN
• THE MEDICAL STAFF
• THE EMPLOYMENT AGREEMENT
• SOURCES OF CONFLICT FOR THE PHYSICIAN EMPLOYEE
• LEGAL ISSUES ARISING FROM PHYSICIAN EMPLOYMENT
• SUMMARY

ETHICAL, LEGAL, & MEDICAL CONSEQUENCES OF PHYSICIAN EMPLOYMENT

BE CAREFUL WHAT YOU WISH FOR, YOU MIGHT GET IT.

WE LOOK TOWARDS THE DAY WHEN MEDICINE WILL EVOLVE FROM A SOCIAL MODEL TO AN ECONOMIC MODEL.

DIRECTOR OF MEDICAL, 1985

EMPLOYMENT

• PERCENT OF ALL DOCTORS WITH AN EQUITY STAKE IN THEIR MEDICAL PRACTICE

<table>
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<th>PERCENT</th>
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<td>2000</td>
<td>57</td>
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<td>2016</td>
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AMA

EMPLOYMENT

• PERCENT OF MEDICAL RESIDENTS WHO ANTICIPATE OWNING A STAKE IN A PRACTICE

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<th>PERCENT</th>
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<td>2015</td>
<td>26</td>
</tr>
<tr>
<td>2016</td>
<td>21</td>
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MEDSCAPE

EMPLOYMENT

• PERCENT OF PHYSICIAN SEARCHES CONDUCTED BY HOSPITALS

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<tr>
<th>YEAR</th>
<th>PERCENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>11</td>
</tr>
<tr>
<td>2013</td>
<td>63</td>
</tr>
</tbody>
</table>

AHA

EMPLOYMENT

• PHYSICIANS EMPLOYED BY HOSPITALS

<table>
<thead>
<tr>
<th>YEAR</th>
<th>NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>160,000</td>
</tr>
<tr>
<td>2010</td>
<td>212,000</td>
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</tbody>
</table>

AHA
HYPOTHETICAL

• Dr. Smith is a cardiologist with Community Cardiology, LLC (CC). General Hospital (GH) approached CC about an employment arrangement whereby all of the physicians and staff of CC would be employees of GH.
• CC and GH finalized an employment agreement that included the following provisions:
  1) Physician will comply with all policies of GH including the utilization of referral sources approved by GH
  2) Physician must be a member of the medical staff of GH and is subject to the bylaws and rules and regulations issued by the medical staff and approved by GH

HYPOTHETICAL - 2

3) Employment can be terminated for cause – loss of license, DEA, or hospital clinical privileges, fraud, a criminal act, endangering patients or staff, substance abuse – or for no cause
4) Termination of employment results in termination of medical staff membership and clinical privileges.

In the course of his employment, Dr. Smith referred a number of patients requiring aortic valve surgery to a surgeon in another system renowned for her skill and outcomes in performing this surgery.

HYPOTHETICAL - 3

Additionally, Dr. Smith was repeatedly notified that he kept many of the patients he was treating for congestive heart failure in the hospital long after the length of stay determined to be necessary by outside agencies.

GH advised that these actions constituted breaches of his employment agreement and terminated the agreement.

QUESTIONS

• 1) To whom does Dr. Smith owe a duty of care? His patients? GH per his employment agreement?
• 2) Is the termination of Dr. Smith’s employment for a cause identified in the agreement or for no cause?
• 3) Can Dr. Smith invoke the medical staff bylaws and request a hearing to appeal the termination and loss of medical staff membership and clinical privileges?
• 4) Is the termination of Dr. Smith’s membership on the medical staff and clinical privileges reportable to the National Practitioner Data Bank?

WHO ARE THE PARTIES IN THIS CASE AND WHAT ARE THEIR ROLES AND RESPONSIBILITIES?

• The physician: Duty of care to the patient and adherence to the terms of the employment agreement
• The medical staff: Responsible for overseeing the quality of care in the hospital
• The institutional employer: Promoting the mission and financial viability of the institution

PHYSICIAN EMPLOYMENT

• Rationale for employment of physicians by hospitals
  Hospital perspective
  1) Increase referral of patients to the hospital – avoid ‘leakage’
  2) Increase revenue by charging facility fees
  3) Increase negotiating clout with payers
  4) Increase greater integration of care
  Physician perspective
  1) Avoid increasing burdens of practice management
  2) Achieve stable income
  3) Be able to focus on patient care
  4) Achieve more satisfactory work-life balance
DUTIES OF THE EMPLOYED PHYSICIAN

- Adhere to the ethical principles that guide patient care
  - A commitment to act in the patient’s best interest
  - Avoid harm
  - Respect patient autonomy
  - Strive for justice in health care
- Comply with the terms of the employment agreement and exhibit loyalty to the employer

THE MEDICAL STAFF

- The medical staff of a hospital is the body of licensed physicians and other qualified categories of health care providers who are vested with the responsibility for the delivery of patient care at the hospital.
- The organized medical staff is defined by the Joint Commission as a “self-governing entity accountable to the hospital governing body that operates under a set of bylaws and rules and regulations and policies developed and adopted by the medical staff and approved by the governing body.”

THE MEDICAL STAFF - 2

- The key responsibility of a medical staff is to account for the quality and appropriateness of patient care rendered by all practitioners authorized to practice in the hospital.
- This responsibility is carried out via three major activities:
  1) Appointment and credentialing
  2) Peer review
  3) Collegial intervention and corrective actions
- These activities are conducted in accord with policies and procedures that are set out in the medical staff bylaws.

THE MEDICAL STAFF - 3

- Collegial interventions and corrective actions are taken if there is an issue with respect to a practitioner’s competency or professional conduct.
- Corrective actions that result in a limitation to or loss of a practitioner’s clinical privileges are reportable to the National Practitioners Data Bank (NPDB).
- Under the Health Care Quality Improvement Act of 1986 (HCQIA) loss of privileges not due to issues of competency or professional conduct is not reportable to the NPDB.

PHYSICIAN EMPLOYMENT

- The employment agreement
  1) Under common law, employment creates a master-servant relationship – the employer has the right to tell the employee how, when, and where to perform the services.
  2) Key terms pertain to duties, compensation, reassignment and billing, term and termination, and restrictive covenants.
  3) Requirement for medical staff membership and adherence to medical staff bylaws and rules and regulations.

PHYSICIAN EMPLOYMENT

- Sources of conflict for the physician employee
  1) Control over clinical decisions and patient care
    a) Utilization
    b) Duration of patient visits
    c) Referrals
    d) Pharmacy – choice of drugs
    e) Use of protocols
    f) Electronic medical record
  2) Termination
    a) For cause
    b) For no cause
    c) Availability of due process rights in medical staff bylaws
SOURCES OF LEGAL ISSUES ARISING FROM PHYSICIAN EMPLOYMENT

• DUTIES: CLINICAL, ADMINISTRATIVE
• COMPENSATION – PERFORMANCE/PRODUCTIVITY MEASUREMENTS, COMPLIANCE WITH MEANINGFUL USE, PQRS
• TERMINATION – ACCESS TO DUE PROCESS HEARING RIGHTS UNDER THE MEDICAL STAFF BYLAWS; REPORTABLE TO THE NPDB

WOODRUFF V. HAWAI PACIFIC HEALTH, No.29447, 2014 Haw. App. 1-14-2014
BRYANT V. GLEN OAKS MEDICAL CENTER, 650 N.E.2d 622
LANGENGERT V. WARREN GEN. HOSP., 2013 U.S. Dist LEXIS 166183
• RESTRICTIVE COVENANTS

QUESTIONS

• TO WHOM DOES DR. SMITH OWE A DUTY OF CARE?
• IS THE TERMINATION OF DR. SMITH’S EMPLOYMENT FOR CAUSE OR FOR NO CAUSE?
• DOES DR. SMITH HAVE A RIGHT TO A HEARING UNDER THE MEDICAL STAFF BYLAWS?
• IS THE TERMINATION OF DR. SMITH’S EMPLOYMENT, MEDICAL STAFF MEMBERSHIP, AND CLINICAL PRIVILEGES REPORTABLE TO THE NPDB?
FRIDAY, FEBRUARY 23

PICKNEY | 1:00 pm - 2:45 pm

DENTAL SESSION II
Moderator: Chester Gary, DDS, JD, FCLM

- 1:00 PM - 1:30 PM Ethical & Legal Aspects of Dental Advertising (Ethics credit) Lillian Obucina DDS, JD, FCLM
- 1:30 PM - 2:00 PM Advertising, Specialty Status and Board Regulations Pamela Zarkowski, JD, FCLM
- 2:00 PM - 2:30 PM Advertising, Specialty Status and Board Regulations Mert Aksu DDS, JD, FCLM
- 2:30 PM - 2:45 PM Q & A Dental Session II
ETHICS AND PROFESSIONALISM IN ADVERTISING

FEB. 23, 2018
ACLM ANNUAL MEETING, CHARLESTON, SC
DENTAL SESSION II: 1:00-1:30PM
LILLIAN OBUCINA, DDS, JD

OBJECTIVES
1. KNOW THE ADA PRINCIPLES OF ETHICS AND HOW THEY RELATE TO ADVERTISING
2. IDENTIFY MISLEADING STATEMENTS IN ADVERTISING
3. UNDERSTAND HOW TO CORRECT MISLEADING STATEMENTS IN ADVERTISING
4. KNOW WHERE TO FIND LAWS ON ADVERTISING

5 ETHICAL PRINCIPLES:
• Patient Autonomy
• Nonmaleficence
• Beneficence
• Justice
• Veracity

THE LAW SETS THE MINIMUM STANDARDS.
ETHICAL OBLIGATIONS OFTEN EXCEED LEGAL ONES.

FEDERAL RULES ON ADVERTISING
FEDERAL RULES & REGULATIONS

1. ADVERTISING CLAIMS: GENERAL RULES
   GOVERNED FTC, FEDERAL TRADE COMMISSION

   TRUTH IN ADVERTISING
   • advertising must be truthful (not misleading in a material way)
   • advertisers must have evidence to back up their claims
   • ad cannot be unfair (likely to cause injury, risk does not outweigh benefit)

ADVERTISING

IT IS ETHICAL SO LONG AS IT IS NOT "FALSE OR MISLEADING IN ANY MATERIAL RESPECT."

WHAT IS MATERIAL?

INFORMATION THAT IS LIKELY TO AFFECT THE PATIENTS' CHOICE

   COST
   TIME
   INSURANCE
   LONGEVITY OF WORK
   WHAT ELSE?

"REMEMBER YOUR FIRST NEW SET OF WHEELS?"

FALSE/MISLEADING

• NO SHOTS
• NO DRILLING
• NO PAIN
• ALWAYS GENTLE
• INSTANT
FEDERAL RULES & REGULATIONS

2. ASSESSING AN ADVERTISEMENT FOR PROBLEMS

- look at the whole ad
- what it says and what it implies matter
- what the ad does not say can also count (ad needs to disclose if a product or service is not currently available, and when it will become available)
- what is material matters (likely to influence consumer’s decision)
- puffery (obvious hype “try it, you’ll like it”) does not count

FEDERAL RULES & REGULATIONS

3. POPULAR CLAIMS

- PRICING –
  a. “FORMER PRICE” must have been true and in effect for substantial period of time
  b. competitor price listed must be true
  c. SAVINGS BASED ON PURCHASE OF ANOTHER ITEM – this other item should be regularly priced
  d. FREE OFFERS – must not have indirect way of charging; must not be a constant ad – free offer must be a singular event so saving is genuine
  e. WARRANTIES OR GUARANTEES must be available prior to sale for consumer to read, must be fully refundable if conditions apply

FEDERAL RULES & REGULATIONS

4. ENDORSEMENTS & TESTIMONIALS

MUST BE ABLE TO UNDERSTAND RELATIONSHIP OF ENDORSER AND ADVERTISER

- Expert – must be using product, must have examined using expertise, but can offer comments on personal taste
- Organizational – collective judgment
- Consumer – must be using product
- Example – posting fake Yelp review is a likely a violation

FEDERAL RULES & REGULATIONS

6. DISCLOSING MATERIAL INFORMATION

CONSPICUOUSLY PLACED

- UNDERSTANDABLE
  - size – not too small
  - color – on contrasting background
  - placement/proximity – asterisk to disclosure on bottom, or closely placed
  - Social media – if on Twitter, use #paidad

FEDERAL RULES & REGULATIONS

7. SOCIAL COUPONING

ALL INTERNET COUPONS

FEDERAL ANTI-KICKBACK STATUTE – prohibits those dentists accepting money from federal healthcare programs from knowingly and willfully offering or paying cash to any person to induce the person or entity to refer a patient for services

OTHER COMPLICATIONS – 3rd party payor contracts “most favored nation” clause (guarantees the insurer the best price the dentist charges for a particular service)

ALSO CHECK YOUR STATE’S DENTAL PRACTICE ACT – some allow it to be called an “advertising fee” if the amount of money going to the referring entity is “reasonable”, others say it is fee splitting

INSURANCE CONCERNS IN ADVERTISING

BILLING SOME PATIENTS LOWER FEES THAN THOSE PATIENTS USING INSURANCE – INSURANCE FRAUD
WOULD YOU DO THIS?
“EVERY PATIENT WHO REFERS A NEW PATIENT TO THE PRACTICE RECEIVES A FREE AT HOME WHITENING KIT.”
HAVE YOU SEEN ADS LIKE THIS?

FEDERAL RULES & REGULATIONS

PRIVACY ISSUES RELATED TO SOCIAL MEDIA

• phi – patient records, video/photo, waiting room photos with patients, patient name
• responses to negative reviews – still protect patient privacy even of patient himself has publically disclosed
• terms and conditions of sites such as facebook allow them to access and use private information, even private messaging (staff training is imperative)

ONLINE RESOURCES:

ADA PRINCIPLES OF ETHICS AND CODE OF PROFESSIONAL CONDUCT:

ADVERTISING FAQ’S: A GUIDE FOR SMALL BUSINESS:
WWW.BUSINESS.FTC.GOV/DOCUMENTS/BUS35-ADVERTISING-FAQS-GUIDE-SMALL-BUSINESS

ONLINE RESOURCES – FEDERAL LAWS

FEDERAL TRADE COMMISSION ACT:
WWW.FTC.GOV/ABOUT-FTC/WHAT-WE-DO

FTC GUIDES AGAINST DECEPTIVE PRICING 16 C.F.R. SECTION 233:

ONLINE RESOURCES – FEDERAL LAWS

FTC GUIDES CONCERNING THE USE OF ENDORSEMENTS AND TESTIMONIALS:
HTTPS://WWW.FTC.GOV/SITES/DEFAULT/FILES/ATTACHMENTS/PRESS-RELEASES/FTC-PUBLISHES-FINAL-GUIDES-GOVERNING-ENDORSEMENTS-TESTIMONIALS/091005REVISEDENDORSEMENTGUIDES.PDF

FTC GUIDE CONCERNING THE USE OF THE WORD “FREE” AND SIMILAR:
HTTP://WWW.ECFR.GOV/CGI-BIN/TEXT-IDX?SID=D5BD3B2868EE9A2BCCFE3FBC8BD33357&MC=TRUE&NODE=PPT16.1.239&RGN=DIV5

ONLINE RESOURCES – FEDERAL LAWS

FTC GUIDES FOR THE ADVERTISING WARRANTIES AND GUARANTEES:
HTTP://WWW.ECFR.GOV/CGI-BIN/TEXT-IDX?SID=D5BD3B2868EE9A2BCCFE3FBC8BD33357&MC=TRUE&NODE=PPT16.1.239&RGN=DIV5
ONLINE RESOURCES
– FEDERAL LAWS

FTC GUIDES FOR THE ADVERTISING BIG PRINT LITTLE PRINT & INTERNET DISCLOSURES:

HTTPS://WWW.FTC.GOV/TIPS-ADVICE/BUSINESS-CENTER/GUIDANCE/BIG-PRINT-LITTLE-PRINT-WHATS-DEAL

STATE LAWS & REGULATIONS SPECIFICALLY RESTRICTING ADVERTISING IN DENTISTRY

IN GENERAL, STATE LAWS TEND TO FOLLOW FEDERAL LAWS

SOME CONCERNS ESPECIALLY RELATED TO HEALTHCARE AND PATIENT PROTECTION

WHAT HAPPENS WHEN STATE BOARD RULES ARE BROKEN AND THE STATE’S INVESTIGATORY PROCESS FINDS YOU WERE IN VIOLATION?

STATE LAWS

GENERAL PROHIBITIONS OF FALSE, DECEPTIVE OR UNSUBSTANTIATED ADVERTISING OF DENTAL SERVICES

IF VIOLATION FOUND:
• license reprimand, probation, suspension, revocation
  • money fines, per violation
  • additional CE
  • public service requirement
  • retake ethics portion of board exams

FURTHER RAMIFICATIONS

• ONLINE AT STATE’S WEBSITE FOREVER
• PUBLISHED IN PROFESSIONAL JOURNALS
• NATIONAL PRACTITIONER DATA BANK
• EMPLOYER NOTIFICATION
• HMO/PPO’S MAY DROP YOU
• MALPRACTICE INSURANCE PREMIUM WILL LIKELY INCREASE

STATE LAWS

GENERAL PROHIBITIONS OF FALSE, DECEPTIVE OR UNSUBSTANTIATED ADVERTISING OF DENTAL SERVICES: EXAMPLES FROM VARIOUS STATES

• RESTRICTION ON SPECIALTY ADVERTISING – “practice limited to”, giving special attention to a branch of dentistry
• RESTRICTION ON TRADITIONAL FEE AND DISCOUNT ADVERTISING – length of time special offer applicable, accurate (same as used in dental coding) language to describe the service, no additional fees or statement listing all the things that make the quoted fee vary, discount not contingent on referring a new patient
• SOCIAL COUPONS — some state it to be called an “advertising fee” if the amount of money going to the referring entity is “reasonable fair market value for advertising services provided”, others may still say it’s fee splitting
SPECIALTY ANNOUNCEMENT & LIMITATION OF PRACTICE

1. DENTAL PUBLIC HEALTH
2. ENDODONTICS
3. ORAL AND MAXILLOFACIAL PATHOLOGY
4. ORAL AND MAXILLOFACIAL RADIOLOGY
5. ORAL AND MAXILLOFACIAL SURGERY
6. ORTHODONTICS & DENTOFACIAL ORTHOPEDICS
7. PEDIATRIC DENTISTRY
8. PERIODONTICS
9. PROSTHODONTICS


FEDERAL RULES & REGULATIONS

5. SUBSTANTIATING CLAIMS

MUST HAVE “COMPETENT AND RELIABLE” SCIENTIFIC EVIDENCE PRIOR TO RUNNING AD

Tests, surveys, analysis, research studies done by qualified individuals using objective methods that are generally accepted by the profession

STATE LAWS

GENERAL PROHIBITIONS OF FALSE, DECEPTIVE OR UNSUBSTANTIATED ADVERTISING OF DENTAL SERVICES: EXAMPLES FROM VARIOUS STATES

• ILLINOIS: it is unlawful for any dentist to charge a fee to any new patient for any dental service provided at the time that such free/discounted exam or free/discounted dental service is provided

STATE LAWS

GENERAL PROHIBITIONS OF FALSE, DECEPTIVE OR UNSUBSTANTIATED ADVERTISING OF DENTAL SERVICES: EXAMPLES FROM VARIOUS STATES

• SUPERIORITY CLAIMS PROHIBITED
• TESTIMONIALS PROHIBITED
• GUARANTEES PROHIBITED

Bait advertising defined: Bait advertising is an alluring but insincere offer to sell a product or service which the advertiser in truth does not intend or want to sell. Its purpose is to switch consumers from buying the advertised merchandise in order to sell something else, usually at a higher price or on a basis more advantageous to the advertiser. The primary aim of a bait advertisement is to obtain leads as to persons interested in buying merchandise of the type so advertised.

1For the purpose of this part “advertising” includes any form of public notice however disseminated or utilized.
“I HAVE THE BEST/NEWEST/MOST ACCURATE/ONLY…..”

IS THIS A FAIR AND ACCURATE STATEMENT?
IS THIS UNFAIRLY DISPARAGING TO THE DENTISTS IN YOUR COMMUNITY?

STATE LAWS
2. GENERAL STATE ADVERTISING RESTRICTIONS – UNFAIR AND DECEPTIVE ACTS AND PRACTICES STATUTE
• Causing confusion and misunderstanding – certifications, affiliations, ingredients, benefits, quantities
  • Representations of “newness”, quality, styles or models
• Unable to meet expected public demand, unless limit the quantity
  • Not stating need for parts, replacement or repair

COMMON DENTAL PRACTICE ACT
ETHICAL POINTS
• MAKING FALSE PROMISES TO INDUCE DENTAL PATIENTS (VERACITY)
• FALSE REPRESENTATIONS TO OBTAIN MONEY (JUSTICE, VERACITY)
• UNPROFESSIONAL CONDUCT – DECEIVE, DEFRAUD, OR HARM PUBLIC (NONMALEFICIENCE)
  • ADVERTISING VIOLATIONS (VERACITY)
  • BILLING IRREGULARITIES (VERACITY)

PRACTICAL APPLICATIONS & CONSIDERATIONS
ADVERTISING IN DENTISTRY IS NOT GOING AWAY. DENTISTS ARE DOING IT, AND PATIENTS ARE USING IT TO MAKE DECISIONS

ETHICAL DILEMMA:
MARKETING OR SALE OF PRODUCTS OR SERVICES –

PATIENT TRUST V. $$$ GAIN
INTERNAL v EXTERNAL ADVERTISING

INTERNAL ADVERTISING
Aimed at your current patients to induce them to remain patients and to refer friends and family

What are some examples?

INTERNAL ADVERTISING
Your business card at your front desk
Appointment cards
Goodies bags at the end of each recall appointment/brochures/post-op instructions
Holiday card to your patients of record
The politeness of the team members
Cleanliness, office technology, waiting room amenities
Treatment plan presentations

DR. T. M. JAY’S WEBSITE

How do you feel about the first statement? The second statement?

INTERNAL ADVERTISING
Does not have to be a “special offer” but it could be
Could there be a favored nation clause violation?

Insurance laws violations?

How can you eliminate this problem?

DR. T. M. JAY’S DISCOUNT PLAN

Could there be a favored nation clause violation?

Insurance laws violations?

How can you eliminate this problem?

DR. T. M. JAY’S MARKETING

(815 ILCS 505/2B.3)

Sec. 2B.3. Deceptive sale or promotion of health-related cash discount cards. It is an unlawful practice for any person to sell, market, promote, advertise, or otherwise distribute any card or other purchasing mechanism or device that purports to offer discounts or access to discounts from health care providers in health related purchases if:

1. the card or other purchasing mechanism or device does not expressly provide in bold and prominent type that the discounts are not insurance;
2. the discounts are not specifically authorized by a contract with each health care provider listed in conjunction with the card or other purchasing mechanism or device;
3. the discounts or access to discounts offered or the range of discounts or access to the range of discounts offered are misleading, deceptive or fraudulent, regardless of the literal wording used.

(Source: P.A. 92-296, eff. 1-1-02.)

Each state has its own regulations pertaining to in-house discount plans. In some states, plans are regulated by the insurance commissioner, whereas in other states, they are categorized as “discount plans” or “prepaid plans” that require registration with the state or another organization. Due to state requirements, you may need to submit a copy of your plan and marketing materials for approval. In addition to government requirements, your ability to offer a discount plan may be restricted by contracts with insurance companies. A common insurance clause requires you to accept the lower amount between the stated fee schedule and your published fees. Have an attorney review your insurance contracts and state requirements to advise you prior to implementing your in-house discount plan.

EXTERNAL ADVERTISING

ADVERTISING AIMED AT THE PUBLIC TO INDUCE THEM TO BECOME PATIENTS

YOUR OFFICE SIGNAGE VISIBLE FROM STREET

PRINT (MAILER, FLYER, PHONE BOOK), RADIO & WEB ADVERTISING
WHAT ARE SOME QUESTIONABLE ELEMENTS?

SOCIAL MEDIA & ADVERTISING
SOCIAL MEDIA & E-PROFESSIONALISM

OFFICE WEBSITE
BLOG
FACEBOOK, TWITTER, PINTEREST, ETC

DEFINITION of E-PROFESSIONALISM

The attitudes and behaviors reflecting traditional professionalism paradigms but manifested through digital media


http://dx.doi.org/10.1016/j.cptl.2009.10.001

Why is e-professionalism important?

- Implied contract between licensed healthcare professionals and society
- In exchange for great professional autonomy, healthcare professionals are held to a higher standard of behavior
- Ethical principles are our guide to behavioral expectations

Where does professionalism and e-professionalism start?

Is it something that can be taught in advanced education curriculum?

Are these attitudes and behaviors something that can be changed, once formed?

What happens when things go wrong?

Is this good enough?
REMEMBER THAT WHAT WE DO AND SAY CREATES LASTING IMPRESSIONS
FRIDAY, FEBRUARY 23

COLONIAL | 3:00 pm - 5:00 pm

BREAKOUT SESSION II: Current Issues in Transgender Development, Health, Civil Rights and the Law
Moderator: Eli Avila, MD, JD, FCLM

This presentation made available through support from the World Professional Association for Transgender Health (WPATH)

• 3:00 PM - 3:30 PM Transgender Issues in Children and Adolescents Alexandra Karydi, PhD

• 3:30 PM - 4:00 PM Transitioning: Bathrooms are Only the Beginning Randi Ettner, PhD

• 4:00 PM - 4:30 PM Transgender Civil Rights in the Workplace, in Healthcare and Beyond Jamison Green, PhD

• 4:30 PM - 5:00 PM Q & A Breakout Session II
TRANSGENDER CHILDREN AND ADOLESCENTS: AND THE BARRIERS THEY FACE

DR. ALEX KARYDI, LMFT, CSAC, CAC, PROGRAM DIRECTOR
SOUTH CAROLINA YOUTH SUICIDE PREVENTION INITIATIVE

BE A MAN
BE A LADY

DEMOGRAPHICS

- New estimates show that 150,000 youth ages 13 to 17 identify as Transgender in the US
- In addition to 0.6% of U.S. adults (1.4 million individuals), new study finds that 0.7% of youth ages 13 to 17 identify as transgender

INTERSECTIONS OF HEALTH DISPARITIES

- Discrimination and marginalization of Trans people creates stressors, which can help to explain increased risk behaviors and mental health issues.
- Intersecting identities create compounded health disparities for Trans people.

IMPACT OF FAMILY REJECTION

- Stigma, rejection, and harassment negatively impact the development of LGBT youth
- Family rejection leads to:
  - Suicide
  - Depression
  - Drug use
  - Self-Cutting
  - Social Isolation

Transgender Issues in Children and Adolescents Alexandra Karydi, PhD
LGBT YOUTH REJECTED BY THEIR FAMILIES ARE...

- **8.4 times** more likely to have attempted suicide
- **5.9 times** more likely to report high levels of depression
- **3.4 times** more likely to use illegal drugs
- **3.4 times** more likely to report having engaged in unprotected sexual intercourse (which puts them at high risk for HIV and STDs)

8.4 times

5.9 times

3.4 times

3.4 times

Pediatrics Vol. 123 No. 1 January 1, 2009, (pp. 346 –352)

TRANSGENDER YOUTH DISCRIMINATION

- **55%** of transgender youth report being physically attacked.
- **74%** of transgender youth reported being sexually harassed at school.
- **48%** reported having been victims of assault, including assault with a weapon, sexual assault, or rape.

55%

74%

48%


HATE CRIMES

- Hate-motivated sexual violence occurs when a LGBTQ person is raped to “cure” their sexual orientation or gender identity.
- This has also been referred to as “corrective rape.”
- Hate crimes increases every year.

LGBT HOMELESSNESS

- LGBT youth are **twice** as likely to experience sexual abuse **before the age of 12**.
- **58.7%** of LGBT homeless youth have been sexually victimized compared to **33.4%** of heterosexual homeless youth.
- LGBT youth are roughly **7.4 times** more likely to experience acts of sexual violence than heterosexual Homeless youth.
- LGBT homeless youth die by suicide at **higher rates (62%)** than heterosexual homeless youth (**29%)**.
- **13.5**: The average age that transgender youth in New York become homeless.

LGBT HOMELESSNESS

In America, up to **1.6 million youth** experience homelessness each year. LGBT youth represents up to **40%** all young people experiencing homelessness.

National Coalition for the Homeless, June 2009
SUICIDE IN TRANSGENDER YOUTH

- 33% of transgender youth have attempted suicide
- 1 in 2 Trans youth will not see their 21st birthday
- Transgender teen Leelah Alcorn, committed suicide in December 2015 after her parents forced her to attend conversion therapy.

Hostility within systems of care force many Trans youth to be forced into “survival sex” or “couch surfing” that involves sexual exchange rather than subjecting themselves to abuse within foster care.

These activities often lead to involvement with the juvenile justice system.

LGBT YOUTH MAKE UP 20% OF THE JUVENILE JUSTICE SYSTEM.

Of the 20% in the juvenile justice system, 85% are youth of color.

#1 risk factor for becoming a domestic minor sex trafficking victim

RUNNING AWAY

6 LGBTQ HOMELESS KIDS WILL DIE ON THE STREET TODAY!

Lost-n-Found LGBT Homeless Shelter of the Atlanta Sisters of Perpetual Indulgence (2014)

VIOLENCE AGAINST THE TRANSGENDER COMMUNITY IN 2017

- These victims were killed by acquaintances, partners and strangers
- Some of these cases involve clear anti-transgender bias.
- In others, the victim’s transgender status may have put them at risk in other ways, such as forcing them into homelessness.
- Fatal violence disproportionately affects transgender women of color.
- In 2017 at least 28 transgender people fatally shot or killed by other violent means, the most ever recorded.
https://www.youtube.com/watch?v=7ZEEVEKA6LM

Generations of care #touchofcare

Alex Karydi, Ph.D.
Program Director
SC Youth Suicide Prevention Initiative
E-mail: Alexandra.Karydi@scdmh.org

“There can be no keener revelation of a society’s soul than the way in which it treats its children.”
- Nelson Mandela

Resources
- Advocates for Youth – www.advocatesforyouth.org/lgbtq-issues-home
- Practice Brief: Providing Services and Supports for Youth Who Are Lesbian, Gay, Bisexual, Transgender, Questioning, Intersex, or Two-Spirit (LGBTQI2-S):
  www.tapartnership.org/docs/pb1_lgbti2s_web.pdf
- South Carolina Equality – www.scequality.org
- Family Acceptance Project – familyproject.sfsu.edu
- Fenway Health – National LGBT Health Education Center – www.lgbthealtheducation.org/
- GLSEN – www.glsen.org
- Parents, Families, & Friends of Lesbians and Gays – www.PFLAG.org
- Transgender Student Education Resources – http://tser.org/

Instill hope but first do no harm
Transgender Civil Rights in the Workplace, in Healthcare and Beyond

Jamison Green, PhD

1870-2000: MEDICALIZATION OF SEX AND GENDER

"VARIANTS" — THE U.S. WAS ABOUT 70 YEARS BEHIND!

By the 1990s, a FOIA request had been filed to determine why Medicare had excluded transsexual surgery in 1970 and 1981 but had not excluded gender confirmation surgery for intersex people. By the 1940s, the first petition for legal recognition was heard in Switzerland (cases in other Western European countries followed).

Early surgical transitions (1900-1930) were primarily in Germany;

By the 1970s, trans people in the U.S. were bringing legal claims concerning legal recognition, the right to marry an opposite-sex partner, and workplace discrimination;

By the 1980s, a FOIA request had been filed to determine why Medicare had excluded transsexual surgery in 1970 and 1981 but had not excluded gender confirmation surgery for intersex people. By the 1940s, the first petition for legal recognition was heard in Switzerland (cases in other Western European countries followed).

A MEDICAL-LEGAL DISCONNECT

- Doctors were intent on "making normal women and men."
- The Law was concerned with Fraud and Misrepresentation.
- Medical Experts gave evidence for all sides.

A MEDICAL-LEGAL DISCONNECT

- Doctors were intent on "making normal women and men."
- The Law was concerned with Fraud and Misrepresentation.
- Medical Experts gave evidence for all sides.

20TH CENTURY TRACKS THE STORY OF TRANSGENDER RIGHTS

- Early surgical transitions (1900-1930) were primarily in Germany;
- By the 1940s, the first petition for legal recognition was heard in Switzerland (cases in other Western European countries followed);
- By the 1970s, trans people in the U.S. were bringing legal claims concerning legal recognition, the right to marry an opposite-sex partner, and workplace discrimination;
- By the 1980s, a FOIA request had been filed to determine why Medicare had excluded transsexual surgery in 1970 and 1981 but had not excluded gender confirmation surgery for intersex people. By the 1940s, the first petition for legal recognition was heard in Switzerland (cases in other Western European countries followed).

STEALTH vs. VISIBILITY

AN IDEOLOGICAL AND PRACTICAL CONUNDRUM
FRAMING CIVIL RIGHTS

- Strategies:
  - Conformance to the Binary model – Rights inherent to the lived gender: E.g., Spouse, Husband, Man, Wife, Woman, and insisting on class membership.
  - Disability Rights model – Dependent upon medical diagnoses.
  - Equality Framework – Rights inherent to basic humanity – challenges preconceptions predicated upon definitions of Gender and Sex, and relies on awareness that sexism is harmful.

BUILDING ALLIANCES

- Trans people were too disorganized and too fearful of being visible to win changes.
- Trans people needed to align with other civil rights seekers: POC and LGB.
- Trans people needed to nurture a nimble, diverse, and geographically dispersed core of community leaders who could be alert to opportunities for education and advocacy.

FROM THE LOCAL TO THE NATIONAL

- Minneapolis, 1975; Minnesota, 1993
- Currently:
  - 16 States + District of Columbia
  - 143 Cities and Counties
  - Total 160 Jurisdictions
- One Federal Law explicitly protects Trans people:
  - The Matthew Shepard and James Byrd, Jr. Hate Crimes Prevention Act (2009)

DR. BEN BARRES
Neuroscientist, department chair at Stanford University, died December 27, 2017, 20 months after being diagnosed with pancreatic cancer. He was 63. Pioneered study of glial cells, establishing their importance in brain function. Transitioned from Female-to-Male in 1997. Championed women and POC in science.

HON. PHYLLIS FRYE
A proud Texan, first openly transgender appointed municipal judge in 1975. For over a decade behind the “transgender revolution.”

DR. STEPHEN WHITTLE
Left home at 17 and began living as a man. He was let go from human resources jobs, often because he looked like a woman. He was also put through actions to “prove he wasn’t transgender.” The judge told him, “be an amazing biological sex and be at peace.”
WORKPLACE DISCRIMINATION

- Joblessness exacerbates mental health issues and downward spirals.
- Healthcare system linked to employment is problematic.
- Training can be highly effective, but reluctance to engage is problematic.
- Issues training can address:
  - Demystifying the conflation of sex, sexual orientation, and gender
  - Explaining what it feels like (and what it means) to be transgender
  - Reinforcing principles of equality and fairness contained in company policies
  - Describing “dos” and “don’ts” for co-workers and supervisors
  - Answering questions “off the cuff”
  - Providing communication pathways should employees have further questions

CASE LAW BEGINS TO AFFIRM TRANS PEOPLE

- Favorable settlements lead to unwritten and unpublicized decisions.
- Efforts to get attention of the EEOC began to pay off with Macy v Holder, 2012.
- Current administration creates considerable trepidation, but Hively v Ivy Tech (2017) in the 7th Circuit reinforced judicial reasoning in favor of trans people.
FRIDAY, FEBRUARY 23

PICKNEY  |  3:00 pm - 5:00 pm
DENTAL SESSION III Moderator: Daniel Orr, DDS, MD, JD, FCLM, DABE, ACLM, Past President

- 3:00 PM - 3:30 PM  Tort Liability and the Mini Dental Implant  *Olivia Palmer, DMD, JD*
- 3:30 PM - 4:00 PM  The First Amendment and Dentistry: The Revolution  *Frank Recker, DDS, JD, FCLM*
- 4:00 PM - 4:30 PM  Dental Ethics in a Small Island Nation (Ethics credit)  *Michael Williams, JD*
- 4:30 PM - 5:00 PM  Update on E-Mailing Patient Records  *Joseph Graskemper, DDS, JD, FCLM, DABLM*
Caveat Emptor: Tort Liability and the Mini Dental Implant

Olivia C. Palmer, D.M.D., J.D.
Diplomate: American Board of Oral Implantology/Implant Dentistry
Honored Fellow: American Academy of implant Dentistry
Palmer Law Firm, L.L.C.
843-577-2727
drpalmer@drpalmerlaw.com
American College of Legal Medicine
February 23, 2018

Biting force reduced from 200 psi to 50
Limits selection healthy foods
40% decrease in chewing efficiency

Advantages of Dental Implants
Anchor and stabilize denture
Maintain patient’s bone
Maintain esthetics of face
Improved psychological health
Improved ability chew/digest/health
Improved ability to speak

Root Form Implant

Mini Dental Implant
Treatment Planning Dental Implants

Medical/dental history
Diagnostic imaging
Study models
The Mini Dental Implant
Rationale for the Mini Medical issues
Anatomic contraints
Cost

Osseointegration vs Osseoapposition

Biocompatibility
Design/surface implant
Surgical technique
Loading conditions
Liability

Osseointegration vs osseapposition
Lack of clinical literature
Long term prognosis vs short term

Cost Difference

Root Form Implant:
$2235.00

Mini Dental Implant:
$350.00-$800
Informed Consent

Canterbury v Spence 1972

Malpractice vs Assault

Professional Negligence

Intentional Act

Damages

Past dental bills
Hospitalization, subsequent care
Prescription bills
Cost of remediation
Pain and suffering

Loss of Consortium

Case Evaluation

Statutes on Professional Negligence
Deviations Standard of Care
Statute of Limitations
Statute of Repose
Damages

Misrepresentation
Fraud

False/misleading advertising
Specialty status “specializes in”
Intentional torts
No liability coverage
Regulations

State Board of Dentistry

Code of Laws

American Dental Association Code of Ethics

FOIA Request

Dental/Medical Records

Patient copy

Attorney request

Subpoena

Expert Witness

Qualified in Implant Dentistry

American Board of Oral Implantology/Implant Dentistry

American Academy of Implant Dentistry
The First Amendment and Dentistry: The Revolution

Frank Recker, DDS, JD, FCLM

ACLMTM
February 23, 2018

Dental Advertising
The (R)evolution

FRANK R. RECKER DDS, JD

DENTAL SPECIALTIES
A PERSPECTIVE ON DENTAL ADVERTISING AND DENTAL SPECIALTIES
THE EVOLUTION OF THE LEGAL ISSUES

FRANK R. RECKER, DDS, JD

SPEAKER CV
- DDS, JD (OSU 1971/NKU 1981)
- LICENSED DENTIST OH/FL; BAR OH/FL/KY
- LIFE MEMBER AMERICAN DENTAL ASSOCIATION/AMERICAN ASSOCIATION OF DENTAL BOARDS
- MEMBER: ACD/ACLMTM/AGD/ODA/FDA/ABA
- FORMER MEMBER, OHIO STATE DENTAL BOARD
- LEGAL COUNSEL TO AAID, AAOM, ASDA, AAOP

IN THE BEGINNING
- THE EVOLUTION OF ‘DENTAL SPECIALTIES’
- THE ADA PROCESS: WHAT IS IT? HOW DOES IT ‘WORK’? WHEN DID IT COLLAPSE?
- WHEN THE ADA BEGAN DESIGNATING ‘SPECIALTIES’

1947 TO 2016
- THE ADA SPECIALTY RECOGNITION PROCESS
- THE LAWS GOVERNING PROFESSIONAL ADVERTISING
- THE SPECTRE OF FIRST AMENDMENT AND ANTITRUST CONCERNS
- THE CREATION OF THE ABDS
- LOOKING FORWARD
LONG, LONG AGO

- 1947-ORAL SURGERY, ORTHODONTICS, PEDODONTICS, PERIODONTIA, PROSTHODONTICS
- 1949-ORAL PATHOLOGY
- 1950-PUBLIC HEALTH
- Seven by 1950—NO HOOPLA!
- 1963-ENDODONTICS-Then 36 years pass
- 1999-ORAL RADIOLOGY—CDA V FTC

SPECIALTY APPLICATION DENIALS: 1986-2012


ADVERTISING SPECIALTIES PRE 1980'S

- THE COMPLETE LOSS OF CREDIBILITY AND RELATED ANTITRUST CONCERNS

Virginia Board of Pharmacy 1976

- Supreme Court decides that advertising price, although commercial speech, should receive freedom protections under the First Amendment; public is entitled to have knowledge about competitive pricing terms.
- OPENS THE DOOR FOR PROFESSIONAL ADVERTISING

BATES V STATE BAR 1977

- ARIZONA ATTORNEYS NOT ALLOWED TO ADVERTISE
- COMMERCIAL SPEECH MERITS FIRST AMENDMENT PROTECTION, PROVIDING CONSUMERS INFORMATION ABOUT SERVICES AND PRODUCTS
- WOULD NOT HARM LEGAL PROFESSION

Virginia Board of Pharmacy 1976

- Supreme Court decides that advertising price, although commercial speech, should receive freedom protections under the First Amendment; public is entitled to have knowledge about competitive pricing terms.
- OPENS THE DOOR FOR PROFESSIONAL ADVERTISING
**BOARD REGULATIONS**

- PRIOR TO 1980’s MOST STATES SIMPLY PROHIBITED PROFESSIONAL ADVERTISING, EXCEPT OHIO
- THE PUBLIC HAD NO ACCESS TO INFORMATION REGARDING PROFESSIONAL MEMBERSHIPS, CREDENTIALS, ‘SPECIALIST’, ACHIEVEMENTS, AREAS OF INTEREST

**STATE RESTRICTIONS**

- COURTS BEGIN TO ANALYZE THE POWER OF THE STATE TO RESTRICT COMMERCIAL SPEECH
- SUPREME COURT ISSUES PIVOTAL DECISION IN MID 1980’S; COMMERCIAL FREE SPEECH ENTITLED TO PROTECTION UNDER FIRST AMENDMENT
- BURDEN ON STATE TO JUSTIFY RESTRICTIONS

**COMMERCIAL FREE SPEECH**

SUPREME COURT DECISIONS EVOLVE TO CLARIFY HOW STATE RESTRICTIONS MUST BE JUSTIFIED

**CENTRAL HUDSON V PUBLIC SERVICES COMMISSION** 1986

- FOUR STEP ANALYSIS DEVELOPED:
  - SPEECH AT ISSUE MUST CONCERN LAWFUL ACTIVITY AND NOT BE MISLEADING
  - ASSERTED GOVERNMENTAL INTEREST MUST BE SUBSTANTIAL
  - DOES REGULATION DIRECTLY ADVANCE GOVERNMENTAL INTEREST ASSERTED?
  - IS REGULATION MORE EXTENSIVE THAN NECESSARY TO SERVE THAT INTEREST?

**PEEL V. ILLINOIS (1991)**

- ATTORNEY DISCIPLINED FOR USING ‘CERTIFIED’ BY NBTA ON LETTERHEAD
- NBTA IS ‘NATIONAL BOARD OF TRIAL ADVOCACY,’ A PRIVATE ORGANIZATION
- NBTA NOT RECOGNIZED BY ILLINOIS SUPREME COURT AS CERTIFYING ENTITY
- SUPREME COURT HELD IT WAS A BONA FIDE CERTIFYING ENTITY; STATE FAILED TO MEET BURDEN UNDER CENTRAL HUDSON TEST

**IBANEZ V FLORIDA DPR, 1994**

- IBANEZ, PRACTICING ATTORNEY
- ADVERTISED CPA AND CFP
- BOARD OF ACCOUNTANCY CHARGED HER WITH FALSE ADVERTISING (‘CPA’ BUT DIDN’T PRACTICE PA)
- CFP NOT APPROVED AS ‘SPECIALTY’ DESIGNATION
- USSC REVERSED, NO EVIDENCE THAT PUBLIC COULD BE, WOULD BE, OR WAS HARMED IN ANY WAY
AAID CHALLENGES
RESTRICTIONS ON
ADVERTISING CREDENTIALS

- SUITS FILED IN CALIFORNIA FEDERAL COURT, BINGHAM V DCA: ‘BINGHAM I’...
- (1998) SUIT FILED AGAIN, ‘BINGHAM II’...HOW THAT CASE PROCEEDED
- POTTS V DCA.....DECISION 2010..VICTORY FOR AAID

FLORIDA DURING SAME TIME

- BORGNER I, DECIDED 1998; STRUCK DOWN STATUTE DEFERRING TO ADA; PROHIBITED ADVERTISING MEMBERSHIPS OR CREDENTIALS NOT RECOGNIZED BY ADA. DECISION NOT APPEALED BY STATE
- FEE RECOVERY UNDER 42 USC 1988
- BORGNER II UPHOLD AMENDED STATUTE
- PLAINTIFFS GO TO STATE COURT

HOLDING IN STATE COURT
‘DUCOIN’ DECISION-2009

- ‘OF GREAT INTEREST TO THE COURT IS THAT THE CHALLENGED STATUTE DELEGATES TO THE ADA THE SOLE DISCRETION TO DESIGNATE WHAT SPECIALTIES OR SPECIALTY CREDENTIALING ORGANIZATIONS WILL BE RECOGNIZED BY THE FBD AND ENFORCED UNDER THE LAW OF THIS STATE.’

DUCOIN (CONT)

- ‘IN FACT, UNDER FLORIDA LAW, THE LEGISLATURE MAY NOT DELEGATE UNGUIDED AND UNCONTROLLED AUTHORITY TO A PRIVATE ORGANIZATION TO DETERMINE PROSPECTIVELY THE LAWFULNESS OR UNLAWFULNESS OF COMMERCIAL SPEECH. THIS IS PRECISELY WHAT THE STATE DID BY THE IMPLEMENTATION OF SECTION 466.0282, FLORIDA STATUTES.’

42 USC 1988-Fee Recovery

42 USC 1988
FROM 1980 TO 1990'S
- There was far less professional advertising
- Few legal concerns about the ADA specialty recognition process
- Little thought about legal issues
- Perceived as a level playing field

ADVERTISING TODAY
- Profession more diverse
- Younger dentists in competitive market
- DSO's and other practice models
- Competition for consumers/patients
- Public exposed to an array of professional advertising
- Specialists in competition with other specialists—note AAP change proposal
- States removing ‘limit to area of specialty’
- Result will be increased competition and related advertising among all sectors

STATE ADVERTISING RESTRICTIONS
- Do not fulfill the requirements imposed by Central Hudson
- Have no evidence of consumer harm, potential consumer harm or actual consumer harm to justify restrictions
- Rarely challenged by individual licensees—'chilling effects'
- Sometimes promulgated by boards with agendas to protect certain segments of profession
- Advertising complaints often filed by professional competitors

TYPICAL STATE ASSUMPTIONS
- Consumer will believe dentist is a specialist
- Consumer attaches a specific meaning to 'specialist' in dentistry
- Consumer will be somehow harmed because of such belief
- What past 'surveys' or 'polls' have failed to establish

HOD 2012-ASDA
- Political fervor seen in various publications
- Associations took strong stand both for and against
- Lobbying for HOD votes
- ASDA complied with the process
- Approved at every level
- Rejected by HOD
- Something else was needed

THE 2012 ANESTHESIA OUTCOME
- Graphically revealed the protectionist influences on a specialty decision
- Politics and lobbying on the path leading to ADA HOD discussion
- Transcript reveals input of ADA counsel minimized
- HOD vote was the de facto end of ADA specialty process
TEXAS LITIGATION 2014

- ORGANIZATIONS/PLAINTIFFS AAID, ASDA, AAOM, AAOP AND INDIVIDUALS
- CHALLENGING TEXAS DEFERRAL TO ADA
- Sought right to advertise as specialists
- ADA process heavily influenced by ‘politics’ and lobbying by entities with economic interests at stake

DECISION JANUARY 21, 2016

- SUMMARY JUDGMENT GRANTED TO PLAINTIFFS (AAID/ASDA, AAOM, AAOP), NO TRIAL NECESSARY
- "THE RIGHT TO ADVERTISE AS A SPECIALIST IN TEXAS IS UNDOUBTEDLY A FINANCIAL BOON TO DENTISTS IN THE STATE. WHILE OSTENSIBLY PROMULGATED TO PROTECT CONSUMERS FROM MISLEADING SPEECH, IT APPEARS FROM THE DEARTH OF EVIDENCE THAT RULE 108.54'S TRUE PURPOSE IS TO PROTECT THE ENTRANCED ECONOMIC INTERESTS OF ORGANIZATIONS AND DENTISTS IN ADA-RECOGNIZED SPECIALTY AREAS. INDEED, DEFENDANTS HAVE PRODUCED LITTLE MORE THAN INDUSTRY BIAS IN FAVOR OF THE ADA TO SUPPORT THE ARGUMENT PLAINTIFFS' DESIRED SPEECH IS DECEPTIVE, FALSE OR MISLEADING OR THAT THE STATE DENTAL BOARD CAN TRUST THE ADA TO CARVE OUT SPECIALTY AREAS WITHOUT THE NEED TO MAKE ANY SUBSTANTIVE DETERMINATION OF WHETHER THE PLAINTIFFS' DENTAL ORGANIZATIONS ARE ACTUALLY BONA FIDE. THE FIRST AMENDMENT DEMANDS MORE."

5th Circuit, June 2017

- Affirmed District Court 2/1
- One Judge felt ‘specialist’ had no meaning
- Texas regulations unconstitutional infringement on commercial free speech
- State did not seek cert
- Effects on various state dental boards

PRESENT STATUS

- STATE DEFERRAL TO ADA DECLARED UNCONSTITUTIONAL IN SEVERAL JURISDICTIONS
- FTC V NC BOARD EFFECTS ON STATE BOARD ACTIONS
- DENTAL BOARD REGULATIONS CAN BE VIEWED AS PROFESSIONAL PROTECTIONISM
- ADA PROCESS DETERMINED BY ECONOMIC COMPETITORS-ANTITRUST IMPLICATIONS
- ADA Created new Commission For Specialty Recognition-2017-Composition

A PROPOSED SOLUTION

- THE MEDICAL MODEL
- ABMS: AMERICAN BOARD OF MEDICAL SPECIALTIES
- Recognizes certifying boards for specialization
- Input from AMA, but not controlled by AMA

THE AMERICAN BOARD OF DENTAL SPECIALTIES (ABDS)

- FORMED IN 2014 TO PROVIDE NON PROFESSIONAL ASSOCIATION CONTROLLED PROCESS—SIMILAR TO ABMS
- FOCUS ON ‘RECOGNIZING’ CERTIFYING BOARDS AS ‘SPECIALTY BOARDS’
- AVOIDS FIRST AMENDMENT AND ANTITRUST ISSUES
- ORGANIZED BY ABOP, ABOM, ADBA, ABOI/ID
- EACH BOARD HAS TWO REPRESENTATIVES
ABDS
- CURRENTLY RECOGNIZES FOUR CERTIFYING BOARDS AS CONFFERRING SPECIALTY STATUS IN THOSE AREAS: Oral Medicine, Oral Facial Pain, Implant Dentistry (ABOI/ID), Anesthesia
- INTEREST EXPRESSED BY CERTIFYING BOARDS IN, AMONG OTHERS, SLEEP DENTISTRY, GENERAL DENTISTRY, COSMETIC DENTISTRY, FORENSIC DENTISTRY AND SEVERAL ADA RECOGNIZED CERTIFYING BOARDS
- CHANGING TIMES AND EVOLVING TO REMAIN RELEVANT

Resolution 65
- ADOPTED BY ADA HOD ON MONDAY, OCTOBER 24, 2016

5.H as Adopted
- A dentist may ethically announce as a specialist to the public in any area of the dental specialties recognized by the ADA...........and in any other areas of dentistry for which specialty recognition has been granted under the standards required or recognized in the practitioner’s jurisdiction, provided the dentist meets the educational requirements required for recognition as a specialist adopted by the ADA or accepted in the jurisdiction in which they practice.' “Dentists who choose to announce specialization should use ‘specialist in’ and shall devote a sufficient portion of their practice to the announced specialty or specialties to maintain expertise in that specialty or those specialties.”

DENTAL ADVERTISING
- FROM COMPLETE PROHIBITION CIRCA 1980
- CREDENTIAL PROHIBITIONS DECLARED UNCONSTITUTIONAL CIRCA 1998-2014
- ‘SPECIALIST’ DEFERRAL TO ADA DECLARED UNCONSTITUTIONAL 2009/2010/2014 (FL/CA/TX)

QUESTIONS?
- THANK YOU FOR YOUR ATTENTION!

AICLM
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Stony Brook School of Dental Medicine

Professional Responsibility in Dentistry
A Practical Guide to Law and Ethics
Joseph P. Graskemper

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.

Paperback | July 2011 | 220 pages | 978-0-470-95977-0 | $51.99

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A little history

• Prior to internet:
  • Patient would pick up copies
  • You could mail them
  • It was simple

Then Came HIPAA

Patients have right:

• access

Patients have right:

• access
Patients have right:
• access,
• copy,
• inspect

Patients have right:
• access,
• copy,
• inspect,
• amend their healthcare information,
• request restrictions on disclosures

Patients have right:
• access,
• copy,
• inspect,
• amend their healthcare information,
• request restrictions on disclosures

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Patients have right:
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• inspect,
• amend their healthcare information,
• request restrictions on disclosures

Must have
• Written patient signed authorization
• Directing the disclosure of any personal protected health information (PHI)
• Including x-rays and any digital images.

(Most understood that to mean information to a non-healthcare.)
It was then widely pointed out that any information sent to anyone regarding the patient must have a signed disclosure.

With the growth and ease of the internet and use of e-mails as an avenue to transmit patient information, patient radiographs and digital images were readily transmitted to another healthcare office.

This was found:
- to limit the patient’s ability to access their protected health information (PHI).
- to be cumbersome and untimely in emergency situations.
- to create another filter or server to become involved in the transmission of PHI.

The Office for Civil Rights clarifies the transferring of a Pt’s protected health information (PHI) to a third party, including another healthcare facility. (March 2016)

Individuals’ Rights under HIPAA to Access their Health Information
45 CFR Sect. 164.524
1. Must be in writing
2. Sign by the individual/guardian
3. Must clearly identify the designated person to receive
4. Must clearly identify where to send the specific PHI
Include ONLY:
• Labor

Include ONLY:
• Labor
• Needed supplies
• Postage if mailed

Fees may not include:
• Costs of verification
• Costs of documentation
• Costs of searching and retrieval of PHI
• Costs associated to recouping capital for data storage, access or infrastructure.

All states have maximum allowable fees.
(Except Alaska, Idaho and S. Dakota)
Ranges from “a reasonable fee” to very specific fees on number of pages, radiographs and other media, and certification.

**HITECH ACT**

The Act provides that only a fee equal to the labor cost can be charged for an electronic request.

**Timeliness**

Thirty days (30) from the date the request to access or transfer PHI

If unable—30 day extension provided

-----the patient was informed during the initial 30 days

-----the reasons for the delay in writing

-----pt. is given the date to provide access

Only 1 extension allowed.

**State Laws?**

It allows for greater rights to access PHI than HIPAA, the state law prevails.

If allows lesser rights to access or is contrary to the Privacy Rule of HIPAA, the state law does not apply.

I, _____ hereby authorize and request Dr._____ to disclose and give/send copies to Dr._____ at (e-mail address__) of any and all requested x-rays, records and information concerning the above patient (specifically [whole mouth, #14, left side, etc.]).

In consideration of such disclosure on the part of the above named person, I hereby release them from any and all liability arising from such disclosure.
I, ____ hereby authorize and request Dr._____ to disclose and give/send copies to Dr.______ at (__e-mail address__) of any and all requested x-rays, records and information concerning the above patient (specifically [whole mouth, #14, left side, etc.______]).

In consideration of such disclosure on the part of the above named person, I hereby release them from any and all liability arising from such disclosure.

I hereby consent to have my x-rays and any other necessary or requested records to be sent to Dr. _____ in a regular un-encrypted format. I understand that this is an open un-encrypted unsecured e-mail network and all risks associated with such e-mail.

Sign___________ Date___________________

Texting a Patient

It is okay to send text messages to a patient, provided that the message complies with the technical safeguards of the HIPAA Security Rule: “Minimum necessary standards”.

The content of the message does not include “Personal Identifiers”

Technical Safeguards

- Access to PHI only for authorized users that require info.
- System must monitor activity of users
- Users must authenticate identities with unique centrally issued username and PIN.
- Policies and procedures must prevent inappropriate altering or destroying of PHI
- Data transmitted beyond system should be encrypted to make unusable if intercepted.

De-identification

Two Methods

1. Expert (no definitive qualifier)
2. Safe Harbor

18 Safe Harbor data elements = “any other unique identifying number, characteristic, or code,” (45 CFR. § 164.514(b)(2)(i)(R).

1. Names
2. All geographic subdivisions smaller than a state
3. Dates (other than year) directly related to the individual
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health insurance plan beneficiary numbers

10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers including license plate
13. Device identifiers and serial numbers
14. Web URLs
15. Internet protocol (IP) addresses
16. Biometric identifiers (i.e. retinal scans, fingerprints, Etc.)
17. Full face photos and comparable images (unique facial identifiable characteristics)
18. Any unique identifying number, characteristic or code.
**Texting (Closed Network – Hospital)**

Must have a secure texting platform:
1. have administration controls/monitors/audit trails (cannot send outside network, copy or paste, or save to external device)
2. ability to retract and delete messages
3. assign message lifespan (automatic delete, achieve, and expire from backup after a finite period of time)
4. time out or disconnect device if inactive for a period of time
5. remove user if mobile device is lost or stolen

(HIPAA Journal 2017 p. 52, 59)

**5 Inherent Risks**

1. Unintended phone auto-correction
2. Using potentially confusing abbreviated text terminology
3. Possible patient misidentification
4. Misspellings
5. Incomplete orders

Institute for Safe Medication Practices (ISMP) August 2017

Moderator: Bill Hinnant, MD, JD, FCLM

- 8:00 AM - 8:25 AM The Epidemiology and Science of Opioids: Tolerance, Dependence and Addiction Richard Kelly, MD, JD, FCLM
- 8:25 AM - 8:50 AM Iatrogenic Opioid Addiction David Benjamin, PhD, FCLM
- 8:50 AM - 9:15 AM Risk Evaluation & Mitigation Strategy (REMS) in Opioid Risk Management Jack Snyder, MD, JD, PhD, FCLM
- 9:15 AM - 9:40 AM The Impact of the Opioid Epidemic on Policy, Legal Practice and Medicine Ken Berger, MD, JD, FCLM
- 9:40 AM - 9:45 AM Q&A Breakout Session III

DENTAL SESSION IV

Moderator: Frank Riccio, DDS, JD, FCLM

- 8:00 AM - 8:25 AM Opioid Crisis, Really? Daniel Orr, DDS, MD, JD, FCLM, DABE
- 8:25 AM - 8:50 AM Practice Transactions: Worst Case Scenarios Chester Gary, DDS, JD, FCLM
- 8:50 AM - 9:15 AM History of the Prescription Epidemic in the US Richard Harold, DMD, JD, FCLM
- 9:15 AM - 9:40 AM Legal Issues in Dental Education Margaret Hill, DMD; Roger Moore, DDS
- 9:40 AM - 9:45 AM Q&A Dental Session IV

BREAKOUT SESSION IV: Current Medicolegal Issues in Israel and America

Moderator: Weldon Havins, MD, JD, FCLM

- 10:00 AM - 10:25 AM Sham Peer Review in Israeli Hospitals Jonathan Davies, LLM
- 10:25 AM - 10:50 AM Legal and Ethical Dilemmas of Statutory Tribunals in Determinations of Involuntary Hospitalization in Israel Samuel Wolfman, MD, JD, FCLM
- 11:15 AM - 11:40 AM Trumpcare, Jack Conomy, MD, JD, FCLM
- 11:40 AM - 11:50 AM Q&A Breakout Session IV

DENTAL SESSION V

Moderator: Bruce Seidberg, DDS, MScD, JD, FCLM, DABE, ACLM Past President

- 10:00 AM - 10:25 AM Examining Legislative & Regulatory Framework Aimed at Redesigning Jamaican Oral Health System for Improving Access to Care Dean Irving McKennzie, DDS
- 10:25 AM - 10:50 AM Appellate Decisions Concerning the Doctor - Patient Relationship Laurence Jerrold, DDS, JD, FCLM
- 10:50 AM - 11:15 AM Employee or Independent Contractor: Categorizing Associate Dentists in the Dental Office Jennifer Sullivan, DMD, JD, FCLM
- 11:15 AM - 11:40 AM The Dentist as an Expert Witness Frank Riccio, DDS, JD, FCLM
- 11:40 AM - 11:50 AM Q&A Dental Session V

CYRIL WECHT LUNCHEON

Invited Presenter: F. Lee Bailey, JD
### COLONIAL | 1:30 pm - 3:30 pm

**BREAKOUT SESSION V: Credentialing, Privileging and Peer Review**

**Moderator:** Cyril Wecht, MD, JD, FCLM, DABE, Founder, ACLM Past President

- **1:30 PM - 1:55 PM** Process of Credentialing and Privileging Healthcare Providers **Victoria Green, MD, JD, FLCM**
- **1:55 PM - 2:20 PM** Negligent Credentialing and Corporate Responsibility/Liability **John Busowski, MD, JD, FCLM**
- **2:20 PM - 2:45 PM** Peer Review: Confidentiality; Discoverability; Admissibility; and Privilege **Marvin H. Firestone MD JD FCLM**
- **2:45 PM - 3:15 PM** Telemedicine Credentialing of Health Care Providers **Michael Brooks, MD, JD, FCLM**
- **3:15 PM - 3:30 PM** Q&A Breakout Session V

### PICKNEY | 1:30 pm - 3:30 pm

**DENTAL SESSION VI**

**Moderator:** Kalu Ogbureke, DDS, JD, FCLM, DABE

- **1:30 PM - 2:00 PM** Forensic Dentistry **Michael Kaner, DMD, JD**
- **2:00 PM - 2:30 PM** Use of Patients for Dental Licensure Examinations **Nicholas Panometros, DDS, JD, FCLM**
- **2:30 PM - 3:00 PM** Use of Patients for Dental Licensure Examinations **David Preble, DDS, JD, FCLM**
- **3:00 PM - 3:30 PM** Q&A Dental Session VI

### COLONIAL | 3:45 pm - 5:00 pm

**GENERAL SESSION II: Physician/Attorney Financial Planning, Business and Asset Protection**

**Moderator:** Raymund King, MD, JD, FCLM

- **3:45 PM - 4:15 PM** Retirement and Asset Protection Trusts, **Mark Monasky, MD, JD, FCLM**
- **4:15 PM - 4:45 PM** Winding Up and Practice Transfers, **Mark Monasky, MD, JD, FCLM**
- **4:45 PM - 5:00 PM** Q&A General Session II

### GOLD | 7:30 pm - 9:15 pm

**ANNUAL AWARDS BANQUET (Ethics credit)**

Age Friendly Cities: Promoting, Health, Ethics and Justice

**Presenter:** Anabel Pelham, PhD
SATURDAY, FEBRUARY 24

COLONIAL | 8:00 am – 9:45 am

Moderator: Bill Hinnant, MD, JD, FCLM

• 8:00 AM - 8:25 AM The Epidemiology and Science of Opioids: Tolerance, Dependence and Addiction Richard Kelly, MD, JD, FCLM

• 8:25 AM - 8:50 AM Iatrogenic Opioid Addiction David Benjamin, PhD, FCLM

• 8:50 AM - 9:15 AM Risk Evaluation & Mitigation Strategy (REMS) in Opioid Risk Management Jack Snyder, MD, JD, PhD, FCLM

• 9:15 AM - 9:40 AM The Impact of the Opioid Epidemic on Policy, Legal Practice and Medicine Ken Berger, MD, JD, FCLM

• 9:40 AM - 9:45 AM Q & A Breakout Session III
The Science of opioid drugs: Tolerance, Dependence & Addiction

Janis Joplin
27 years old (1943-1970)

Overview

Opioids abuse as an international public health problem
How opioids affect the human body
Concepts of tolerance, dependence, & addiction

Financial Disclosures

Consultant
Samsung Corporation
Rubicon Biotechnology
Editor-in-Chief
Journal of Legal Medicine

The Price of Opioid Dependence
Worldwide Public Health Issue

- Between 26.4 and 36 million people worldwide abuse opioids
- Overdose of opioids kill more than 27,000 people in US annually
- Opioid use called worst drug crisis in US history

In the United States:

- Opioid use is now leading cause of substance use-related ambulatory visits
- Number of fatal opioid drug overdoses have quadrupled between 1999 and 2010
- Overdose deaths are leading cause of death in U.S. (more than motor vehicle accidents)
- Opioid abuse cost insurers $14,000 more than average patient

Opioid Sales Admissions & Treatment 1999-2010

Jim Morrison
27 years old (1943-1971)

Understanding Pain

Foot injury

Understanding Pain

Signal travels to spinal cord

Foot injury
Understanding Pain

Foot injury
Signal travels to spinal cord
Pain registers in the brain

Opioid

John Belushi
33 years old (1949-1982)

Heroin
Understanding Pain

Pain signal opens Ca++ channel and blocks Na+ channel.

Effects of Opioids

<table>
<thead>
<tr>
<th>Organ System</th>
<th>Effect</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain and Spinal Cord</td>
<td>Analgesia ☑️</td>
<td>Primary purpose</td>
</tr>
<tr>
<td></td>
<td>Euphoria ☑️</td>
<td>Risk of addiction &amp; abuse</td>
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<tr>
<td></td>
<td>Sedation ☑️</td>
<td>Cause of overdose death</td>
</tr>
<tr>
<td></td>
<td>Respiratory rate ☑️</td>
<td>Codeine used for cough</td>
</tr>
<tr>
<td></td>
<td>Cough reflex ☑️</td>
<td>Unpleasant side effect</td>
</tr>
<tr>
<td></td>
<td>Constriction of pupils ☑️</td>
<td></td>
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<tr>
<td></td>
<td>Nausea &amp; vomiting ☑️</td>
<td></td>
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<tr>
<td>Digestive System</td>
<td>Constipation ☑️</td>
<td>Can relieve diarrhea</td>
</tr>
<tr>
<td></td>
<td>Gastric motility ☑️</td>
<td></td>
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<tr>
<td></td>
<td>Peristalsis ☑️</td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>Itching &amp; sweating ☑️</td>
<td></td>
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<tr>
<td></td>
<td>Flushing of face ☑️</td>
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</table>

Action of Opioids

River Phoenix

Tolerance

- Need to administer larger and larger doses of opioid to achieve same effect
- Prolonged use of opioids sets up an oppositional process to restore equilibrium and more drug is needed to overcome this corrective process
- Body uses two processes:
  - Blocks the action of the opioid
  - "Downregulation"
Tolerance requires dose escalation

Opioid dose requirements in patients with chronic pain

Tolerance is complicated

- Affected by:
  - Presence/absence of painful input
  - Type of opioid used (morphine vs. hydrocodone)
  - Frequency of use
  - Type of pain (neuropathic vs. nociceptive)
  - Age of user
  - Pain patient vs. drug abuser
- Animal studies have produced conflicting results

Dependence

- Defined as use of an opioid to the extent that negative withdrawal symptoms will result from abrupt discontinuation
- After prolonged use the brain has adapted to a constant supply of opioid
- When discontinued, the imbalance of chemicals in the brain causes the classical withdrawal symptoms: nausea, muscle spasms, cramps, anxiety, fever, & diarrhea
- Dependence implies need of the drug to avoid withdrawal physical withdrawal symptoms but not for psychological reasons
Addiction

- Individual has lost the power of self-control and abuses opioids to the extent that it harms the individual, society, or both
- Reward pathways in the brain are stimulated by opioid use causing dependence that is at least, in part, psychological
- Body uses two process:
  - Blocks the action of the opioid
  - “Downregulation”

Conclusion

- Opioid abuse is a major problem worldwide
- Tolerance to opioids occurs with daily use, requiring an escalation of drug dose to achieve same effect
- Dependence is a physical need for opioids while addiction is a psychological need for opioids
- Opioids should be used intermittently to avoid dose escalation, tolerance, and addiction
Iatrogenic Opioid Addiction

David M. Benjamin, Ph.D., Sc.D. (hon.)
Clinical Pharmacologist & Toxicologist
Affiliate 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

Terminology

- **Opium poppy** – *papaver somniferans* also synthesizes morphine-like alkaloids and “non-narcotic” alkaloids: e.g., papaverine (smooth muscle relaxant) and noscapine, a cough suppressant.
- **Opiate** – naturally occurring (morphine-like) alkaloid from the opium poppy, e.g., morphine, codeine and thebaine (which is used to make semi-synthetic opioids)
- **Opioid** – morphine-like activity, but not naturally-occurring, e.g., heroin, oxycodone, hydromorphone and others.
- **Semi-Synthetic opioids** – made in lab. from an opiate; not a naturally-occurring alkaloid like codeine or thebaine, but made from one of them or morphine, e.g., heroin, oxycodone, hydromorphone
- **Synthetic opioids** – made in a chemistry. lab. e.g., methadone and fentanyl.

The Opium Poppy, *Papaver Somniferans*

The Opium “Family” – Natural, Semi-Synthetic and Synthetic

Routes of Administration

- Snorting
- Injection, IV or “skin popped”
- Smoked
- Put where the sun doesn’t shine!

Addiction vs.. Dependence

- The term addiction is not found in the DSM IV.
- The DSM IV defines Substance Dependence (in pertinent part) as a maladaptive pattern of substance use, leading to clinically significant impairment or distress. This definition includes: tolerance and withdrawal, and we have summarized other manifestations as: (1) being out of control, (2) use causes a problem, (3) continues use in spite of the problem, (4) denies that a problem exists, and (5) impairment of the quality of life.

Blum and Benjamin, The Dependence-Addiction Paradigm: Good vs.. Bad - Treatment vs.. Abuse, ACLM, ca. 2004.
Where’s the Heroin?

It is uncommon to find heroin in blood or urine after use or overdose. It is rapidly metabolized to 6-monoacetylmorphine (6-MAM) & morphine.

- **T ½ = 6 mins**
  - Heroin (Diacetyl Morphine) → 6-monoacetylmorphine (6-MAM)

- **T ½ = 6-25 mins**
  - 6-monoacetylmorphine → morphine

Phase II Conjugation

Morphine → Morphine glucuronides (more water soluble) and excreted with a T ½ = 2-3 hrs

Why do abusers prefer heroin over morphine?

Morphine is too water-soluble and does not get into the brain as well as H!

Structure of Morphine

![Morphine](Image)

Structure of Heroin (Diacetylmorphine)

![Heroin](Image)

Facts About Heroin

- Heroin is 2-4 times as potent as morphine on a mg per mg basis.
- Heroin is preferred over morphine by addicts because IV injection of heroin rapidly enters the CNS due to its lipophilicity and produces a “rush.”
- Potency of “street heroin” varies and that is why an overdose is always a possibility.
- Naloxone is an antidote and saves lives (some are opposed to its use b/c they think it promotes opioid abuse).

More Facts

- Street heroin is rarely pure and may range from a white to dark brown powder of varying consistency. Such differences typically reflect:
  - the impurities remaining from the manufacturing process and/or
  - the presence of additional substances (fentanyl is a common additive due to rapid onset).
- These "cuts" are often sugar, starch, powdered milk and occasionally other drugs, which are added to provide filler.
Cutting Agents (Excipients)

- Sugars, e.g., lactose, table sugar, etc.
- Other drugs, e.g., quinine, caffeine, lidocaine, etc.
- Toxins, e.g., strychnine, amphetamines, fentanyl, anything they may have “hanging around” etc.

The Heroin Epidemic (crisis)

Cheaper than a prescription drug (especially if you don’t have medical insurance) and easy to buy on the street.

Fentanyl involved in 50+% Deaths in 10 states July-Dec 2016*

- ME, MA, MO, NH, NM, OH, OK, RI, WV, & WI
- *CDC MMWR

Of 5,152 opioid deaths, 3,000 tested positive for fentanyl and more than 700 tested positive for a fentanyl analog like carfentanil.
- Fentanyl also has been found in pills labeled as Oxycodone, Xanax, and Norco.

Structure of Fentanyl

Fentanyl is 80 times as potent as M and 40 times H on a mg per mg basis. Due to potency, higher doses of naloxone may be required to reverse a fentanyl OD. Used as an adulterant b/c it comes on v. fast.

Difference Between the structures of Morphine and Fentanyl

<table>
<thead>
<tr>
<th>Structure of Morphine</th>
<th>Structure of Fentanyl</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]</td>
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</tbody>
</table>

Pupil Sizes and Opioids

Tolerance does not develop to Pinpoint Pupils

Pupil Sizes

“Pinpoint” Pupils (Opioid OD)

Bladed pupils

Normal size pupils
Abusers Switching from Controlled Prescription Drugs (CPDs) to Heroin

Those who switch from abusing CPDs to abusing heroin do so because of:
- Availability (e.g., lack of availability)
- Price differences,
- And the reformulation of ER oxycodone with naloxone precluding crushing and snorting or injecting.

Abusers Switching from Controlled Prescription Drugs (CPDs) to Heroin

- Increased demand for and abuse of heroin has been driven by:
  - A recent NSDUH study found that heroin abuse was 19 times higher among those who had previously abused pain reliever CPDs.
  - Four out of five recent heroin initiates had previously abused pain reliever CPDs.
  - While the number of CPD abusers switching to heroin abuse is estimated at 3.6% of the total number of CPD abusers, it represents a large percentage of heroin initiates (79.5%).

How Bad is the Problem?

- "More people died of drug overdoses in 2014 in the U.S. than in any other year, and 60% of them were because of painkillers."
  - "Over the past 17 years, rates of opioid--overdose deaths have quadrupled, fueled by over-prescription of painkillers and the proliferation of cheaper forms of heroin and synthetic opioids."

- Why We Need Drugs to Treat Opioid Addiction, Alice Park, *Time*, Oct. 12, 2016

Heroin-related ED Visits

Heroin Epidemiology
Medication Use Process

Transcription
Prescribing -> Dispensing -> Administering -> Monitoring

Communication

The opioid “crisis” is a supply-side problem. Prescribers write for more pills than the patient needs for the condition being treated and pills accumulate in the “medicine cabinets” and are diverted by other household members. Rx Opioids are “traded” on the street for heroin, cocaine, etc. and may be adulterated w/fentanyl.

Too many prescriptions, at too high a dose, for too many days. A supply side problem!

“The amount of opioids prescribed in the US is still too high, with too many opioid prescriptions for too many days at too high a dosage,” stated Anne Schuchat, MD, acting director of the CDC. “Healthcare providers have an important role in offering safer and more effective pain management while reducing risks of opioid addiction and overdose.”

Long term opioid use often begins with the treatment of acute pain
- Tolerance ensues
- Dose is increased
- Discontinuation or dosage reduction of the opioid causes a return of the pain (this same scenario occurs with steroid use in RA)
- Prescriber and patient are caught in an upward spiraling dilemma

Opioid Overprescribing in Chronic Non-Cancer Pain
- Chronic pain not caused by cancer is among the most prevalent and debilitating medical conditions but also among the most controversial and complex to manage.
- Patients’ needs, the demonstrated effectiveness of opioid analgesics for the management of acute pain, and the limited therapeutic alternatives for chronic pain have combined to produce an overreliance on opioid medications in the United States,

Chronic Non-Cancer Pain
- with associated alarming increases in diversion, overdose, and addiction. Given the lack of clinical consensus and research-supported guidance, physicians understandably have questions about whether, when, and how to prescribe opioid analgesics for chronic pain without increasing public health risks.

Opioid or Non-Opioid Analgesic?

Of primary importance:
Non-opioid therapy is preferred for treatment of chronic pain.
Opioids should be used only when benefits for pain and function are expected to outweigh risks.

Before starting opioids, clinicians should:
(1) establish treatment goals with patients (eg, pain relief and increases in function) and
(2) consider how opioids will be discontinued if benefits do not outweigh risks. (eg, taper dose, crossover to non-opioid analgesics.) (sedation, ataxia, difficulty concentrating, constipation, postural hypotension, other opioid side effects.)

Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies, Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D.
Opioid or Non-Opioid Analgesic?

Of primary importance, non-opioid therapy is preferred for treatment of chronic pain.

Opioids should be used only when benefits for pain and function are expected to outweigh risks. Before starting opioids, clinicians should establish treatment goals with patients and consider how opioids will be discontinued if benefits do not outweigh risks.

When opioids are used, clinicians should prescribe the lowest effective dosage, carefully reassess benefits and risks when considering increasing dosage to 50 morphine milligram equivalents or more per day, and avoid concurrent opioids and benzodiazepines whenever possible.

Clinicians should evaluate benefits and harms of continued opioid therapy with patients every 3 months or more frequently and review prescription drug monitoring program data, when available, for high-risk combinations or dosages.

NB: Do not prescribe methadone if you have not received specialized training in its use as an analgesic. It is very different from other opioids!

Checklist for Prescribing Opioids for Chronic Non-Cancer Pain

When CONSIDERING long-term opioid therapy:

- Set realistic goals for pain relief and increased function based on diagnosis.
- Check that non-opioid therapies (eg, NSAIDs, PT, etc.) were tried and optimized.
- Discuss benefits and risks (eg, dependence/addiction, overdose) with the patient.
- Evaluate risk of harm or misuse.
- Discuss risk factors with patient (concomitant use of benzodiazepines greatly increases the risk of overdose).
- Check prescription drug monitoring program (PDMP) data.

Checklist for Prescribing Opioids for Chronic Non-Cancer Pain - 2

When CONSIDERING long-term opioid therapy:

- Check urine drug screen.
- Set criteria for stopping or continuing opioids (Pain intensity & relief; poor analgesia, no increase in functional capacity, eg ability to walk or do work).
- Assess baseline pain and function (can determine baseline pain on VAS from 0 to 100 in the office).
- Schedule initial reassessment within 1 – 4 weeks.
- Prescribe short-acting opioids using the lowest dosage on the product labeling (as with all drugs).
- Write for only enough pills to last till the next assessment.

Case Study

- A patient with a legitimate chronic pain problem had been treated with an ER oxycodone product for many years with a good result. One day, he received a letter in the mail from his treating physician informing him that the physician would no longer be able to prescribe oxycodone or any other opioid for him after 30 more days of therapy.

- The patient became highly anxious and went out and robbed a bank in order to obtain money to buy opioids (heroin) on the street.

Case Study-2

- He was arrested by federal agents for robbing the bank and convicted of bank robbery in federal court.

- His defense attorney called me on the phone and asked if I would write a letter to the judge explaining the circumstances and asking the judge for a lenient sentence for the defendant.

- I wrote the judge and told him/her this was a case of “iatrogenic addiction.”
In a Wrongful Death Case, Who Could Be Held Responsible?

- Physician Prescriber
- Pharmacist who Dispensed/Compounded Medication
- Nurse who Administered Medication
- **Hospital Employing MD, Reg. Ph., or RN** (this is a type of vicarious liability, i.e., *Respondeat Superior*)
- Pharmaceutical Manufacturer or Distributor (inadequate warning, overpromoted, or the drug was unfit for its intended use)

Theories of Drug & Device Product Liability:

- Defective Warning (Failure to Warn)
- Inadequate Testing (Animal or Human)
- Overpromotion (Lack of Fair Balance) or exaggerated claims, e.g., not addictive.
- Defectively Designed Drug or Device (alleged to be unfit for intended purpose, e.g., too addictive)
- Adulterated or Contaminated Drug

The Heroin Epidemic (Crisis)

Why do users risk death to abuse heroin?
Because the euphoria is so intense!

Heroin Euphoria is so intense!

How do I know without having used any?

An ACLM MD, JD was in a clinical study of heroin and told me. I’ve heard it before.

CDC Guidelines for Prescribing Opioids for Chronic Pain - 2016

- The guideline addresses:
  - 1) when to initiate or continue opioids for chronic pain;
  - 2) opioid selection, dosage, duration, follow-up, and discontinuation; and
  - 3) assessing risk and addressing harms of opioid use.

CDC Guideline for Prescribing Opioids for Chronic Pain — US, 2016
The Plan will:
- focus on policies aimed at reversing the epidemic
- provide patients in pain access to effective relief
- (FDA will) re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects.

The Plan will:
- develop changes to immediate-release opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting opioid analgesics labeling that is currently required.
- The FDA thinks that if you update the labeling, everything will be OK.
- Unfortunately, studies indicate that prescribers do not read the labeling (package insert)!

The Plan will:
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders.
- Naloxone is a non-prescription drug in some states.

Naloxone

Intranasal Formulation of Naloxone

Naloxone for Injection
The “Pill Mill”
US vs. Freddy Williams, MD
445 F.3d 1302 (11th Cir. 2006)

Dr. Freddy Williams, an MD in Panama City, FL, wrote over 21,000 prescriptions for more than two million doses of controlled substances. He was convicted on 94 federal charges related to the overprescribing of narcotics, most of which were for oxycodone.

US vs. Freddy Williams, MD
445 F.3d 1302 (11th Cir. 2006)

At the trial, an expert testified that Dr. Freddy Williams failed to meet the usual standards of care, and that the prescriptions were for “other than legitimate medical purposes.”

Three patients overdosed, and two died.

Dr. Williams also had billed an insurance company for some of the patient visits where he performed no service other than writing prescriptions for controlled substances.

“Evidence that a physician’s performance … departed from accepted professional standards supported the proposition that the physician was not practicing medicine, but was instead cloaking drug deals under the guise of a professional medical practice.” (Id at 1302)

Prison and restitution of $2+ million

See: Legal Med Perspectives July/August 2006 p.57 for a more complete review (Am College of Legal Med, publisher)
The Challenge of Opioids: Will Litigation, Regulation (REMS), or Legislation Make A Difference?

Jack Snyder, MD, JD, PhD, FCLM

57th Annual Meeting of the American College of Legal Medicine
February 24, 2018

Letter to the Editor (NEJM – Jan 1980)

WHO Pain Relief Ladder for Cancer Pain (1986)

Progress?: Heroin to Oxycontin

Approaches to Risk

Figure 1. Number and Type of Citations of the 1980 Letter, According to Year.

- Shown are number of citations of a 1980 letter to the Journal in which the correspondents claimed that opioid therapy rarely resulted in addiction. The citations are categorized according to whether the authors of the articles affirmed or negated the correspondents’ conclusion about opioids. Details about “other” citation categories are provided in Section 2 in the Supplementary Appendix.

https://www.drugrehab.com/opioid-epidemic/

Letter to the Editor (NEJM – Jan 1980)

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Progress?: Heroin to Oxycontin

Approaches to Risk

- Litigation?
- Regulation?
- Guidance?
- Legislation?
Opioid Litigation

Continuing Medico-Legal Education?

Litigation Timelines

Real Reason for Opioid Litigation?

Opioid Multi-District Litigation (Ohio)
### Examples of Theories of Liability in Opioid Litigation

- Violations of State General Business Laws related to deceptive acts and practices in the conduct of business, trade, or commerce
- Violations of other State General Business Laws
- Public Nuisance
- Violations of State Social Services Laws
- Fraud
- Unjust Enrichment
- RICO

### What About Regulation?

- National Emergency?
- DHHS 5-Point Opioid Strategy
  - Improve access to prevention, treatment, and recovery support services
  - Target the availability and distribution of overdose-reversing drugs
  - Strengthen public health data reporting and collection
  - Support cutting-edge research on addiction and pain
  - Advance the practice of pain management

### FDA Announced Priorities for 2018

- [Link](https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf)
- Reduce the burden of addiction crises that are threatening American families (opioids and nicotine)
- Leverage innovation and competition to improve health care, broaden access, and advance public health goals (generic competition)
- Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease (digital innovation, predictive toxicology)
- Strengthen FDA’s scientific workforce and its tools for efficient risk management
REMS is a Popular Acronym

- REMS = Rapid Eye Movement Sleep
- REMS = Rapid Emergency Medicine Score
- REMS = Remote Electronic Monitoring System
- REMS = Risk Evaluation and Mitigation Strategies
- REMS = RCRA Enforcement Management Systems
- REMS = Rescue and Emergency Medical Services
- REMS = Registered Equipment Management System

Historical Timeline of REMS

REMS Relationships

REMS 101: Authorities, Requirements and Policies (cont.)

- REMS specifies the required elements of a REMS.
- Drug sponsors develop the REMS program based on required elements. FDA reviews and approves the REMS.
- Under a REMS, healthcare professionals may need to follow specific procedures to safely prescribe, dispense, administer or distribute a drug.
- Patients may need to enroll in the REMS program or receive special counseling.
- Each REMS has specific safety measures that are targeted to the serious risk(s) associated with the drug or class of drugs.
"There is a public and health-care provider perception that FDA approval assures the safety and efficacy of a medication. Since this is not accurate, prescribers must become more familiar with the REMS process as well as its limitations. An important role of the FDA is to educate patients, prescribers, and pharmacists about the efficacy and safety of a medication. Complicating this process is the insight that all medications carry inherent risks, and some of which are generally predictable (e.g., mechanism-based), while others are idiosyncratic or otherwise unpredictable (e.g., allergic). REMS therefore maintain a critical role in allowing medications that may have a benefit in selected populations to be marketed despite well-understood or poorly defined risks."

http://remslogic.com/resources/

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Multi-Sponsor REMS

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FDA - REMS Priority Projects

- **Project #1 - Patient Benefit/Risk Information under REMS**
  - Seeks to improve the way physicians communicate the benefits and risks of a drug to their patients. FDA proposes to research existing REMS counseling tools and seek feedback from stakeholders to improve REMS counseling.

- **Project #2 - Prescriber Education under REMS**
  - Seeks to provide continuing education (CE) credit to physicians who undergo certain REMS training programs. FDA proposes to evaluate the types of CE models that would work best and analyze the resources required to implement this idea.

- **Project #3 - Pharmacy Systems under REMS**
  - Seeks to include REMS information in the structured product labeling (SPL) format for drugs with REMS. FDA proposes to standardize the way REMS information is presented for ease of FDA review and make structured information available to physicians, patients, and FDA.

- **Project #4 - Practice Settings under REMS**
  - Seeks to provide a central source of REMS information for practice settings. FDA proposes to investigate a central source of information about what stakeholders are required to do in each REMS program, help stakeholders learn, understand, and comply with REMS requirements, and allow for comparison of REMS requirements across REMS programs.
REMS – Benefit vs. Burden

- Are REMS a burden on the healthcare system?
- Given the choice between obtaining specialized education in order to be able to prescribe a certain drug or not prescribing that drug at all, some physicians have chosen the latter, thus restricting patient access
- Inconsistent communication of safety information, with confusion among pharmacists and physicians seeking to understand risks and comply with REMS requirements

ASCO Response to FDA Request for Comments (28 Dec 2017)

- “…if careful attention is not paid to existing and proposed educational programs, providers will be faced with a patchwork of requirements emanating from various state and federal agencies, many of which will be overlapping and duplicative. If FDA implements mandatory education, it should be tailored to the needs of different providers and linked to existing requirements such as DEA registration, Board examinations, or state licensure...and not to a new set of requirements adding yet another layer of burden and complexity to practice. Mandatory educational program need to be evidence-based, show that they are effective in achieving desire goals, and structure to be part of the normal practice workflow.”

ER LA Opioids Analgesics REMS

- Goal is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of extended-release or long-acting (ER/LA) opioid analgesics (at least 64 currently marketed products) while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death.
erationforPatientsandProviders/UCM311290.pdf
- http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm309742.htm#Q5
- FDA plans to extend REMS to at least 277 IR opioids in 2018

Recent FDA Guidance or Draft Guidance

- FDA’s Application of Statutory Factors in Determining When a REMS Is Necessary
ation/Guidances/UCM521504.pdf
- Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling
ation/Guidances/UCM574460.pdf
- FDA Blueprint for Prescriber Education for Extended-Release and Long-
  Acting Opioid Analgesics

What is “Abuse of REMS”? 

- REMS often limit distribution of innovator drugs (e.g., to and through qualified pharmacies)
- Filers of ANDAs must ask innovators to provide samples for bioequivalence testing (typically acquired through wholesalers)
- Plaintiff claims refusal to sell is unlawful monopolization
- FTC has filed amicus briefs in support of generics, arguing refusal to sell at 1st price to generics would be irrational but for the exclusion of competition

What is “Abuse of REMS”? 

- Lessons Learned To-Date (via 3rd Circuit cases)
  - Generic may not need to allege a prior course of sealing to state a legally sufficient refusal-to-deal claim
  - Courts will likely reject a brand name company’s reliance on safety concerns as a legitimate justification for denying drug samples to rivals
Accountability: Who and How?

**Methods**
- Legislation
- Regulation
- Litigation
- Guidance
- Self-Regulation

**Stakeholders**
- Patients
- Providers
- Hospitals & Medical Centers
- Pharmaceutical Manufacturers
- Payers
- Governmental Authorities

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To be continued...
The Role of policy, law and regulation in curbing the Opioid Epidemic

Dr. Ken J Berger MD JD, Assistant Professor, University of Toronto, Secretary General, World Association for Medical Law, Program Chair 2020, World Association for Medical Law Meeting, Toronto (August 12-16, 2020)

John Kim
Medicine ’19
Dangers of drug use include death, disease (HIV, Hepatitis C), and disability.

Are drug abusers criminals or addicts.

Role of Justice system and Physician

Policies to curb the Opioid Abuse – Reduce Supply and Demand, and intensify regulation and reform drug laws

- Decriminalization – no underground, target trafficking not utilization or simple possession
- Regardless of whether or not there is criminalization need effective policies on treatment, prevention, harm reduction, and reintegration of drug addicts into society
- Reduce supply – strict scrutiny in prescriptions
Opioid Use Rates

Percentage of Opioid Users in Gen Pop.

CCSA Prescription Opioids

Chronic Non Cancer Pain

Institutionalized Seniors
Seniors in Households

Ramage-Morin 2009

Opioid Prescription

Prescription/1000 Individuals
Avg Amt Prescription (mg)

Dhalla 2009

Guidelines and Standards

• College of Physicians and Surgeons of Ontario (CPSO)
  • Released “Evidence-based Recommendations for Medical Management of Chronic Non-Malignant Pain”, 2000 have been further updated in 2017
  • Canadian Guideline for Safe and Effective Use of Opioids for CNCP
    • Replaced CPSO’s previous release as a Guideline – No Regulatory power.

Canadian Guideline for Safe and Effective Use of Opioids for CNCP (I)

• 200 Page Document
• 24 Recommendations
  • 19 Supportive Points (Grade C) are consensus opinions of National Advisory Panel
  • 12 Supportive Points (Grade B) are based on cohort/case-control studies
  • 6 Supportive Points (Grade A) are based on RCTs

Increase in deaths prompt release of U.S. opioid guidance and Canadian guidance now being revised to reflect current evidence in response to increasing number of opioid related deaths

• Centre for Disease Control (CDC) released guidelines more conservative stance on dosing
• Carefully reassess evidence of individual benefits and risks when increasing to greater than 50 morphine milligram equivalents per day.
• Avoid increasing dosages above 90 morphine milligram equivalents per day
• Canadian guidelines used to have 200 mg per day
**Opioid Methods of Obtainment**

- FDA – Abuse-deterrent
  - 1. Physical/chemical barriers – prevent crushing or tamper resistance
  - 2. Agonist/antagonist combinations – add opioid antagonist reduce or defeat euphoria
  - 3. Aversion – add substance unpleasant effects
  - 4. Delivery Systems – drug release designs
  - 5. New drugs – enzyme activation

**Technology Approaches**

- 1. EMR – decision support tools
- 2. Prescription monitoring programs – real time access to all medications for all patients
- 3. Patient return policies (patch for patch)

**Regulator – Professional Misconduct or Incompetence**

- Physicians who come before the College for unsafe prescribing practices appear not to have followed any accepted guideline.
- Common issues: starting opioids without a clear diagnosis, dosages started to high or increased to aggressively, not considering drug interactions particularly between opioids and benzodiazepines and not following accepted practices when dealing with aberrant drug related behaviour

**Following Recommended Practices**

- Safe and effective to continue opioids
- Benefits and risk
- Assess level of function
- Physician tapering and discontinuing
Opioid Medication Treatment Agreement

I understand that I am receiving opioid medication from Dr. to treat my pain condition. I agree to the following:

1. I will not seek opioid medications from another physician. Only Dr. will prescribe opioids for me.
2. I will not take opioid medications in larger amounts or more frequently than is prescribed by Dr.
3. I will not give or sell my medication to anyone else, including family members; nor will I accept any opioid medication from anyone else.
4. I will not use over-the-counter opioid medications.
5. I understand that if my prescription runs out early for any reason (for example, if I lose the medication, or take more than prescribed), Dr. will not prescribe extra medications for me; I will have to wait until the next prescription is due.
6. I will fill my prescriptions at one pharmacy of my choice; pharmacy name:
7. I will store my medication in a secured location.

I understand that if I break these conditions, Dr. may choose to cease writing opioid prescriptions for me.

- Source: Modified from Kahan 2006 Reference:
  http://nationalpaincentre.mcmaster.ca/opioid/opioid_b_app_b05

Narcotic Monitoring System
Ministry of Health, 2012

- Drug utilization patterns and trends to detect unusual prescribing activities i.e. double doctoring
- Harm reduction strategies, educational initiatives, and improving prescription and dispensing practices
- Illegal activity or professional misconduct, the ministry will report to law enforcement and to the regulatory Colleges

CPSO Opioid Investigations as of 2017 August

- 84 Comprehensive Investigations
- 27 physicians mandated remediation – Undertakings
- 3 Prescribing restrictions
- 3 No longer practicing
- 1 Referral to discipline
- 16 No action
- 4 Advice
- 2 Remedial Self-Study

Regulatory Bodies

- Components to be considered for Standard of Care
  - Consistency of appropriate prescription
  - Physician Accountability
  - Physician Protection
  - Regulations on prevention of abuse, addiction, and tolerance

College of Physicians and Surgeons of British Columbia (CPSBC)

- Professional Standards and Guidelines – Safe Prescribing of Drugs with Potential for Misuse/Diversion
  - June 1, 2016 – Recent Document
  - 5 Page Document, concise and clear
  - Refers to more recent research than Canada Guidelines

Professional Standards and Guidelines – Safe Prescribing of Drugs with Potential for Misuse/Diversion

- Standards
  - 3. Document discussion with patients that non-pharmacologic therapy and non-opioid analgesics are preferred for chronic non-cancer pain (CNCP)
  - 5. Always prescribe the lowest effective dosage of opioid medication, document careful reassessment if increasing the dose to >50 morphine milligram equivalents (MME) per day and avoid increasing the dose to >90 MME per day.
  - 9. Document the offer of a take-home naloxone prescription to all patients who are at risk of respiratory depression as a consequence of receiving opioid medication.
  - 11. Order at least annual random urine drug testing (GUDT) and/or random pill counts for all patients on long-term opioids, sedatives or stimulants.
Newfoundland & Labrador Pharmacy Board (NLPB)

- Standards of Pharmacy Operation – Community Pharmacy
  - June 2015
- Standards for Hospital Pharmacies
  - June 2007

Standards of Pharmacy Operation – Community Pharmacy

- Security, Record Keeping, Information Management
- 3.8 Pharmacist-Patient Consultation
  - D) While specific patient counseling is not required for repeat and refill prescriptions, pharmacists are expected to gauge the need for such counseling by asking questions regarding changes in dosage regimens, compliance, efficacy, and the presence of adverse effects and counsel accordingly
- Additional resources on Opioid topics such as Buprenorphine prescription
  - College of Physicians and Surgeons of Newfoundland and Labrador released a document called ‘Guideline – Prescribing Buprenorphine’
  - Comprehensive and detailed guidelines

Regulatory Bodies’ Duties (I)

- Promote and develop systems of interprofessional collaboration
  - Double Doctoring
- Ensure constant checks and balances on Opioid prescription
  - Urine Drug Screens (UDS), Treatment Agreements, Pill number checks, Opioid prescription rates

Regulatory Bodies’ Duties (II)

- Develop Standards of Care that include Physician Accountability
- Incorporate education in current AND future practicing physicians, pharmacists, and other healthcare professionals

Patients

- Opioid abuse and criminal law
- Opioid tolerance may lead to dependence on other substances (narcotics, sedatives etc)
  - Ex. Heroin is cheaper on the ‘street’, and easier to obtain in some communities than prescription Opioids
  - 2010 OxyContin Reformulation (so it cannot be injected or snorted)

Opioid and Heroin Use

Fentanyl (I)

- Synthetic opioid analgesic
- Abused for Heroin-like effects

Fentanyl (II)

- Methadone
  - Oral opioid with slow onset, long half-life
  - Full agonist of opioid receptors
  - Appropriate doses – relieves symptoms of withdrawal without sedation or euphoria
- Buprenorphine
  - Sublingual partial agonist, long duration of action
  - Ceiling agonist effect – can’t overdose
  - Equal effect to 60-80mg Methadone
- Suboxone (Buprenorphine and naloxone)

Methadone Treatment

- Methadone Maintenance Treatment vs Forced withdrawal from Methadone in Prisoners post-release

Rich 2015
SATURDAY, FEBRUARY 24

PICKNEY | 8:00 am - 9:45 am

DENTAL SESSION IV
Moderator: Frank Riccio, DDS, JD, FCLM

• 8:00 AM - 8:25 AM Opioid Crisis, Really? Daniel Orr, DDS, MD, JD, FCLM, DABE
• 8:25 AM - 8:50 AM Practice Transactions: Worst Case Scenarios Chester Gary, DDS, JD, FCLM
• 8:50 AM - 9:15 AM History of the Prescription Epidemic in the US Richard Harold, DMD, JD, FCLM
• 9:15 AM - 9:40 AM Legal Issues in Dental Education Margaret Hill, DMD; Roger Moore, DDS
• 9:40 AM - 9:45 AM Q&A Dental Session IV
Rx Opioid Crisis...Really?

ACLM Annual Meeting  
FEB 2018  
Charleston, SC

• Daniel L. Orr II, DDS, MS (anesth.), PhD, JD, MD  
  • Professor and Director  
  • OMS and Anesthesiology  
  • UNLV SDM

Genesis

• The early 2000’s witnessed an increase in opioid analgesic Rx’s, as well as increases in addiction, diversion, and fatal overdose.
  

Genesis: CDC

• The Centers for Disease Control and Prevention (CDC) noted the pattern; prompt publicizing alerted doctors and the public to the findings. The Drug Enforcement Agency (DEA) and CDC closed multiple “pill mills,” effectively solving the problem.

  – Fudin J, Atkinson TJ. Opioid prescribing levels off, but is less really more? Pain Med 2014;152:184–7

Results 2009–2017

• The 2011 peaks of opioid analgesic prescribing and overdose were followed by multiyear sustained declines, which were not publicized by the CDC, and continue today.


Punishing the Wrong People

• Subsequent actions by the CDC, DEA, and a sensationalistic media have intensified barriers for appropriate access to opioid analgesics for patients with chronic pain.


Doctors’ Response

• From 2012 to 2015, reports from FL, GA, IN, MA, MT, NV, and TX described increasing numbers of physicians refusing to issue opioid prescriptions.

Why not Prescribe I?

- Once a doctor’s prosecution begins, the media portrays the accused as a greedy elite with a degree who has violated the public trust.


Why not Prescribe II?

- NV’s new Rx law effective 01 JAN 2018
- UNLV SDM ER/OMS Clinic:
  - Must now search the often unavailable, always inaccurate PMP databank
  - Must now provide a 3-page informed consent
  - Must issue “days” amounts
  - Etc.
- ≥ 20 minutes average to provide Rx

Regulatory Malpractice?

- Regulators are misdiagnosing the opioid crisis as a doctor-patient problem. While raids on black market drug dealers net hauls from an endless sea of illicit drugs, including opioids, legislators accept the myth that drug crisis is caused by doctors prescriptions. The numbers show that isn’t the case.

  – Singer, JA, Cato Institute, Misdiagnosing the opioid crisis. Inside Sources, SEP 27 2017

The Actual Drug Crisis

- Halloween 1989
- Largest cash seizure in CA Hx
- LA, CA BofA count

Apparatchik Responses

- Increased laws, regulations, and restrictions affecting doctors prescribing.
- PMP programs, intended to stop patients who doctor-shop for opioids, have not reduced the opioid overdose death rate, which continues to rise.
NDAJ Editorials 2010 and 2015

AB474 Changed What in NV?

• NV PMP changed from voluntary to mandatory proof of access
• NSBDE R&R now requires an annual self-check for biennial registration.
• UMC/NSBP Rx CE
  – Question to NSBP: “It seems doctors have morphed from diversion prevention helpers to targets.”
  – Pregnant pause: “You’re right Dr. Orr.”

BTW, Dentists are not the Problem

• In NV, all human prescribers reviewed.
  – Only 2/1500 NV dentists “might” have an issue.
  – Now easier for one’s dog to receive an Rx
    • Which is easier to divert BTW
• Nationally, dentists prescribe 2% of all opioid Rx’s.
  – Office based physicians Rx 80%
    – Axeen, S, Annals of Em Med, JAN 15 2018

Dr. Schatman’s findings

• An average of 6 toxic substances found in OD deaths.
  – EtOH present 44% of cases
  – Amphetamine present 25% of cases
• If one of the toxins happens to be an Rx, the case is signed out as “prescription opioid death.”
• Rhetorical Question: Do we have an Rx opioid crisis or a polypharmacy issue?
SATURDAY, FEBRUARY 24

COLONIAL | 10:00 am - 11:50 am

BREAKOUT SESSION IV: Current Medicolegal Issues in Israel and America
Moderator: Weldon Havins, MD, JD, FCLM

- 10:00 AM - 10:25 AM Sham Peer Review in Israeli Hospitals
  Jonathan Davies, LLM

- 10:25 AM - 10:50 AM Legal and Ethical Dilemmas of Statutory Tribunals in Determinations of Involuntary Hospitalization in Israel
  Samuel Wolfman, MD, JD, FCLM

  Oren Asman, LL.D., Esq.

- 11:15 AM - 11:40 AM Trumpcare, Jack Conomy, MD, JD, FCLM

- 11:40 AM - 11:50 AM Q & A Breakout Session IV
Sham Peer Review in Israeli Hospitals

Jonathan Davies, LL.M.

WHAT IS SHAM PEER REVIEW (SPR)?

- Though peer review is a welcomed and appropriate activity, taking place in the various arenas of the academic world, it seems that where Professionals operate in the Medical world peer review took a step forward and became sham peer review.
- SPR is the name given to the prostitution of the medical peer review which infects harm and attacks a physician for personal reasons related to his medical profession, which are unrelated to the physician’s quality of care and patient’s safety.
- Larry Poliner describes SPR “like a deadly virus sheltered within an immune cell, peer review has been inflected. Ironically, some, who have sworn to “do no harm” now use peer review as a weapon of harm—“Doctors Who-Rent Doctors.”
- Dangerous “concern for patients” is used to conceal malicious motives in a legal and charade where absolute immunity protects those who utter the words “peer review,” and where form bumps substance at every level.
- We will show that the same SPR tactics illustrated in the Poliner case apply in Israel.

THE POLINER CASE

- Larry Poliner is a Cardiologist that was maliciously put out of work, his reputation was ruined, and his practice was destroyed by tactics of SPR as quoted in his article reviewing the writing of an expert opinion for legal purposes is a judicial process in which the expert tries to convince the court and influence the outcome of proceedings.
- In order to overcome hurdles of a malpractice or tortious behavior of a physician, the Medical institution tries to curb the actions of the physician by inflicting harm to his name and reputation, and at the same time, protecting their own interests. The SPR against professionals are done in very shrewd and sophisticated tactics, just to prove that the conduct is against the interest of the institution.
- We will show examples of SPR in the above situations, and try to compare the SPR in Israel to case law in the USA. At the end I will be happy to share with you some of my unanswered questions.

SPR AS A TOOL TO DIMINISH EXPERT OPINION (1)

- The writing of an expert opinion for legal purposes is a judicial process in which the expert tries to convince the court and influence the outcome of proceedings.
- The expert opinion should be supported by medical records and data collected according to Evidence Based Medicine (EBM) rules and rely on medical literature and studies published in scientific text books and journals.
- In order to overcome hurdles of a malpractice or tortious behavior of a physician, the Medical institution tries to curb the actions of the physician by inflicting harm to his name and reputation, and at the same time, protecting their own interests. The SPR against professionals are done in very shrewd and sophisticated tactics, just to prove that the conduct is against the interest of the institution.
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SPR AS A TOOL TO DIMINISH EXPERT OPINION CREDIBILITY

- Another form of SPR of an Expert Opinion is by challenging the credibility of a professional that testified against the interest of the professional body.
- Dr. Maia Forman is a pathologist who applied to work for the government institution. Government Bylaws forbid any physician to testify against the state in any criminal or civil proceedings.
- The prosecution used some comments of the court to claim that Dr. Forman is not suitable for the job and tried to put a stop order on her nomination using SPR tactics attacking her credibility.
- The Labor court dismissed the claim.
We will show that the same SPR tactics illustrated in the Poliner case apply in Israel.

SPR is the name given to the prostitution of the medical peer review which intends harm.

Though peer review is a welcomed and appropriate activity, taking place in the various arenas of the academic world, it seems that where Professionals operate in the Medical world peer review took a step forward and became sham peer review.

Larry Poliner describes SPR, "Like a deadly virus sheltered within an immune cell, peer review has been injected, typically, some, who have sworn to "do no harm," new use peer review as a weapon of harm—Doctors Who Hurt Doctors."

Dangerous "concern for patients" is used to conceal malicious motives in a deadly charade where absolute immunity protects those who utter the words "peer review," rather than where form trumps substance of every level!

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WHAT IS SHAM PEER REVIEW (SPR)?

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SPR IN ISRAELI HS APPEARS IN DIFFERENT MANNERS

- First, as a tool to diminish expert opinion credibility in order to influence the court in Medical malpractice cases or in other issues.
- Second, as a tool to eliminate experts from testifying against the interests of medical professional bodies.
- Third, as a tool to eliminate professionals who are whistleblowers, competitors or become a threat to the medical institution by protecting patient safety and revealing cover-up of Medical Malpractice.
- The SPR against professionals are done in very shrewd and sophisticated tactics under different clauses of immunity, that puts the physician on the defense and intended to prove that his conduct is against the interest of the institution.
- We will show examples of SPR in the above situations, and try to compare the SPR in Israel to case law in the USA. At the end I will be happy to share with you some of my unanswered questions.

THE POLINER CASE

- Larry Poliner is a Cardiologist that was maliciously put out of work, his reputation was ruined and his practice was destroyed by tactics of SPR as quoted in his article review that was written by the court ruled in his favor.
- "The process that unfolded was directed at stopping me from practicing at the hospital by removing my privileges to work there as a cardiologist. I had an interventional practice at the hospital."
- "With the first patient I scheduled in the cardiac catheterization lab, I was informed that my privileges were no longer active and I would not be allowed to treat the patient. After I complained, it was determined that there was no basis for the adverse action against my privileges, and I was allowed to provide treatment to the patient."
- The Labor court dismissed the claim.
**SPR IN ISRAELI HOSPITALS - THE MILGALTER CASE**

- Dr. El Milgalter was the Director of the Heart Transplant Unit at Hadassah Medical Center in Jerusalem, and was appointed as the Director of the Pediatric Cardiothoracic Surgery Unit. The unit was a candidate for the Nobel Prize due to its contribution to the special relationship with the Peres Center that refined Palestinian patients to Hadassah.
- Dr. Milgalter was also a senior lecturer at the Hebrew University.
- Dr. Milgalter was an exceptional surgeon in his abilities and he was highly thought of by peers and patients alike. He specialized in both pediatric and adult surgery.
- Dr. Milgalter was also a senior lecturer at the Hebrew University.
- Since the appointment of a new director of the Cardiothoracic Surgery Department, Dr. Milgalter’s authority and reputation were abused, and he was exposed to a series of harmful actions and procedures that amounted to a tortuous sham peer review as follows:
  - Changing the surgery program and canceling the regular surgery days of certain physicians in the department in order to arrange the director’s private patient list.
  - Decreasing the number of Dr. Milgalter’s patients on the weekly surgery schedule.
  - Taking away Dr. Milgalter’s permanent professional staff in pediatric cardiac surgery.
  - Removing Dr. Milgalter from the teaching staff of the School of Medicine with the allegations that his teaching quality was unsuitable despite the fact that Dr. Milgalter was considered to be an excellent lecturer of the School of Medicine.
  - Adopting arbitrary sanctions against Dr. Milgalter, including forbidding him from conducting surgery for lengthy periods, forbidding his entry into the catheterization unit.
  - Removing Dr. Milgalter from the consultation program for internal medicine department and preventing referrals of medical tourism to him.

**TACTICS OF SHAM PEER REVIEW AGAINST DR. MILGALTER**

- Since the appointment of a new director of the Cardiothoracic Surgery Department, Dr. Milgalter’s authority and reputation were abused, and he was exposed to a series of harmful actions and procedures that amounted to a tortuous sham peer review as follows:
  - Changing the surgery program and canceling the regular surgery days of certain physicians in the department in order to arrange the director’s private patient list.
  - Decreasing Dr. Milgalter patient list in the surgery program; splitting Dr. Milgalter from permanent professional staff in pediatric cardiac surgery.
  - Removing Dr. Milgalter from the teaching staff of the School of Medicine with the allegations that his teaching quality was unsuitable despite the fact that Dr. Milgalter was considered to be an excellent lecturer of the School of Medicine.
  - Adopting arbitrary sanctions against Dr. Milgalter, including forbidding him from conducting surgery for lengthy periods, forbidding his entry into the catheterization unit.
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**ENDANGERING PATIENT SAFETY**

- In July 2009, with the increase of the cases where harm was caused to patients, Dr. Milgalter, driven by his conscious and moral obligation, sent a warning letter to Hadassah’s management titled “Improper management can kill patients!” where he lists the factual events since the appointment of the new head of the department:
  - The hospital’s CEO ignored the content of the letter and instructed all other recipients of the letter to ignore its warnings as well.
  - Following his warnings about the department management in a manner that endangers patients, Dr. Milgalter received a formal complaint that his behavior was unethical and he was summoned to a disciplinary hearing in an improper procedure.
  - As a sanction the extension of Dr. Milgalter’s appointment as the director of the unit was upheld until the results of the disciplinary hearing.

**THE CLAIM OF DR MILGALTER’S ESTATE**

- Following his warnings about the department management in a manner that endangers patients, Dr. Milgalter received a formal complaint that his behavior was unethical and he was summoned to a disciplinary hearing in an improper procedure.
  - As a sanction the extension of Dr. Milgalter’s appointment as the director of the unit was upheld until the results of the disciplinary hearing.
IS THERE CAUSATION BETWEEN THE FOLLOWING HEADING AND SHAM PEER REVIEW?

LEGAL IMMUNITY IN ISRAEL HEALTH SYSTEM

One of the arguments in American literature shows an history of outrageous and unjustified immunity that allows sham peer review that began in the mid-1980s with a perception, probably false, that instances of malpractice by physicians were increasing.

In Israel legislation protects wrong behavior by giving immunity in different ways:

- Testimony of expert witnesses is protected by legislation allowing the witness to say anything against his colleges or anyone else.
- Hospitals conduct in internal investigating hearing are completely immured. This allows them to cover-up any malpractice that occurred within the medical institution.
- Hospital disciplinary hearings are completely immured.
- When Dr. Milgalter asked to complain to the Ministry of health and testify in front of disciplinary hearing committee, Hadassah authorities stopped him from doing so using different tactics.
- Immunity of wrongful conduct within medical clinics is used as a tool to cover mistakes.
- This full immunity allows sham peer review to take place in its different forms mentioned above.
- Immunity allows to cover-up wrongful conduct that the physicians call Defensive Medicine and what I consider as a tool to escape accountability in Medical Malpractice cases.

THE DOUBLE JEOPARDY SYNDROME OF SHAM PEER REVIEW

Once SPR takes place in a severe manner it’s probably unrecoverable.

As Dr Poliner concludes in his review: “Despite the eventual return of all of my privileges, and after a jury unanimously found that defendants acted “maliciously without justification or privilege”, my reputation was ruined, and my practice was destroyed. The sham peer review was highly effective in eliminating me as a competitor, despite there being nothing wrong with the care I provided. It completely destroyed my referral sources. It is hard to undo a label of “dangerous doctor” once it has been indelibly stamped on the physician victim.”

In this story we see that all players lose. The physician, the hospital, the patients and public.

Sham Peer review is like a cancer cells within the system that attacks not only the physician involved but also patient safety, in the sense that patients become the main victim in this arena, but also the public loses an excellent and conscious professional.

So the question is how does the system avoids Sham Peer review within hospitals?

THANK YOU FOR LISTENING

Jonathan Davies, JD, LLM

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Basic Questions: Is legislation a rigid process?

Should the law be followed always without any deviations even when human circumstances make it difficult to follow?

Bioethical considerations in Legal/Forensic Psychiatry

Can Ethics and Law coexist?

Do Bioethical considerations Contradict Strict Legal thinking

QUESTION: Are there any statutory arrangement regarding the admission or hospitalization of medical or surgical patients?? !!!

QUESTION: Which is the medical specialty with the highest involvement of the Judiciary

Legal and Ethical Dilemmas of Statutory Tribunals in Determinations of Involuntary Hospitalization

ACLM 2018, Charlestone, SC

February 24th, 2018

Dr. Samuel Wolfman

Law Faculty Haifa university

And Law School Zefat Academic College
QUESTION: Do the Psychiatrists And the Judiciary Speak the same language

Involuntary Psychiatric Admittance: The different between medical and judicial views regarding Dangerousness

Dr. Samuel Wolfman
Law Faculty Haifa university
And Law School Zefat Academic College

Conclusion? Is there a barrier of language between Psychiatry and the Judicial System?

Basic Difference:
Psychiatrists’ main concern refers to diseases, diagnosis and prognosis

The Judiciary main concern is Legal rights

The Israeli Statute for the Treatment of the Mentally Ill Patients 1991

- The Criminal Route for involuntary commitment of psychiatric patients:
  - Order for involuntary admission is issued by criminal court when defendant:
    1. Had not been able to differentiate between good and wrong at the time of the deed or could not resist the commanding contents of his disease
    2. When defendant was found incompetent to stand trial

- Two routes for involuntary commitment of psychiatric patients:
  1. Criminal route
  2. Civil route
The Israeli statute for the Treatment of the Mentally Ill Patients 1991

The District Psychiatric Committee/Tribunal (Mental Health Court)

- **3 members:**
  - Two senior psychiatrists
  - Chairman: Legal expert in the capacity of Magistrate Judge

The Civil Route for involuntary commitment of psychiatric patients:

- The initial authority to involuntary admissions of a mentally ill patients: The MOH District Psychiatrist
- Initial hospitalization order for 7 days +7 more additional days.
- Appeals on admission orders or extensions of hospitalizations: Statutory Committee (Mental Health Court)

Dilemmas of the Psychiatric Committees

When and under what circumstances should the committee, whose decision is based on only brief examination of the patient, reject requests for involuntary prolongation of hospitalization bases on longer and more thorough follow up of the patient by the hospital doctors?

Data the committee should consider when ruling in Involuntary hospitalization cases

- Exact circumstances of events prior to involuntary admission
- Supporting documents: preliminary community psychiatric request addressed to D.P. for involuntary hospitalization, police or welfare authorities references
- Admission order of D.P: Does it fulfill the legal terms
- Patient hospital medical records, including nurses reports
- Testimonies of relatives, friends (possibility of conflicting interests, property managements)

Committee should consider hearing family or treating physicians testimonies in the absence of the patient.

Dilemmas of the Psychiatric Committees

Careful check of Evidence

- Family whose complaints triggered admission order should be invited to the committee to clarify the picture
- Community social worker should be invited to clarify the condition at home
- Invitation of social worker is particularly important when:
  - Children may be at risk (psychotic mother to a very young baby)
  - Allegations coming from a spouse who may have personal “agenda”

Committee seeks information from anybody who can supply same.

Committee has the authority to subpoena any witnesses (§ 25)
Basic Judicial Assumptions Regarding Characteristics of Dangerousness

- It is impossible to define/measure dangerousness in definite medical/biological units.
- Dangerousness is not an objective but rather a relative feature.
- Dangerousness relates to deeds and not to personality or mental disease.
- “Similar” persons from the medical/psychiatric point of view, are not necessarily similar from the dangerousness point of view.

Dangerousness is the conclusion of the bystander based on the assumption that past behavior or past expressions can predict future behavior.

Dangerousness shall not be expressed without triggering circumstances.

Can we define dangerousness to others in a person on an isolated island?

Summary of Judicial Standpoint: Supreme Court CA 2060/97 Vilenchik vs. District Psychiatrist Tel Aviv

Justice Aharon Barak:

- Mentally ill patients have equal rights as any other person.
- Dignity of Mentally ill pts. Is not less important than any human dignity.
- Breach of Mentally ill pts’ freedom is as harsh as any other breach of freedom.
- A person does not lose rights for dignity and freedom when he is mentally ill. rights for freedom.
Summary of Judicial Standpoint:
CA 2060/97 Vilenchik vs. District Psychiatrist Tel Aviv
Justice Aharon Barak:
❖ Involuntary admissions breach freedom, hurts self esteem, label people

Justice Elon: VA 198/80 Toledano vs. State of Israel
Hospitalization in a mental hospital is harsh and bitter for pts and their families. When such hospitalization is forced on the mentally ill, it is one of the most severe and depressing forms of the breach of the human rights for freedom

Justice Saviona Rotlevy: Tel Aviv district Court:
VA (TA) 1171/03 Jane Doe vs. District Psychiatric committee
According to the Law
It is impossible to enforce medical treatment on a person when he refuses treatment
Even when his physicians are convinced that such treatment is In his benefit and shall cure his disease

Medical Standpoint
❖ There is no real balance between legal and medical consideration at the level of judiciary bodies, such as the Mental Health Tribunal or the Appeal Court
❖ Study Conclusions: Ratio of community 6 months stay of patients released from hospitalization through legal representation vs patients released due to medical decision – 42% vs. 75%.
❖ “We strongly believe that legal representation lacks the balance between the medical and legal aspects, between the will of the patient and his real medical benefit – of which the psychiatrics are accountable”. Remona Durst et al. Involvement of the judiciary system in the psychiatric Treatment, Harefuah, 144, 10 (2005) 696-699

Dilemmas of the Psychiatric Committees
❖ In which cases not to approve short leaves (vacation) to convicted criminal patients
❖ In which cases to limit vacations of convicted criminal patients (hours, no-overnight)
❖ In which cases to discontinue criminal court order for involuntary hospitalization of convicted patients
❖ In which cases to substitute involuntary hospitalization with involuntary out-patient Clinic in hospital or community

Medical Standpoint
❖ Psychiatric society is concerned by the fact that legal representation of involuntary admitted mentally ill pts, is based on the basic disagreements with the judiciary who always prefers judicial evidence over medical considerations.
❖ Judicial system gives preference to patient’s will (desire for freedom) over patient’s medical benefit
❖ Judicial system gives preference to patient’s rights for freedom, although such freedom is not a real one since the patient is tied up by his diseased delusions.
Remona Durst et al. Involvement of the judiciary system in the psychiatric Treatment, Harefuah, 144, 10 (2005) 696-699

Dilemmas of the Psychiatric Committees
❖ When to grant a patient’s appeal and overturn D/P involuntary admission order
❖ When to reject the hospital’s request to prolong involuntary hospitalization
❖ In which cases to prolong hospitalization only for a short period and not accept doctor’s request for long periods hospitalization
❖ In which cases to prolong hospitalization for social reasons (i.e. mental rehabilitation basket, family circumstances etc.)
Ongoing Dilemmas of the Psychiatric Committees

Other "Non Mental" Diseases Patients:

✓ Anorexia Nervosa
✓ "Normal" people who try suicidal acts
✓ Severely ill patients who seek to commit suicide.

Mental patients suffering from various organic diseases who won’t consent to medical treatment such as: Diabetes, Dialysis patients, Malignant diseases etc.

The statute provides for psychiatric treatment (§ 35) however is not clear regarding non psychiatric treatment

Other "Non Mental" Diseases Patients:

Is there a need for legislation changes?

To what extent can society stretch its paternalism over such people?

Is there a medico-legal or human obligation to save the "non-mentals" from their self-dangerousness when the means are involuntary admittance to a secured psychiatric ward – even though they do not meet the criteria of The Statute for the Treatment of the Mentally Ill – 1991

Conclusions:

❖ Committee should examine all evidence and decide each case according to its own merits
❖ In any case, verify patient’s right for representation and try to convince patient to cooperate with public aid attorney
❖ Committee cannot escape—in certain cases—from diverting from the law when circumstances show clearly that there are no legal provisions for a particular case. Is this ethical??

❖ Committee/Mental Health Court should consider the broad medical-legal-personal picture and not limit itself to strict rules that either may bring to sever deprivation of freedom or endanger safety of society
Conclusions:

Open questions:

Is legal always moral?
Is legal always ethical ??

THANKS

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Terms

1. **Advanced Directives**: Personal, Financial or Medical directives a person makes for when s/he is no longer able to make decisions. (e.g.: “a living will”)

2. **(Durable) power of attorney/proxy**: Authorizing another person to act as one’s agency for certain decisions (if the individual is incapacitated)

3. **Ulysses contract**: a (medical) decision binding oneself in the future, in predefined situations. If effective, the original expression of will overrides the current will of the person (patient).

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Israeli Legislation

- 1996: The patients rights law included a possibility to appoint a medical proxy.
- 2005: The patient near death law included both a possibility for advanced directives and a proxy.
- 2016: The legal competence law is amended and now includes: A clear definition of **Durable** power of attorney, Advanced directives, including a Ulysses pact, supported decision making.

- Lack of harmonization between those laws threatens the usefulness of some of its mechanisms.

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The latest developments

- Mid April 2017: the new Durable power of attorney construct went into effect.
- The ministry of health conducted training for more than 1,000 lawyers as a pre-requirement to deposit those.
- Medical AD could be deposited by health care providers (physicians, nurses, social workers) without being required for any training.
- A public campaign is to be launched encouraging the utilization of AD.

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The Israeli example

- An inter-office governmental committee has been formed to follow on the implementation of the competence and guardianship law and draw conclusions and recommendations.
- The legal aid and specifically the elder representation branch trained its 70 lawyers to reach out to persons with disabilities and the elderly and help with AD.
- Process is just starting.

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What may influence health-care professionals attitudes

1. Knowledge of and Experience in AD Use.
2. Support: Respect for autonomy/patient’s wishes
3. Reluctance: Legal problems
4. Culture, Religion
5. Family/relatives influence
6. Fear of increased “Euthanasia/Assisted Suicide”


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Enhancing Durable Power of Attorney in Israel - A Golden Opportunity for Health Law

Oren Asman, L.L.D., Esq.
Practical matters:

1. Who should help the person/patient prepare the Advanced directives?
   a. Time
   b. Compensation
   c. Relevant knowledge


Why only a small portion of population uses AD?

1. It is mostly encouraged in specific hospital settings (Palliative care).
2. Many do not form a “regular” last will and testament – future planning is sub-optimal.
3. The forms bureaucracy is a deterrent
4. It is a fairly new legal construct.
5. Misguided cost-benefit calculations of professionals

A golden opportunity for patients’ autonomy – some suggestions

1. Harmonize the laws
2. Change the prevalent mindset: health-care professionals, practicing lawyers, public.
3. Simplification and specification of various suggested forms.
4. Reversing the top-down process.
5. Increase (responsibly) media involvement
Stumbling Toward Armageddon?:
Health Care Reform in the
United States of America
in the Reign of
Donald J. Trump

by
John P Conomy, MD JD
Cleveland, Ohio USA

Disclaimer
I speak only for myself, and for more
than half the people of the USA

In April, 2010, The Affordable Care Act,
better known as “Obama Care” became the
Law of the Land. It provided Health
Insurance via Government subsidies to 20
million people, many sick, poor and
minorities who had no prior, reasonable
access to health care. Obamacare
survived >70 governmental attempts to
kill it.

President Obama

And Another Disclaimer
The News Cycle in the USA is about 15 minutes
Long, thanks to President Trump who serially,
impulsively and with frequent contradiction
and misspellings, rules by “Tweets”
starting at about 3AM. Hence, anything I have
to say may be light years out of date.
Anything I say which is not out of date may be
out of date 15 minutes after I leave the
podium.
Thanks for you understanding, and welcome to
the World of Donald J. Trump Care
President Obama established the seeds of a National Health Care Plan, the USA having lacked one for 400 years since its founding. It is not perfect. It costs too much, its outcomes are not clear; it lacks a public mandate and it is administered by 430+ private insurance companies. The USA spends over 3 Trillion USD on Health Care annually.

In his campaign and election, President Trump vowed to Repeal and Replace Obamacare, calling it "disastrous." His party, the Republicans, passed the American Care Act by a single vote (HR). The Senate killed it with legislative with non-support.

HRv.1 2017, Trump Care Will--
- Immediately deprive 14 million people of Health Care Insurance
- Deplete 15 million more by 2016
- Eliminate protections for "Pre-existing illnesses"
- Seriously curtail Women's Health and Child Care Programs
- Raise Existing Insurance Rates between 5-50%
- Curtail Medicare Benefits $880M
- Curtail Exclusions for "Pre-Existing Conditions"
- Cut NIH Funding (incl. Fogarty)
- Destabilize the Insurance Market

PASSES HR, FAILS SENATE: TRUMP FUMES

Who Opposes, Who Favors Trump Care?

Trump Care = The Absence of Obama Care

Those Opposed
- Medical Groups
- Medical and Professional Health Educational Groups
- Hospital Associations
- Insurance Companies
- Drug, Device Companies
- Research Organizations
- Religious Orders
- Elected Officials, both parties
- Silicon Valley Corporations
- Pope Francis, Dalai Lama

Those In Favor
- Republican Die-Hards
- American Rifle Association
- "America First Patriots"
- Some Business Owners
- Donald Trump
- Donald Trump’s White House
- Donald Trump’s Family
- Rural White Males, Unemployed
- High School Drop-outs
- Patriarchs of the “Old South”
- Vladimir Putin, Oligarchs

“Medicare is Imploding”
Donald J Trump, President
**Why the ACA (“Obama Care”) is “Imploding”**

* Encourage Cheap “Uncle Bob’s Health Care”.
* DHHS Officials Absent From Enrollment Events
* Cut Funding of “Assist Groups” by 40%
* Slash ACA Advertising by 90%
* Slash Tax Credits for ACA Premiums
* Put Info Critical of ACA on You Tube
* Slash Tax Credits for ACA Premiums
* “News Media” (Fox, Blogs) Negative Reports
* Remove Guidance From ACA Website
* Association Health Plans (More “Uncle Bob’s”)
* Link ACA Repeal to Tax, Immigrant Legislation
* Oppose and Limit Medicaid Expansion
* And:

IT COSTS TOO MUCH!

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**Bob’s Health Care, Inc.**

Bob’s Health Care

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**Donald Trump and The Congress**

“Obama Did it, I Broke it, You Fix it.”

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**How Trump Changes Have Been Made**

As Moses Deals with God

So Trump Deals With Congress

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**Trumpian Method of Dealing with Health Care Has Companions**

- NAFTA
- Clean Air Act
- Iran Nuclear Treaty
- Moslems Keep Out
- Be Nice to Nazis
- X Planned Parenthood
- NFL Genuflection
- Build-a-Wall

- Jail Reporters
- Pacific Free Trade
- Puerto Rico Hurricane
- Emoluments
- Personal Travel
The American Care Act Favors the Young, Wealthy and Healthy

The Ideal Targets of Trump Care, minus One

This is Not an Ideal Family for Trump Care Health Benefits

Florence Owens Thompson and Children, Nipomo California, 1932 (Dorothea Lange)

Hospital Discharge Baltimore, Winter, On the Street

(New York Times, January 11, 2018)

Trump Care is Highly Personal

Donald Trump’s approach to health care is fundamentally no different than his approach to immigration, race, building walls, global warming, religion, financial conflict of interest, nepotism in office, financial self-interest and emolument, truth telling, sex, bullying federal officials, women, demeaning the judiciary and shoving fellow heads-of-state out of the way to gain the front of a NATO Meeting group photograph opportunity line.

Hang your head, Jack

The Assyrian came down, like wolves upon the fold, and his cohorts were gleaming in silver and gold. “The Destruction of Sennacharib”, Lord Byron

What Kind of Country Do You Want, USA?

"we must see the world through the eyes of others." Jimmy Carter

"Golden Rule" Norman Rockwell Saturday Evening Post April 3, 1943
What Kind of Health Care Do You Want?

Heroes & Anti-Heroes

Human Rights in Health Care

Is There a Root Cause of the Anomalies of Health Care in the USA?

“Give me your tired, your poor, your huddled masses yearning to be free, the wretched refuse of your teeming shore…”

Emma Lazarus, “The New Colossus,” 1883

AIM HIGH!
How Should Wealth Be Distributed in the USA?

Distribution that 92% of Americans Choose as IDEAL

Actual Distribution of Wealth in USA, 2015
Eisenhower Inst., WAPO

Actual Distribution of Wealth in the U.S.

What Americans THINK The Distribution is

How Do You Think Wealth is Distributed in the USA?

Trump Rescinds Children’s Health Insurance Program
9,000,000 Children Loose Health Care

Republican’s War on Children: One Wealthy Heir for 1000 Kids....
P. Krugman

What are the Societal Effects of the Maldistribution of Wealth?

They are the Erosion of Trust, Security, Social Order, Opportunity, Prosperity, the Rule of Law and the Failure of the State.

Why is the Institution of National Health Care So Damnably Difficult?

Bismark, Germany 1883

Bevan, Britain 1948

B. Roosevelt, USA 1912
Can There Be *Satyagraha* in Health Care?

In the end, with *insistence on truth, the perpetuation of inequity and inequality will be an impossibility.

The Doctor’s Role in Health Care Reformation

- Leadership
- Adaptation
- Innovation
- Moral Direction
- Coordination

The Lawyer’s Role in Health Care Reformation

- Human Rights Foundation
- Equality, Equity, Access, Safety
- The Rule of Law
- Property, Rights

Rules for Surviving HC Reform

Never take your eyes, your hearts and your minds off your patients, your clients or your nation.

Never forget Principles of Human Rights and the Rule of Law. Civilization depends on them.

Never forget where you came from, your moral roots and why you have chosen this course of life.

Hold your head down in sadness, never in shame.

If you do not understand these rules, read them again, then get up and continue the struggle.

And Hope that Your Brothers and Sisters in the USA survive Donald Trump, and Emerge more Humble and More Dedicated than before.

This Presentation was made possible by a generous grant from the Trump Presidential Library.

Mar-A-Lago, Florida
SATURDAY, FEBRUARY 24

PICKNEY | 10:00 am - 11:50 am

DENTAL SESSION V
Moderator: Bruce Seidberg, DDS, MScD, JD, FCLM, DABE, ACLM Past President

• 10:00 AM - 10:25 AM Examining Legislative & Regulatory Framework Aimed at Redesigning Jamaican Oral Health System for Improving Access to Care Dean Irving McKennzie, DDS

• 10:25 AM - 10:50 AM Appellate Decisions Concerning the Doctor - Patient Relationship Laurence Jerrold, DDS, JD, FCLM

• 10:50 AM - 11:15 AM Employee or Independent Contractor: Categorizing Associate Dentists in the Dental Office Jennifer Sullivan, DMD, JD, FCLM

• 11:15 AM - 11:40 AM The Dentist as an Expert Witness Frank Riccio, DDS, JD, FCLM

• 11:40 AM - 11:50 AM Q & A Dental Session V
APPELLATE DECISIONS REGARDING THE DOCTOR PATIENT RELATIONSHIP

American College of Legal Medicine
February 24, 2018 - Charleston, S.C.

Laurence Jerrold DDS, JD, ABO
Chair, Division of Orthodontics
Program Director, Advanced Education Program in Orthodontics
NYU Langone Hospital - Brooklyn
Department of Dental Medicine

THE LEGAL BASICS

1. Medical Malpractice is a type of negligence
2. Negligence is a type of tort
3. A tort is a civil wrong for breaching a duty owed that results in injury to another
4. A heightened duty can be imposed by law upon finding the existence of a special relationship
5. Special relationships are
   - Priest – Penitent
   - Teacher/School – Student
   - Innkeeper – Patron
   - Shopkeeper – Invitee
   - Doctor – Patient

FORMING THE DOCTOR PATIENT RELATIONSHIP

NO DUTY OWED W/O AN ESTABLISHED RELATIONSHIP
The existence of a duty of care is dependent on the existence of a doctor patient relationship
- Irvin v. Smith 31 P3d 934 (Kan. 2001)

NO REQUIREMENT TO TREAT
In obtaining the state’s license (permission) to practice medicine, the state does not require, and the licensee does not engage, that he will practice at all or on other terms than he may choose to accept.
- Hurley v. Eddingfield, Sup. Ct. Ind., 156 Ind. 416 (1901)

MUTUAL CONSENT
A physician patient relationship arises out of a consensual contract of employment, express or implied, under which the patient seeks medical assistance and the physician agrees to render treatment
- McKinney v. Schlatter 692 NE2d 1045 (Ohio 1995)

ACTIVE v. PASSIVE
…consent to a physician patient relationship may be found only where a physician has done something, such as actively participate in the patient’s diagnosis and treatment, that supports the implication of consenting to a doctor patient relationship.

FORMING THE DOCTOR PATIENT RELATIONSHIP

I GOT YOU BABE
- Sonny & Cher

THE ESSENCE OF THE DOCTOR PATIENT RELATIONSHIP:
A doctor and patient enter into a simple contract, the patient hoping that he will be cured and the doctor optimistically assuming that he will be compensated.
- Hammonds v Aetna Casualty 243 F Supp 793 (1965)

THE PROBLEM:
social consults, curbside opinions, internet communiques

THE GENERAL RULE:
The minute you offer a professional opinion on which you expect the patient to rely and upon which the patient acts, a doctor patient relationship is established.
- Osborne v. Frazier 425 SW2d 768 (1968)

IMPLIED DUTIES OWED BY THE DOCTOR TO THE PATIENT

How Much Do I Owe You
- Paul Overstreet

- Dr. & staff properly licensed
- Keep current thru cont. ed
- Obtain Consent & Info. Con.
- Charge reasonable fees
- Keep pt. informed of progress
- Complete care in a timely manner
- Maintain pt. confidentiality
- Comply with all Rules & Regs
- Employ, train & supervise personnel
- Do not experiment
- Avail for emerg – no abandonment
- Do not exceed scope of practice
- Don’t do procedures if untrained
- Take and keep accurate records
- Make appropriate referrals
- Abide by Code of Ethics

IMPLIED DUTIES OWED BY THE PATIENT TO THE DOCTOR

Right Back At You
- The Roys

1. All instructions will be followed
2. Will not dictate inappropriate treatment
3. Appointments will be kept
4. Fees for services rendered will be paid
5. Pts will be truthful regarding all valid clinical and administrative inquiries
6. Pts will conform to accepted modes of behavior
PRACTITIONER AUTONOMY

Do I have to treat everyone who wants treatment?]

Professionals do not owe a duty to exercise their particular talents, knowledge, and skill on behalf of every person they encounter in the course of the day. As is true of all callings, physicians are not obligated to practice their profession or render services to everyone who asks. It is only with the physician's consent, whether express or implied, that a doctor-patient relationship comes into being.

Physicians are not public servants who are bound to serve all who seek them, as are innkeepers, common carriers, and the like.

PATIENT AUTONOMY VS. PRACTITIONER AUTONOMY

If a patient selects a course of treatment, even from among reasonable alternatives, and the physician regards it as inappropriate or disagreeable, the physician is free to refuse to participate and to withdraw from the case upon providing reasonable assurance that the patient's condition will continue, and in such circumstances, there can be no liability for refusal.

TERMINATING THE DOCTOR PATIENT RELATIONSHIP

Both parties agree to end it
Pt is cured
Dr or pt dies
Pt unilaterally terminates by act or statement
Dr wants to unilaterally terminate

Inform patient that treatment is completed especially in discovery jurisdictions.

Illegal Discrimination
- Race, religion, gender, age, Country of national origin, Handicapping condition, Sexual orientation, weight, etc.

Legal Discrimination
- Don't provide service requested, Don't participate in pt's 3rd party plan, Inability to pay for treatment, Bad vibes, poor chemistry

Lack of SKEEE results in a duty to refer

"If a practitioner discovers, or should know or discover, that the patient's ailment is beyond his knowledge or technical skill, or ability or capacity to treat with a likelihood of reasonable success, he is under a duty to disclose the situation to his patient, or advise him of the necessity of other or different treatment.

TERMINATING THE DOCTOR PATIENT RELATIONSHIP

Both parties agree to end it
Pt is cured
Dr or pt dies
Pt unilaterally terminates by act or statement
Dr wants to unilaterally terminate

The patient is cured
- Once a physician has taken charge of a case, that relationship continues until the medical situation becomes one in which the physician's services are no longer needed.
TERMINATING THE DOCTOR PATIENT RELATIONSHIP

Dead and Gone
- Justin Timberlake

Both parties agree to end it
Pt is cured
Dr or pt dies
Pt unilaterally terminates by act or statement
Dr wants to unilaterally terminate

Terminating the Doctor Patient Relationship

The 3 D’s

driver

dies: custodial records obligations remain

disabled: coverage obligations remain

don: gone with practice: coverage & custodial records obligations remain

Where defendant... was obliged to leave the vicinity because of his own ill health, but left plaintiff in the charge of another physician who continued the treatment, it was held that there was no ground for complaint of abandonment... because of the change in doctors.

- Warwick v Bliss, 195 NW 501, App 216 NW 85 (S.D. 1923)

I'm Outta Here
- Shania Twain

Both parties agree to end it
Pt is cured
Dr or pt dies
Pt unilaterally terminates by act or statement
Dr wants to unilaterally terminate

The patient unilaterally terminates by act or statement

Once a physician has taken charge of a case, that relationship continues until the physician's dismissal by the patient...

- Glenn v Carlstrom, 556 NW2d 800 (Iowa, 1996)

Nuts
- Marceline

Pt is cured
Dr or pt dies
Both parties agree to end it
Pt unilaterally terminates by act or statement
Dr wants to unilaterally terminate

The doctor wants to unilaterally terminate

The physician has a definite right to withdraw from the case provided he gives the patient reasonable notice so as to enable him to secure other medical attendance. Such a withdrawal does not constitute an abandonment...

- Tierney v University of Michigan Regents, Docket # 239860, Aug 5, 2003
HOW TO DO IT

Step By Step
- The Greats

- Provide both notice & basis
- Inform of need for cont. professional care
- Provide adequate time for substituted care
- Help obtain substituted care if necessary
- What can I say about pf as is?
- Should I remove appliances or temps?
- Make records available to subsequent dr or pt
- Be available for emergency care, referrals, and consultations only for a reasonable period of time
- Should I take patients back after dismissal?

NOTICE

Let Me Know
- Tamar Braxton

Certified Return Receipt Requested
Certificate of Mailing
Copies / Scans of above in patient record
Copy / Scan of dismissal letter in patient record

BASIS

Tell Me Why
- The Beatles

1- Not following clinical instructions/directions
2- Inappropriately trying to dictate treatment
3- Not keeping appointments as scheduled
4- Not paying for services rendered
5- Being untruthful regarding their health histories and other administrative inquiries
6- Inability to conform to accepted modes of behavior

BASIS:

NOT FOLLOWING INSTRUCTIONS

You Won’t Listen
- B. B. King

… if a physician is ever justified in withdrawing when it is apparent that to do so must result in injury, it can only be where the patient obstinately refuses to follow the treatment prescribed.
- Urrutia v Patino 297 SW 512, App 10 SW2d 582 (Tex. 1927)

Alienate:

INAPPROPRIATELY DICTATING TREATMENT

Don’t Tell Me What To Do
- Pam Tillis

…the doctor’s conscience and professional oath must also be respected. In the present case, the patient voluntarily submitted himself to and insisted upon medical care. Simultaneously he sought to dictate to treating physicians a course of treatment amounting to medical malpractice. To require these doctors to ignore the mandates of their own conscience, even in the name of free religious exercise, cannot be justified under these circumstances. The patient may knowingly decline treatment, but he may not demand mistreatment.
- United States v George 239 F.Supp. 192 (D.Conn. 1965)

BASIS:

NOT KEEPING SCHEDULED APPOINTMENTS

Always Late
- Lefty Frizzel

If a patient fails to come to the office of the physician or surgeon whom he employs and from whom he has received the care and treatment to which he is entitled, he is not entitled to maintain an action against the physician, because it is his own default and mistake.
- United States v Atchison 129 F. 704 (C.C.A. 9th 1896)

Where a doctor instructed a patient to return in 2 weeks but patient failed to do so, patient could not be heard to complain that doctor abandoned her as a patient.
- Roberts v Wood 206 F.Supp 579 (S.D. Ala. 1962)
**BASIS: NOT PAYING FOR SERVICES RENDERED**

*For the Love of Money*  
- The O'Jays

A physician is *entitled to protect his ability to generate an income* and need not accept a prospective patient who cannot pay the established fee charged all patients.  
- Goldman v Ambro 512 N.Y.S.2d 636 (1987)

What if you have already started bridge or taken out 4 bicuspids?  
Can still unilaterally terminate except in cases where pt is in extremis.

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**BASIS: NOT PAYING FOR SERVICES RENDERED**

*Money, Money, Money*  
- ABBA

Abandonment was not established by patient who had gastric bypass operation and suffered abscesses afterwards for which she sought treatment from physician whose bookkeeper told her she was no longer a patient because she had not paid her bill; physician had seen patient 11 times following surgery and advised her how to treat her abscesses, so that patient was not at critical stage of treatment when physician terminated his care for her.  
- Surgical Consultants, PC v Ball  447 NW2d 676 (Iowa Ct App, 1989)

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**BASIS: VERACITY REGARDING VALID CLINICAL AND ADMINISTRATIVE INQUIRIES**

*Don't Lie to Me*  
- The Rolling Stones

... a patient has a duty to respond accurately and truthfully to all questions posed to him ...  
- Axelrad v Jackson 142 SW3d 418 (Tx App, 2004)

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**BASIS: INABILITY TO CONFORM TO ACCEPTED MODES OF BEHAVIOR**

*Out of Control*  
- U2

Kidney specialist and clinic with which he was associated had no legal obligation to continue providing dialysis treatment to an unruly and uncooperative patient, where patient was given sufficient notice that treatment would be terminated and was provided with a list of other dialysis providers in the area.  
- Payton v Weaver, 182 Cal. Rptr. 225 (1st Dist. 1982)

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**HOW TO DO IT**

- Provide both notice & basis
- Inform of need for cont. professional care
- Provide adequate time for substituted care
- Help obtain substituted care if necessary
- What can I say about pt if asked?
- Should I remove appliances or temps?
- Make records avail to subsequent dr or pt
- Be available for emergency care, referrals, and consultations only for a reasonable period of time
- Should I take patients back after dismissal?

---

**INFORM OF NEED FOR CONTINUED PROFESSIONAL CARE**

*Stay with me*  
- Sam Smith

...abandonment generally means the unilateral severance of a professional relationship between doctor and patient, without reasonable notice, and at a time when there is still the necessity of continuing medical attention.  
HOW TO DO IT

- Provide both notice & basis
- Inform of need for cont. professional care
- Provide adequate time for substituted care
- Make records avail to subsequent dr or pt
- Be available for emergency care, referrals, and consultations only for a reasonable period of time
- Should I take patients back after dismissal?

PROVIDE ADEQUATE TIME FOR SUBSTITUTED CARE

Time

-Pink Floyd

Where there was nothing to show that patient could not have received adequate medical care within reasonable time after defendant left case, no cause of action would lie.

- Carroll v Griffin, 101 SE2d 764 (Ga. App. 1958)

What is a reasonable period of time and who determines that?

- Expert testimony was required to establish the appropriate standard of care for patient’s abandonment claim, so that a trier of fact could determine whether the conduct of patient’s primary physician in visiting patient in 9 day intervals, and in scheduling knee surgery 1 month after patient was admitted to the hospital, met the established standard of care


PROVIDE ADEQUATE TIME FOR SUBSTITUTED CARE

Substitution

-Silversun Pickups

Do I have to help obtain substituted care if asked?

Where a patient is not in need of immediate medical attention, supplying the patient with a list of substitute physicians to replace the attending physician is a reasonable means of severing the professional relationship.

- Miller v Greater Southeast Community Hosp., 508 A2d 927 (D.C. 1986)

HOW TO DO IT

OTHER CONSIDERATIONS

- What can I say about pt if asked by new doctor?
  - Don’t interfere w/ their ability to obtain substituted care
  - Should I remove appliances or temps?
  - Don’t interfere w/ their ability to obtain substituted care
  - Make records avail to subsequent dr or pt
  - Don’t interfere w/ their ability to obtain substituted care

- Be available only for emergency care, referrals, and consultations for a reasonable period of time
  - Not doing so is cause for a claim of abandonment
  - Should I take patients back after dismissal?
  - Show me the money

DISCONTINUING TREATMENT vs. TERMINATING CARE

It’s Over

-Roy Orbison

What is the difference?

Discontinuing treatment:
Utilizes a risk benefit ratio for continued treatment
Utilizes the best interest of the patient test
Must be based on the sound medical judgment of the dr
Treatment is still ongoing, the dr-pt relationship still exists

Terminating care:
Severing of the doctor patient relationship

ABANDONMENT

-Blondie

- Refusing to see a patient before treatment is completed without a valid legal basis

- Not being available to provide
  - Follow up care
  - Emergency care or coverage
  - Substitute temporary coverage

- Constructive abandonment
ABANDONMENT:
Refusing to see a patient before treatment is completed without a valid legal basis

*I Don’t Want You* Anymore ~ Jessica Lowndes

Abandonment of a case by a physician without sufficient notice or adequate excuse is a dereliction of duty, and if injury results therefore, the physician may be held liable in damages.

- 57 A.L.R.2d 432

ABANDONMENT:
NOT BEING AVAILABLE TO PROVIDE:

Follow up care: A dentist is under the duty not only to use the requisite care and skill to perform a particular operation, but also to give such follow up care to the patient as the necessity of the case demands.

- Specht v Gaines, 16 SE2d 507 (Ga. App. 1941)

Emergency care or coverage: In demonstrating that a physician abandoned his or her patient, a plaintiff must show that: (1) the physician became unavailable to treat the patient at a time when he knew the patient was at a critical stage of treatment, and (2) the physician either failed to provide sufficient notice to enable the patient to secure another physician or failed to arrange for a competent physician to care for the patient in his or her absence.

- King v Zakaria, 634 SE2d 444 (Ga. Ct. App. 2006)

Substitute temporary coverage: Physician is under duty to give patient all necessary and continued attention as long as case requires it while making suitable arrangements for attendance of another physician.

- Johnson v Vaughn, 370 SW2d 591 (Ky. 1963)

ABANDONMENT:
CONSTRUCTIVE ABANDONMENT

Slow Down ~ Selena Gomez

- No more appointments until they bring their account up to date
- Slow down treatment until they bring their account up to date

Active treatment should never be impacted for non clinical reasons

The standard of care "very clearly" requires a dentist to continue to see an orthodontic patient even though there is an outstanding balance on his or her account. It requires a dentist to continue treating a patient who is not making payments unless and until the dentist (1) sends the patient a letter terminating the dentist-patient relationship and (2) provides the patient with an opportunity to find another orthodontist.


ABANDONMENT:
The Ultimate Question to Be Asked

Questions ~ Emmanuel Hudson

Will the patient be harmed or their future care compromised if the doctor patient relationship is severed?

THE RIGHT WAY TO GET RID OF THE WRONG PATIENT

Breaking up is hard to do ~ Neil Sedaka

So Long, Farewell ~ Rogers & Hammerstein

Hit the Road Jack ~ Ray Charles

Freedom ~ Richie Havens

Employee or Independent Contractor: Categorizing Associate Dentists in the Dental Office

Jennifer Sullivan, DMD, JD, FCLM
INDEPENDENT CONTRACTOR VS. EMPLOYEE ASSOCIATE DENTIST

Benefits to treating an Associate dentist as an Employee

- Can control the result of the work, and the means and method that the Associate Dentist uses to accomplish their job. “How”
Benefits to treating an Associate dentist as an Employee

- Can control the result of the work, and the means and method that the Associate Dentist uses to accomplish their job. “How”
- Can dictate hours & days of work, and can control other various scheduling issues.

Benefits to treating an Associate dentist as an Employee

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- Can dictate hours & days of work, and can control other various scheduling issues.
- Can require Associate Dentist to use certain supply houses or dental labs to keep costs of the practice down.

Benefits to treating an Associate dentist as an Employee

- Can control the result of the work, and the means and method that the Associate Dentist uses to accomplish their job. “How”
- Can dictate hours & days of work, and can control other various scheduling issues.
- Can require Associate Dentist to use certain supply houses or dental labs to keep costs of the practice down.
- The Associate Dentist can be discharged just as any other employee in the practice. (At Will in Pennsylvania)

Benefits to treating an Associate dentist as an Independent Contractor

- Not responsible for withholding or payment of income taxes.

Benefits to treating an Associate dentist as an Independent Contractor

- Not responsible for withholding or payment of income taxes.
- Not responsible for withholding or payment of FICA (Medicare & social security) or FUTA (unemployment).
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- Not included in Employee type benefits such as paid vacation, paid holidays, medical benefits.

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- Not included in Employee type benefits such as paid vacation, paid holidays, medical benefits.
- Not include in Pension or Profit Sharing Plan.

WHO CARES?

The IRS reports a $15 billion payroll “tax gap” per year. Unpaid FICA and FUTA taxes make up $14 billion of the deficit.

Douglas W. Chames, IRS takes Aim at Employment Tax Returns (Forms 941) (July 22, 2009)

$1.6 billion of lost taxes were found to be from misclassified workers in 2006.

According to the U.S. Department of Labor’s Wage and Hour Division, in 2015 alone, $74 million in back wages for over 102,000 workers was collected due to mislabeling workers.

Information obtained from “PA and DOI Collaborate in Employee Misclassification Enforcement Efforts” found at https://www.employmentlawmatters.net/2016

MICROSOFT CASES

Vizcaino v. Microsoft Corp, 97 F.3d. 1187 (9th Cir. 1996)

Vizcaino v. Microsoft Corp, 120 F.3d. 1006 (9th Cir. 1997)

Please explain why you feel that the Associate Dentist should have been classified as an Independent Contractor as opposed to an employee (using the 20 common-law factors).
The IRS 20 Factor test, which is the common law test, is used to evaluate the extent of control that an owner dentist has over an associate dentist.

20 FACTOR TEST

1. **INSTRUCTIONS**: The Contractor is not required to follow any instruction of when, where and how to perform his work.

2. **TRAINING**: The Contractor does not receive any training from Owner Dentist, nor is he reimbursed for any continuing education fees or seminars.

3. **ORDER OF SEQUENCE SET**: The Contractor is not required to follow any protocol or consult with any other dentist regarding methods, means, or sequence.

4. **SET HOURS OF WORK**: The Contractor makes his own schedule.
5. **PAYMENT BY HOUR, WEEK OR MONTH**: Contractor is not paid by the hour, but rather by \% of collections, less 50\% of lab fees.

   a) He is not given any guaranteed income.
   
   b) He will continue to receive payment for services even after he no longer actively performs services.
   
   c) He is not afforded any sick leave, vacation pay, pension or profit sharing benefits, or any other employee benefits.
   
   d) No Employee type deductions are taken from his pay, such as FICA, FUTA, withholding taxes.
   
   e) He receives a 1099 at year end.
6. **PAYMENT OF BUSINESS OR TRAVELING EXPENSES:** Contractor pays at his own expense:

   a) Malpractice Insurance & Disability Insurance

   b) License and Permit Fees

   c) Continuing Education

   d) Travel & Entertainment

   e) Dues & Subscriptions
7. WORKING ON OWNER DENTIST’S PREMISES: Dentistry is not a profession that lends itself to portability. It is necessary for a dentist to present to an office in order to provide adequate services.

8. FURNISHING OF TOOLS & MATERIALS: Although Contractor is provided with a dental chair, X-ray unit and some other equipment that is impractical to transport, the Contractor provides for himself, other essential equipment.

9. INTEGRATION: The services provided by the Contractor are not necessary to the overall business operations of Owner Dentist. The Contractor has his own patient base and chooses when he will be available to see them.

10. RIGHT TO DISCHARGE: Contractor cannot be fired at will as would be an option with an employer-employee relationship.

11. RIGHT TO TERMINATE: Contractor can terminate his relationship with Owner Dentist ONLY pursuant to the terms and conditions of the agreement.

12. CONTINUING RELATIONSHIP: The Independent Contractor Agreement should not be deemed automatically renewable and/or reoccurring. Admittedly, there is an extended contractual term, but it is a contractual term, non the less.
13. **MAKING SERVICES AVAILABLE TO THE PUBLIC**: Contractor makes his services available to the general public on a regular and consistent basis, which is the very nature of the practice of dentistry.

14. **SERVICES RENDERED PERSONALLY**: Contractor has at his expense, staff personnel that he may delegate responsibility, for which the services they provide he will receive payment. He has the freedom to delegate when deemed appropriate.

15. **HIRING, SUPERVISING, AND PAYING ASSISTANTS**: By means of the retained percentage of collections by Owner Dentist, the contractor is reimbursing Owner Dentist for use of the Owner Dentist’s employees.

16. **REALIZING PROFIT OR LOSS**: Contractor bears the risk of loss and/or realizes profitability based solely on the compensation received from his patients, which is a direct result of his treatment decisions and performance under his sole discretion and direction.

17. **SIGNIFICANT INVESTMENT**: A percentage of the fees retained by Owner Dentist acts as payment for the use and improvement of the facility, which serves as an investment.

18. **ORAL OR WRITTEN REPORTS**: Contractor is not required to submit any written reports and is not required to verbally consult with or report to anyone.
19. **DEVOTION OF TIME TO OWNER DENTIST:** Contractor is not required to devote his full time to Owner Dentist. He is in charge of his schedule without restraints.

20. **WORKING MORE THAN ONE FIRM AT A TIME:** It is unknown to Owner Dentist whether Contractor is performing services anywhere other than Owner Dentist. It is known that Contractor has the ability and opportunity to perform services elsewhere if he so desires.

**SECTION 530 OF THE REVENUE ACT OF 1978 PROVIDES RELIEF FOR BUSINESS OWNERS REGARDLESS OF THE WORKER’S ACTUAL STATUS UNDER THE COMMON-LAW TEST**

Present Law and Background Relating to Worker Classification for Federal Tax Purposes, Joint Committee on Taxation, May 7, 2007, JCC-26-07, Pg 5

**SECTION 530 REQUIREMENTS FOR RELIEF**

- “SIMILAR WORKER CONSISTENCY REQUIREMENT” THE BUSINESS OWNER (OR PREDECESSOR) MUST NOT HAVE TREATED ANY WORKER HOLDING A SUBSTANTIALLY SIMILAR POSITION AS AN EMPLOYEE FOR PURPOSES OF EMPLOYMENT TAXES.
- THE OWNER FILED ALL TAX FORMS CONSISTENT WITH NONEMPLOYEE STATUS. FORM 1099’S RATHER THAN FORM W-2’S.
- THE OWNER HAD A “REASONABLE BASIS” FOR ITS CLASSIFICATION OF WORKER AS AN INDEPENDENT CONTRACTOR.

**WHAT Qualifies as a “Reasonable Basis” FOR CONTRACTOR CLASSIFICATION UNDER SECTION 530?**

- JUDICIAL PRECEDENT, PUBLISHED RULINGS, OR IRS TECHNICAL ADVICE OR LETTER RULING TO THE TAXPAYER.
- PAST IRS EMPLOYMENT TAX AUDIT IN WHICH NO ASSESSMENT WAS DUE TO IMPROPER CLASSIFICATION OF WORKERS HOLDING SUBSTANTIALLY SIMILAR POSITIONS.
- A RECOGNIZED LONG-STANDING PRACTICE IN THE INDUSTRY TO TREAT WORKER AS AN INDEPENDENT CONTRACTOR.
WHY WOULD ANYONE THINK THAT AN ASSOCIATE DENTIST COULD, SHOULD, OR WOULD BE TREATED AS AN INDEPENDENT CONTRACTOR RATHER THAN AN EMPLOYEE?

CODE OF FEDERAL REGULATIONS (CFR)
26 CFR 31.3121(d)-1 (c) (2)
“....Individuals such as physicians, lawyers, dentists, veterinarians, construction contractors, public stenographers, and auctioneers, engaged in the pursuit of an independent trade, business, or profession, in which they offer their services to the public, are independent contractors and not employees.”

BEHAVIOR CONTROL
- INSTRUCTIONS
- TRAINING

FINANCIAL CONTROL
- SIGNIFICANT INVESTMENT
- UNREIMBURSED EXPENSES
- SERVICES AVAILABLE TO PUBLIC
- METHOD OF PAYMENT
- OPPORTUNITY FOR PROFIT AND LOSS

RELATIONSHIP TO PARTIES
- EMPLOYEE BENEFITS
- DISCHARGE/TERMINATION
- REGULAR BUSINESS ACTIVITY

In 1997 the IRS condensed the 20 Factor Test into an 11 Factor Test
SATURDAY, FEBRUARY 24

GOLD | 11:50 am - 1:15 pm

CYRIL WECHT LUNCHEON
Invited Presenter: F. Lee Bailey, JD
THE MAKING OF A WITNESS

F. Lee Bailey, JD

[NOTE:*** this document is not in conventional outline form, since all of my speeches are extemporaneous, grounded in habitual knowledge, and not to any extent prompted by outlines, teleprompters, crib notes, or other supportive devices. Therefore, this submission is in narrative form and will cover the topics to be discussed during the lecture. Hopefully, this will satisfy CLE requirements.]

Although the average person is quite at ease interacting with others in casual conversation, he or she is normally less than comfortable when called upon to address a group – particularly a group of strangers – or to give evidence from the witness stand in front of a judge, jury, and a public audience. This sort of apprehension is particularly true of those who – having been sworn in a public courtroom – are quite worried that opposing counsel will make them look foolish or frustrate their ability to deliver what they perceive as the truth. As to those people who come to the witness stand with a purpose to deceive, their worries are more apt to derive from the survival instinct which is a basic element of all of our personalities, whether we be saints or sociopaths.

The shortest path to witness stardom is most often that available to stable personalities who have a healthy attitude toward life and a pleasant demeanor. Such people tend to be friendly, and optimistic. They are the sort that acquaintances usually describe as a “nice person”. One’s first impression of people of this sort is apt to be, “I’d like to have that guy out for a drink,” or “I think it would be nice to take this woman home to dinner and introduce her to my family”.

While these people are generally easy to work with in the various stages of preparing a layman to become a credible witness, there are many who have difficulties of one kind or another in making the transition from cocktail party guest to a credible witness. This is an undertaking which requires a patient and experienced lawyer, first to diminish the sense of stage fright which troubles many
THE MAKING OF A WITNESS

F. Lee Bailey, JD

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The shortest path to witness stardom is most often that available to stable personalities who have a healthy attitude toward life and a pleasant demeanor. Such people tend to be friendly, and optimistic. They are the sort that acquaintances usually describe as a “nice person”. One’s first impression of people of this sort is apt to be, “I’d like to have that guy out for a drink,” or “I think it would be nice to take this woman home to dinner and introduce her to my family”.

While these people are generally easy to work with in the various stages of preparing a layman to become a credible witness, there are many who have difficulties of one kind or another in making the transition from cocktail party guest to a credible witness. This is an undertaking which requires a patient and experienced lawyer, first to diminish the sense of stage fright which troubles many
prospective witnesses, and second to advise on the book of rules that witnesses must follow if they are to be deemed believable. Among the many kinds of advice which lawyers might give in a specific case, here are some guidelines that should develop noticeable improvements in a witness’ presentation:

First, the witness must be convinced that there is nothing but grief to be found in any attitude which evinces hostility, anger, abruptness, smirking, raising one’s voice, using foul language or even the mildest kind or any remark or gesture which smacks of derision. Prospective witnesses must be made to understand that in order to be successful they must walk a bright line, because they are in need of being thought to be credible by even the most difficult personalities in the jury box. Many witnesses – especially those who have gone through life as a “wise guy” – enjoy being flippant and sometimes rude, simply for the gratification they experience when annoying others. Such people are a very large problem for the trial lawyers who must call them to the stand, and need to spend some time with them in the woodshed of discipline - before ever being paraded before the public in open court - is absolutely essential.

As to all witnesses it is a good idea to spend some little time explaining the legal process and the roles that are played by its various operators: the lawyers, the judge, the jurors, and the witnesses and other evidence. It is important that witnesses – particularly those who are parties to the lawsuit – further understand that the appearance they make will be a one-stop opportunity to drive the case in the direction of a successful conclusion. Unlike the dramas which are crafted in Hollywood, retakes, cutting, pasting, and editing are off-limits. With each question asked and each answer given the moment is etched in granite, called the transcript. There are no buttons on a keyboard which will allow the witness to "UNDO" or “REBOOT”. Therefore, much as in controlling an aircraft in flight, it is necessary that everything be done correctly on the first try. Although this set of circumstances might be readily apparent to many, even among the uninitiated, at least an equal number are unaware of the gravity of their undertaking when they give evidence.
Whether your prospective witness falls into the “nice guy” category, or sports a generically antagonistic attitude toward life and other people, the basic mechanics of adducing testimonial evidence from the witness stand need to be reviewed with some care. Foremost, this is a new world fraught with intimidating aspects, and some confidence building is warranted if the witness is of the difficult kind: that confidence building must also include the most stringent language befitting the circumstances. In cases where a witness is constantly resentful and aggressive, it sometimes becomes necessary to get out the leather strop and lay down the rules in very clear terms. I have in the past used what I call a “shock treatment” such as: “If despite all of our hard work in attempting to make you an effective witness, you persist in giving me less than direct and responsive answers, or you make facial expressions which are inappropriate to the gravity of this case, I will not continue to allow you to damage the case which is important to both of us. I will simply sit down, terminate the direct examination, and exercise what I believe to be damage control.

“However, that will leave you exposed to cross-examination by opposing counsel who will have observed your very unappealing performance while congratulating himself that good fortune has come his way in such a juicy package. If you did that bad a job on direct examination, the chances are that even a lawyer of mediocre skills and experience will annihilate you before your testimony is concluded. No matter what you might think you have accomplished in the past, this is not line of your work. Either follow my advice very carefully, or you will lose your case.”

In helping inexperienced witnesses to find their way through the thicket of court testimony, some thoughtful instruction upon the hazards of cross-examination is absolutely necessary. Juries have little sympathy for those who give poor testimonial performances, not because they were being overmatched by some slick lawyer but because they were not very nice people to begin, with and cannot help show it when faced with adversity. The most important rules that a witness must follow in order to successfully fend off the slings and arrows of outrageous questions include the following:
First, the client or witness must be persuaded that the worst mistake he or she could possibly make – even though it is a very natural tendency – is to look at his or her lawyer immediately after the cross-examiner poses a question. This will inevitably give rise to an inference that the witness is looking to the lawyer for a hint of some sort, a transgression akin to copying from the exam paper of the person sitting next to you in the minds of many. It must be drilled into the conscious and subconscious minds of the witness inexorably, for such conduct can irretrievably damage an otherwise meritorious case. (If, despite the most dire of warnings, the witness persists in looking at counsel after a question is asked and before the answer is given, the only remedy available is to adopt an absolutely frozen visage at once, giving the witness no comfort whatsoever. Any movement of counsel’s head can easily be interpreted as the signal that the jury suspects was being sought, and simply multiplies the damage.

Second, the client must learn to give a reasonably responsive answer to each question, and to keep the answer as tight as is possible. In other words, the natural tendency of one engaged in ordinary conversation is to explain what is going on in the mind of the responder. This will be viewed by the court as an attempt to “volunteer” information, and may result in a cursory instruction to simply answer the question and no more. After this happens on several occasions, the witness is likely to be perceived as argumentative, and therefore not the kind of person in whom great trust should be reposed.

Third, the prospective witness must be mightily convinced that answers which are in fact argumentative – an attempt to spar with the cross-examiner – are life-threatening and therefore absolutely verboten. Smartass, embellished, attempts to “get even” with the “mean questioner” almost certainly portend that at the end of the day, the witness will have done the case more harm than good, and perhaps been a principal cause of the verdict going south. If the witness is also a party, the risk that this will occur multiplies exponentially.

Arduous though the task may be to successfully prepare a witness to provide a credible performance while giving his or her evidence, even with difficult personalities, a great deal can be accomplished. I have occasionally
SATURDAY, FEBRUARY 24

COLONIAL  |  1:30 pm - 3:30 pm

BREAKOUT SESSION V: Credentialing, Privileging and Peer Review
Moderator: Cyril Wecht, MD, JD, FCLM, DABE, Founder, ACLM Past President

• 1:30 PM - 1:55 PM Process of Credentialing and Privileging Healthcare Providers
  Victoria Green, MD, JD, FLCM

• 1:55 PM - 2:20 PM Negligent Credentialing and Corporate Responsibility/Liability
  John Busowski, MD, JD, FCLM

• 2:20 PM - 2:45 PM Peer Review: Confidentiality; Discoverability; Admissibility; and Privilege
  Marvin H. Firestone MD JD FCLM

• 2:45 PM - 3:15 PM Telemedicine Credentialing of Health Care Providers
  Michael Brooks, MD, JD, FCLM

• 3:15 PM - 3:30 PM Q&A Breakout Session V
Credentialing & Privileging

Conflict of Interest

- I have no conflict to declare with respect to this presentation.

Objectives

Upon completion of this presentation, the participant will:

1. Understand the duties and responsibilities of Hospital Governing Body vis-à-vis credentialing and privileging of medical staff and other providers.
2. Know the “Red Flags” that trigger investigation during review of applications for appointment to the medical staff.

Credentialing & Privileging of

1. Physicians – MD’s and DO’s
2. Dentists & others Doctorate
3. Non-Physician Practitioners (NPP):
   - Former terms:
     - Midlevel Practitioner or
     - Allied Health Practitioner

Non-Physician Practitioners

- Includes, but not limited to:
  1. Nurse Practitioner
  2. Physician Assistant
  3. Clinical Nurse Specialist
  4. Certified Nurse Anesthesiologist
  5. Anesthesiologist Assistant
  6. Certified Nurse Midwife
  7. Clinical Social Worker
  8. Clinical Psychologist
Credentialing requires:
1. Educational and training background
2. Work history
3. Current licensure
4. References, and
5. Ability to perform the services / privileges requested.

Privileging Requires:
- Listing of Specific patient care diagnostic or therapeutic procedures
- Thorough evaluation of the practitioner’s competency by peers who prepare recommendations to the executive committee and the governing body.
- Only the Governing Body has the authority to grant:
  1) Clinical privileges and/or
  2) Medical Staff membership

Primary Source Verification (PSV)
- The verification of information directly from the original source.
- Primary source verification is required to verify the accuracy of education, training, licensure, exams, and board certification information.

Appointment and Re-appointment
A. Initial Appointment to the medical staff.
   - No longer than 2 years.
B. Re-appointment(s) – Appraisal to determine current competence
   - Purpose of appraisal: To determine suitability of continuing the medical staff membership and/or clinical privileges.
   - Reappraisal at least every 24 months.

“Complete” Application
**Elements of a Complete Application:**
1) All questions on application answered;
2) All requested documents provided;
3) Three (3) or more letters of recommendation received;
4) Information has undergone Primary Source Verification;
5) Fees have been paid.

The Governing Body
1. Legally responsible for care provided.
2. Must determine categories of practitioners
3. Must appoint members of the medical staff
4. Must approve medical staff membership
5. Make final decisions regarding length of appointment and granting of privileges
6. Determines whether to grant, deny etc... medical staff membership.
Who should receive regular training in credentialing?

1. Medical Staff Office personnel
2. Medical Staff Department Chairs
3. Medical Staff Officers
4. Members of the:
   - Medical Executive Committee
   - Peer Review Credentials Committee
5. Members of the Governing Body

All individuals involved in credentialing must be familiar with institutional policies.

1. Hospital Bylaws, Rules & Regs, and medical staff policies (Not Static)
2. **Understand** Bylaws and policies
3. Consistent application of Bylaws and policies; and
4. Update Bylaws and policies

Audit Bylaws to determine gaps

1. Ensure Bylaws are current and consistent with State, Federal, and accreditation requirements
2. Are the Medical Staff Bylaws consistent with Governing Body Bylaws?
3. Are members of the medical staff required to comply with “Code of Conduct/Disruptive Behavior” policy?

Requirement to report to the Medical Staff

A. Within 5 days –
   1. Insurance coverage reduced below required limits
   2. Felony convictions
   3. Medicare/Medicaid sanctions
   4. Loss of privileges
   5. Loss of license
B. Malpractice suits within established timelines

On-call requirements

A. Expected response time
B. Responsibility to identify the back-up physician
   1) Person with same privileges
   2) Person agreed to serve as back-up for the dates specified
C. Physician responsibility to provide post-ER follow-up treatment

Medical record documentation expectations

A. History & Physical within 30 days
B. Written Updated Examination to the History & Physical:
   - Within 24 hours of admission
   - Prior to anesthesia
C. Discharge Summary
D. Authentication of verbal orders
Requirements to Query the NPDB

A. When Medical Staff will Query:
   1) Initial Appointment
   2) Request for NEW Privileges
   3) Re-appointment

B. Whom the Medical Staff will Query:
   1) Physicians and Dentists
   2) Non-physician practitioners
   3) Locum Tenens
   4) Requests for Temporary Privileges

What the Medical Staff will Report to NPDB

- Denials or restrictions of clinical privileges for more than 30 days
- that result from professional review actions relating to the practitioner’s professional competence or professional conduct
- that adversely affects, or could adversely affect, the health or welfare of a patient.

The Application Process

- Some Hospitals have a Pre-Application Process.

  Purpose:
  1. To screen applicants for basic eligibility.
  2. Denial of a Pre-Application is NOT reportable to NPDB.

Pre-Application Packet

Medical Staff with Legal Counsel Determine Materials:

1. Eligibility Requirements to Receive Full Application
2. Applicant to sign an “Absolute Release and Waiver of Liability” Form
3. Affiliation with Competitor

Application Materials

1. State Mandated Application form
2. Hospital–specific Application form
3. Request for Privileges
4. Medical Staff Bylaws, Governing Body Bylaws and Rules & Regulations, relevant Medical Staff Policies, etc.
5. Request List of Professional References
6. Applicant to sign an affidavit:
   - “Information provided is current and accurate.”
   - This cannot be delegated.
**Begin Processing Application**

1. Hospital sends requests for references:
   - Absolute Waiver
   - photo
2. Electronic request for references
3. Data collection and verification – Credentials File & Application Checklist

**Step 1**
- Ministerial Administrative, Not Privileged
- Performed by Non–Professionals
- Receive Application & Verify all entries

**Step 2**
- Peer Review of Completed Application – Privileged
- By Credential Committee of Peers
- Decision to Hospital Executive Committee

**Step 3**
- Administrative Actions – Not Privileged
- Executive Committee Action
- Board of Governors – Final action

**Evaluation of Application**
Key elements to identify during review process

**Red Flags**

- Red flags do not automatically preclude a practitioner from the medical staff.
- These trigger the need for investigation of the circumstances.

**Red Flags (Cont’d)**

6. Inability to maintain a medical practice in the facility’s service area.
7. Resignation from a medical staff at any time in career.
8. Reports of problems in an applicant’s professional practice.
9. One or more references that raise concerns or questions, e.g., “Please call for information.”
10. No response to a reference inquiry from an applicant’s past affiliation.

**Red Flags (Cont’d)**

11. Disciplinary actions by medical staff organizations, hospitals, state medical boards, or professional societies.
12. Any past or pending state licensing board, medical staff organization, or professional society investigative proceedings.
13. Any claims or investigations of fraud, abuse and/or misconduct from professional review organizations, third–party payers, or government entities.
14. Little or no verified coverage from a professional liability insurance policy.
Red Flags (Cont’d)

15. Jury verdicts and settlements for professional liability claims.
16. Any discrepancies identified between:
   • Application
   • Primary Source Verification information
   • References

Must Check Thoroughly:

1. Licensure
2. Education
3. Medical Malpractice Insurance History
4. Board Certification
5. Sanctions or Disciplinary Actions
6. Criminal History
7. Healthcare Employment History
8. Professional References
9. Clinical Activity

Credentialing and Privileging Process

A. Review of Applications:
   1. Consistent application of policy
   2. Incomplete applications may not be forwarded for review
   3. Medical Staff policy defines time limits for application completion

B. Summary of Red Flags
   ➢ Document findings, discussions, and actions.

Completed Application is submitted to:

1. Chair, respective Medical Department
2. Credentials Committee: Prepares recommendations for privileges
3. Medical Executive Committee: Prepares recommendations for privileges
4. Governing Body: Reviews Medical Staff recommendations; grants / denies / revises privileges
5. Applicant is notified of the Governing Body’s decision
6. Begin: FPPE and OPPE

Governing Body Meeting Minutes to Reflect

1) “At the recommendation of the Medical Staff…”
2) “The Governing Body grants to (NAME) the following privileges ….”
3) Effective date of the privileges and expiration date, e.g.,
   a) Effective at Midnight, May 1, 2016
   b) Expires at 11:59 pm, April 30, 2018
Multi-hospital Health Systems

Privileges may only be granted for procedures offered at the hospital:

The Governing Body meeting minutes must reflect the privileges granted to each practitioner for each hospital.
Negligent Credentialing and Corporate Responsibility/Liability

John D Busowski MD, JD
Department of Obstetrics and Gynecology
Division of Maternal Fetal Medicine
Winnie Palmer Hospital for Women and Babies
Orlando Health
Orlando, Florida

Objectives

- How to avoid negligent credentialing risk
- Review recent cases and their impact on hospital’s duty to protect patients
- State requirements for plaintiff to establish in order to succeed in a negligent credentialing case
- Discuss how to successfully defend negligent credentialing cases

Why an issue?

- Man poses as "Plastic surgeon" for 16 months
- Fake "Psychiatrist" 5 years
- Maryland doctor sued 18 times in 20 years; 9 suits total >$20 million, ignored by Board of Medicine
- California surgeon removed wrong healthy kidney; No privileges to perform surgery !!!

Sometimes serial killers wear white lab coat!!!

- Dr. Joseph Michael Swango
- U.S. Penitentiary, Administrative. Florence, CO
- Serving 3 consecutive life sentences for murdering four patients
- Suspected of poisoning deaths of 60 patients and colleagues over almost 20 years

Hospital Liability - Historical

- Only employees, including physician employees (Respondeat superior)
- Hazardous conditions
- Equipment provided by the hospital
- Hospital was NOT licensed to practice medicine; only physicians were
- Physician was independent contractor
Historically: Hospital Liability

1. Respondeat superior
2. Apparent, or ostensible, agency
3. Non-delegable duty

*These claims were based on vicarious liability and generally do not assert that the institution (hospital) did anything to contribute to the plaintiff’s alleged injuries.*

Today: Hospital Liability

- Hospitals have grown and expanded
- Charitable immunity laws have eroded
- Hospital are responsible for monitoring and supervising the quality of medical care of its medical staff
- Types of claims against hospitals have multiplied
- Currently, >40 states recognize negligent credentialing as a cause of action
- Three states have rejected negligent credentialing claims: Delaware, Kansas, and Kentucky

What is negligent credentialing?

- “Failure (of the hospital and its medical staff) to act as an ordinary prudent person or conduct contrary to that of a reasonable person under specific circumstances.”

Duty – Doctrine of Corporate Negligence

- Hospital, along with its medical staff, is required to exercise reasonable care to make sure that physicians applying to the medical staff or seeking reappointment are competent and qualified to exercise the requested clinical privileges.
- Doctrine also applies to managed care organizations – e.g. PHOs & IPAs

Credentialing

- Process of obtaining, verifying from primary source and assessing the **all qualifications** of a practitioner to provide care or services in/for a healthcare organization
- Documented evidence of licensure, education, training, experience and other qualifications

Privileging

- Process where specific scope and content of clinical privileges/patient care services are authorized for a healthcare practitioner
- Basically granting the provider authorization to provide care
- Organization must verify credentials before granting privileges
Credentialing – The Basics

- Medical staff bylaws provide the framework for administrative procedures to ensure practitioners provide safe and competent care.
- Credentialing process should be complete before a provider is allowed to provide patient care services.
- Re-credentialing should occur at least every 2 years.

Credentialing – Basics (Cont’d)

- Collect information regarding each practitioner’s current licensure status, training, experience, competency and ability to perform requested privileges.
- Bylaws should set out the process for credentialing and approval/granting of privileges.

Three Elements of Negligent Credentialing

1. Hospital fails to meet the standard of reasonable care in granting privileges;
2. Physician then breaches the standard of care in treating a patient; and,
3. The granting of staff privileges to the negligent physician was a proximate cause of the plaintiff’s injuries.

Result of Negligent Credentialing

- Granting privileges to a doctor who may seriously injure or cause of death to patients.
- Because the applicant may be hiding:
  ◦ Past or pending investigative proceedings
  ◦ Disciplinary actions
  ◦ Evidence of fraud, abuse, misconduct
  ◦ Jury verdicts (criminal & civil court cases)
  ◦ Settlements for claims (malpractice)

Negligent Credentialing

**In a nutshell**

Imposition of a duty on corporate health care providers and their staff to properly screen physicians who are given permission to see patients within the provider’s walls, *regardless of whether or not they are ever actually employed by the corporate provider.*

Frequent Credentialing Errors

1) Missing Details:
   - Supporting documentation; training; education/work “gaps”
2) Incomplete applications:
   - Blank portions; Incorrect info on application;
   - Peer recommendations (Do you have them?/Are they REALLY peers?)
Frequent Credentialing Errors

3) Credentialing Mid-Level Providers
4) Postgraduate Training:
   - Completion of Residency?
   - Board Eligible and/or Board Certified
5) Initial Granting of Privileges pending completion… but NEVER completed…..
6) Not knowing, following or updating bylaws
7) Pressured to get credentialing done

Negligent Credentialing

- Most cases are based on;
  A. Procedural/Practice Failures
  B. Substantive Reasons
  - Failure to follow sound credentialing process
  - Credentialing process was inadequate
  - Patient must be harmed by the negligence of the physician

Credentialing Red Flags

- Failure by any hospital medical staff, health care entity, training program, or professional society with which the applicant or member has been affiliated to respond completely to any written or oral reference inquiry.
- "Off the record" (but credible) reports of problems relating in any way to the professional practice of the applicant or member.
- Difficulty in verifying compliance with general requirements, such as training and education, professional liability insurance coverage, patient coverage arrangements, and establishment of office practice in the hospital’s geographic service area.
- Any resignation or withdrawal of an application for appointment or reappointment from any hospital medical staff, health care entity, or professional society at any time in the career of an applicant or member
- Any gaps in education or work history.
- Past disciplinary action by another hospital medical staff, health care entity, or professional society.
- Pending investigations by any hospital medical staff, health care entity, or professional society.
- Past or present investigation by state licensing board in any state
- Settlement of any professional liability claims (whether or not they resulted in litigation) within the past five years.
- Pending professional liability actions.
- Other civil litigation relating to professional practice or qualifications of the applicant or member (e.g., claims of sexual misconduct with patients or claims of insurance fraud).
- Investigations or disciplinary actions by any third-party payer (including Medicare, Medicaid, or private insurance).
- Criminal investigations, charges, and/or actual convictions of a misdemeanor or felony.
- Participating in the last five years in any treatment or diversion program relating to drug use, alcohol dependency, or psychiatric problems.

Credentialing Red Flags

- Any discrepancy in the responses provided by the applicant and verification information received from primary sources.

  - Practical Tips:
    - Know what questions to ask.
    - Carefully review all verification information.
    - Know how to follow up.
    - Document verification and clarification efforts.
Negligent Credentialing

Soooo....
If the physician was not negligent, the hospital is not negligent.

AND.... A finding that the physician was negligent does not automatically mean that the hospital was negligent in its credentialing.

Elements of “negligent credentialing”

1. Hospital unreasonably selected and screened the physician it granted medical staff privileges to;
2. while practicing pursuant to negligently granted staff privileges, the physician was negligent;
3. Hospital’s negligent granting medical staff privileges was a proximate cause of plaintiff’s injuries
   • Frigo v Silver Cross Hospital and Medical Center
   • No. 1-05-1240 (Ill. App. 2007)

Defending Against a Corporate Negligence Claim

- Usually requires expert testimony
- Must establish the existence of duty and that there was a breach of the duty.
- Expert must establish that duty was not met
- Defense – That hospital adopted and followed all standards as reflected in its bylaws and procedures, and/or no breach occurred and/or if there was a breach, it did not cause patient’s injuries

Defending Against a Corporate Negligence Claim (Cont’d)

- Establish – there is not necessarily a black-and-white standard on what qualifications are absolutely required before issuing clinical privileges
- Argue – reduction or termination of privileges is not always the appropriate response.
- Preferred path – work with physician to get back on track by implementing remedial measures such as monitoring, proctoring, additional training
- Introduce – physician’s peer review record to establish that hospital met its duty.

Defending Against a Corporate Negligence Claim (Cont’d)

- Evaluate whether the peer review statute regarding:
  - Discovery of peer review record
  - Admissibility into evidence.
- Most statutes do not permit the discovery or admissibility
- There is no statutory exception that allows a hospital to pick and choose when it can or cannot introduce information into evidence.
- Denying a plaintiff access to this information usually makes it more difficult to prove up a negligent credentialing claim.
Defending against a corporate negligence claim (Cont’d)

- Courts and juries may be less likely to hold in favor of the plaintiff even if, for example, a physician’s lack of qualifications or history of malpractice actions raises the issue of whether privileges should have been granted, as long as some action was taken, i.e., physician was being monitored or proctored or was under a mandatory consultation.
- A judge and jury will be more likely to find in favor of the plaintiff if the hospital did absolutely nothing with respect to the physician’s privileges.

Preventative Steps

- Conduct audit to determine whether hospital and medical staff bylaws, rules and regulations and policies comply with all legal accreditation standards and requirements.
- If there are compliance gaps, fix them.
- Determine whether you are actually following your own bylaws, policies and procedures.
- If you are not following your bylaws and policies, either come into compliance or change the policies.
- Update bylaws and policies to stay compliant.

Preventative Steps

- Confer with peers. Standard of care can be viewed as national, i.e., the Joint Commission, internal or area-wide so as to include the peer hospitals in your market.
- If your practices deviate from your peers, this will be held against you as a breach of the standard of care.
- Understand from your insurance defense counsel how plaintiff’s attempt to prove a corporate negligence violation as well as how these actions are defended.

Take-Away

- To avoid liability for negligent credentialing, hospitals must be diligent, comprehensive and thorough in the credentialing process, and
- Physicians seeking privileges should be prepared to offer full and fair disclosure of all issues, and to have their credentials and behavior examined.

Errors, errors and more errors

A Doctor's Tale Shows Weaknesses In Medical Vetting Despite Erratic Education, Trial of Suits, Dr. King Got Job at HCA Hospital

Carter v. Putnam General Hospital

- John King received temporary privileges at Putnam General Hospital in November 2002.
- In seven months, the orthopedic surgeon performed about 500 operations, mainly on patients' spines, arms and legs.
- During a routine review of the doctor’s work, the hospital became concerned about some of his surgeries.
In May 2003, Putnam, (HCA hospital) suspended his privileges, pending an internal investigation. Peer review, called Dr. King a "snake–oil salesman" who was "not competent to practice medicine". In August 2003, before the hospital completed its inquiry, King resigned & turned in his W. Virginia medical license.

How did Dr. King get the job?
- Putnam, small 68–bed facility
- Financial pressures, hire doctors in highly profitable fields such as orthopedics
- Retained Comprehensive Healthcare Staffing
- Dr. King interviewed on Oct. 9, 2002; "hot button = $, “no indications of problems”
- Putnam "retained ultimate responsibility". Putnam's revenue from orthopedics rose sharply after Dr. King arrived.

Carter v. Putnam General Hospital
- HCA performed background check
- AMA web site: Dr. King graduated from Meharry Medical College, Nashville
- Resident at five institutions in orthopedic surgery, obstetrics and gynecology, and anesthesiology.
  - Graduated from University of New England College of Osteopathic Medicine in Biddeford, Maine. (AMA couldn’t explain the discrepancy)
- King was not certified by national medical boards
- Putnam didn’t verify anesthesiology and ob/gyn training.

Carter v. Putnam General Hospital
- 1989 – King worked as PC physician, Walker Regional Med. Center, Jasper, Ala.
  - Suspended – falsified patient records. Walker then lifted the suspension, and Dr. King resigned.
- 1995–97 – "performed the duties" of an orthopedic resident at Lincoln Medical and Mental Health Center in New York's Bronx borough. Dr. King "was not an approved resident"

Late 1990s, Dr. King worked at Jackson County Hospital in Marianna, Fla., where he was arrested and charged with theft.
- Removed two log books from the OR
- Putnam did not do criminal–record checks or drug tests; part of doctor–hiring process.
- While in Florida, Dr. King was named in four malpractice suits
  - These settlements weren't listed in the NPDB

How did this happen?
- Hospital desperate to recruit orthopedic surgeon
- Surgeon insisted on doing spine surgery
- CEO had limited credentialing knowledge
- Department chair was experienced but relied on medical staff coordinator
- Medical staff coordinator had no training/experience; only on job by herself for 3 weeks
**Carter v. Putnam General Hospital**

- **Facts:**
  - Incomplete application
  - Multiple residencies (incomplete) in various specialties with no PSV
  - No formal subspecialty residency/fellowship
  - Board certification not ABMS/AOA
  - Competency letter was a copy sent to another hospital years before (not PSV)
  - AMA profile was copy (and incorrect)
  - Not all malpractice claims on application
  - Gaps in work history

- **End Result:**
  - 100+ malpractice suits
  - Jury verdict ruled "negligent credentialing" of temporary privilege process had occurred
  - No monetary settlement
  - Now each individual suit able to include outcome
  - Corporation settled all for undisclosed amount
  - Corporation sold hospital

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**Questions?**

**Documented Court Cases**

**Precedent-Setting Cases of Negligent Credentialing**

- **Darling v. Charleston Community Mem. Hospital**
  - 1st case to hold that hospitals have an independent duty to monitor patient care being provided in the facility
- **Johnson v. Miserko & Associates**
  - False information & omitted information on the application
  - Hospital did not verify the information
- **Piper v. Silver Cross Hospital (2007) ($7,775,688)**
  - Physician did not properly meet eligibility requirements
  - Reappointed without meeting eligibility requirements
- **Kadlec v. Lakeview Anesthesiologists Assoc. and Lakeview Medical Center**
  - Peer references provided misleading information

**Darling v. Charleston Community Memorial Hospital**

- First case in the country to apply the Doctrine of Corporate Negligence
- The court held that hospitals have an independent duty to monitor patient care being provided in the facility.
- Employees must observe condition of patients and report findings to higher authority if attending physician does not do what is clearly proper.
- Hospital found liable for negligent treatment of patient by physician.

Darling v. Charleston Community Mem. Hospital, 211 N.E. 2d 253 (Ill. 1965)
**Case involved a teenage athlete who had a broken leg with complications and was treated by a family practitioner**

- Leg was not set properly and patient suffered permanent injury
- Physician was found to be negligent
- Hospital claimed no responsibility over the patient care provided by its staff physician
- Court rejected this position as well as the charitable immunity protections previously provided to hospitals
- Part of the basis for the decision was that hospital had incorporated the Joint Commission's credentialing standards into its corporate and medical staff bylaws

**Darling v. Charleston Community Mem. Hospital**

- Supreme Court Illinois health first time in United States that a hospital is legally responsible for making sure that a physician seeking appointment or reappointment to medical staff is qualified to exercise each and every clinical privilege that is granted him as determine to the hospital medical staff credentialing and privileging procedures
- If a hospital fails in its duty and knew, or should have known, that the physician is unqualified and the physician subsequently commits an act of negligence that injures a patient, the hospital can be held separately liable for compensatory damages

**Significance of Darling....**

- Prior to Darling, Hospitals were not deemed to have a special obligation to assure the quality of the healthcare provided by independent medical staff.
- Darling changed that custom, and led to the creation and subsequent expansion of the concept of hospital corporate liability.
- Darling bypasses the independent contractor limitation placed upon hospital’s vicarious liability
- The Darling court held that a hospital board of trustees had an oversight duty to assure the competency, qualifications, and proficiency of individual medical staff at the hospital.

**Elam v. College Park Hospital, 132 Cal. App. 332, 183 Cal. Rptr. 156 (Ca. 1982)**

- First case in California involving negligent credentialing
- Hospital liable for podiatrist’s negligence; failed to obtain malpractice claims data; although medical records department aware of claims.
- Court held that a hospital has a duty to both select and review and periodically evaluate the competency of staff physicians adequately.

**Elam v. College Park Hospital**

- Allegation of medical malpractice by a hospital staff podiatrist in the performance of foot surgery.
- Plaintiff named the hospital in her complaint, alleging that it breached its duty to insure the competence of its staff physician.
- The court held that it is the responsibility of the hospital to exercise reasonable care in selecting and periodically evaluating the competence of private physicians who are granted medical staff privileges and allowed to use the hospital’s medical facilities.
- Prior to Elam, the doctrine of hospital corporate negligence apparently had not been recognized in California.

- Elam court reasoned that this duty is consistent with existing California judicial and statutory law.
- The court cited relevant cases, accreditation standards and several Health and Safety Code sections which charge a hospital’s governing body with the duty to provide quality health care and which grant the board plenary power to accomplish that goal.
  - Health and Safety Code sections:
    - 32128 (which imposed the duty on a hospital’s governing body to operate the hospital "in the best interests of the public health").
Bell v. Sharp Cabrillo Hospital
(Ca. 1989) 212 Cal. App. 3d 1034

- A patient was taken to the hospital’s emergency room complaining of abdominal pains. The on-call emergency physician, performed exploratory surgery that resulted in complications causing the patient’s death twelve days later.
- Suit was filed against the hospital contending that the hospital consciously disregarded the safety of its patients by granting staff privileges to the physician without investigating warnings of his possible incompetence.
- Before the surgery which gave rise to the claim, physician’s application for renewal of his medical staff privileges had disclosed that his medical staff privileges at another hospital had not been renewed, and that his privileges had been suspended at a third hospital.
- The chief of surgery at the hospital did not contact the hospital where physician’s privileges had been revoked.

Excerpts from Bell court ruling:

“...This is not a case where the hospital intentionally and completely ignored its duty to screen the competency of its medical staff to ensure the adequacy of its medical care. Rather, this suit faults a corporate healthcare provider for not exercising reasonable care when reviewing the competence of a long-time medical staff member by failing to conduct a complete review by inquiring of another hospital who had revoked that physician’s privileges.”

Johnson v. Misericordia Community Hospital, 294 N.W. 2d 501, 97 Wis. 2d 521 (Wis. 1981)

- During surgery to remove a pin, the surgeon severed the plaintiff’s femoral artery and nerve, resulting in permanent paralysis.
- Surgeon began working at the hospital after falsifying a number of statements on his application for privileges.
- These falsehoods were not uncovered because of an inadequate review of his application.
- Result was the surgeon was hired and later elected to chief of staff at the hospital.

Johnson v. Misericordia Community Hospital

- Plaintiff settled with the surgeon.
- A jury later apportioned the hospital 80% of the liability, under a finding of corporate negligence.
- The surgeon’s application for privileges was incomplete and contained incorrect information concerning his qualifications and professional history.
- Hospital did not verify the information.

Johnson v. Misericordia Community Hospital

- Negligent credentialing; Failure of Initial Credentialing Process
- Court ruled the hospital owed a duty to its patients to use due care in the selection of its medical staff. The hospital should have verified information at the time of credentialing and thus contributed to the patient’s injury simply by allowing the physician to have staff privileges.
Podiatric physician operated on the plaintiff's foot, despite the presence of an infected ulceration on the foot, which ultimately had to be amputated.

The plaintiff claimed that the defendant hospital should not have given the podiatrist surgical privileges as he failed to meet the hospital's criteria for receiving Level II surgical privileges.

Court found the podiatrist had failed to meet the standards set out in the medical staff bylaws for Level II privileges.

Illinois appellate court upheld the $7.7 million jury verdict based on negligent credentialing.

At the time of his reappointment, the standard was changed to require a completed 12-month podiatric surgical residency training program, successful completion of the written eligibility exam, and documentation of having completed 30 Level II operative procedures.

The podiatrist never met these standards and was never grandfathered.

In 1998, when the alleged negligence occurred, he had only performed six Level II procedures and none of them at Silver Cross.

Frigo argued that because the podiatrist did not meet the required standard, he should have never been given the privileges to perform the surgery.

Frigo maintained that the granting of privileges to an unqualified practitioner who was never grandfathered was a violation of the hospital’s duty to make sure that only qualified physicians are to be given surgical privileges.

The hospital’s breach of this duty caused her amputation because of podiatrist’s negligence.

Jury reached a verdict of $7,775,668.02 against Silver Cross.

Podiatrist had previously settled for $9 million.

Hospital had argued that its criteria did not establish nor was there an industrywide standard governing the issuance of surgical privileges to podiatrists.

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Cost of Silence in Medical Staff Credentialing

Recent Negligent Credentialing Cases

Rabelo v. Nasif, Massachusetts Superior Court, 2012

- Orthopedic surgeon and hospital sued by patient who was assigned to surgeon through ER.
- Court recognized that negligent credentialing is similar to “negligent hiring or retention” tort that is recognized in Massachusetts.
- Duty owed to patient is premised on the “special relationship” and a hospital could reasonably foresee that it should protect patients from incompetent or careless surgeons.

The court disagreed and held that the jury acted properly because the hospital’s bylaws and the 1992 and 1993 credentialing requirements created an internal standard of care against which the hospital’s decision to grant privileges could be measured.

Court noted that podiatrist had not been grandfathered and that there was sufficient evidence to support a finding that the hospital had breached its own standard, and hence, its duty to the patient.

This finding, coupled with the jury’s determination that physician’s negligence in treatment and follow-up care caused the amputation, supported the jury’s finding that her injury would not have been caused had the hospital not issued privileges to podiatrist in violation of its standards.

Rabelo v. Nasif, Massachusetts Superior Court, 2012

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- Court recognized that negligent credentialing is similar to “negligent hiring or retention” tort that is recognized in Massachusetts.
- Duty owed to patient is premised on the “special relationship” and a hospital could reasonably foresee that it should protect patients from incompetent or careless surgeons.
Dr. Berry was terminated by his anesthesia group and his privileges at Lakeview expired and were not renewed based on the underlying allegation that he abused Demerol.

After being terminated by Lakeview Medical and LAA, Dr. Berry sought work at Kadlec Medical Center through Staff Care.

Upon receiving his application, Kadlec began its credentialing process and examined a variety of materials, including referral letters from LAA and Lakeview Medical.

LAA’s Dr. Preau and Dr. Dennis, two months after firing Dr. Berry for his on-the-job drug use, submitted referral letters for Dr. Berry to Staff Care, with the intention that they be provided to future employers.

When requested by Kadlec to provide credentialing information, Lakeview Regional Medical Center (LRMC) provided dates of service only, with a notation that other information was not available “due to large volume of inquiries received in this office.”

Lakeview Regional Medical Center (LRMC) did not answer any questions on the questionnaire that Kadlec sent to Lakeview.

Kadlec conducts routine credentialing and no red flags were identified.

12/01 Dr. Berry is approved by Kadlec MC as anesthesiologist.

12/02 Patient Kimberly Jones stops breathing during tubal ligation and Dr. Barry fails to resuscitate; she remained in a permanent vegetative state.

Plaintiff’s attorney uncovers the fact that Dr. Barry was fired from Lakeview Anesthesia Associates for the abuse of Demerol and failure to answer pages.

Family sues Dr. Barry for negligence and sues Kadlec for negligent credentialing under “Respondeat Superior.”
Dr. Berry confessed he had been using Demerol since his car accident and that he had become addicted to Demerol. Jones' family sued Dr. Berry and Kadlec, and both Dr. Berry's and Kadlec's insurers settled the claims. Plaintiff received $8.5 million ($1 million from Dr. Barry and $7.5 million from Kadlec Medical Center).

Kadlec and its insurer have filed suit against LAA, Dr. Dennis, Dr. Preau, Dr. Parr, and Lakeview Medical alleging intentional misrepresentation, negligent misrepresentation, strict responsibility misrepresentation, and general negligence.

Litigation resulted in an $8.2 million award. The court found that Lakeview's response was entirely gratuitous and may have been motivated by fear of defamation action. The court held that, in order to protect future patients of an impaired physician, Lakeview Medical and its physicians had a duty to disclose Dr. Berry's impairment to a second hospital where the physician relocated and applied for privileges. Court said "if and when a hospital chooses to respond to employment referral questionnaire, … policy should encourage the hospital to disclose this sort of information at issue. Kadlec and Lakeview have unique special relationship which existed in part to further communication between health providers so the future patients could be protected."

Lakeview Regional Medical Center (LRMC) did not answer any questions on the questionnaire that Kadlec sent to Lakeview. LRMC later stated in court this is a type response that was part of it standard business practice when responding to inquiries. However Lakeview's response for this position was different than other responses to credentialing requests.

The fifth circuit held under Louisiana state common law, the defendants owed no affirmative duty to disclose negative information about Dr. Barry. However, the court ruled that "after choosing to write referral letter's, the defendants assume the duty not to make affirmative misrepresentations."
The fifth circuit concluded that defendants did not stand in any special relationship with Kadlec upon which a duty to disclose may be premised. Result court reversed a judgment against LRMC.

In contrast, court concluded that the letters written by Dr. Dennis and Dr. Preau were false on its face or materially misleading. Those letters that he was in "excellent physician" and "highly recommended" contradicted their statements and Dr. Barry's termination letter just a few months before. That his "impairment "prevented [him] from properly performing [his] duties and put [their] patients at significant risk." The acts and omission of Lakeview Anesthesia Associates and its shareholders were the legal cause of Kadlec's liability.

Provide correct information when answering verification requests. Don’t omit key information when answering verification requests.
Responding to Recommendation Requests Regarding Difficult Physicians

- You do not have to complete the recommendation form.
- If you complete the reference or recommendation form, it must be accurate and complete.
- Do not allow the requesting physician to review the response or to submit a suggested response.
- Do not feel the need to stay within the form used for the reference request.
- Do not respond to verbal requests for references or provide information via email or by telephone.
- Confirm every answer made with documentation in file.
- Do not rush to complete the reference request and do have it reviewed before it is submitted.

Decreasing the Chance

- Training for Medical Staff Professionals and Medical Staff Leaders
- Medical staff involvement in all phases of credentialing and privileging

Decreasing the Chance

- Following all polices, procedures, bylaws
- Audit bylaws, rules & regulations, and policies
- If your hospital is not in compliance with bylaws:
  - Determine if required
  - If you are making exceptions to the rule, change the rule

CONCLUSIONS FROM TODAY

- Most states allow negligent credentialing claims
- Most are judicially approved, not created by statute
- Damage caps under Med Mal laws are an issue
- Experience of other states is instructive
- Expert testimony is the key to presenting and defending claims of negligent credentialing

Joseph Michael Swango

- 1983 graduated from SIU School of Medicine
- Despite very poor Dean’s letter was accepted at University of Iowa and then OSU Medical Center internship in surgery followed by a residency in neurosurgery
- Patients began dying when Swango was the floor intern
- Nurses reported concerns to administrators, but were met with accusations of paranoia
- Cursory investigation cleared Swango and was allowed to complete internship

Swango
Swango Case Study
- Not hired as resident physician after internship due to poor performance
- Recriminations at Ohio State - revealed several glaring shortcomings in its initial investigation of Swango
- Another decade before Ohio State formally conceded it should have called in outside investigators.
- Franklin County, Ohio prosecutors also considered bringing charges of murder and attempted murder, but decided against it for want of physical evidence
- 1984 moved back to Illinois and began working as EMT
- Coworker paramedics became violent ill
- Arsenic and other poisons found in his possession.
- Convicted of aggravated battery - 5 years in jail

Swango Case Study
- In 1991, legally changed his name to Daniel, Adams
- Applied for a residency program at Ohio Valley Medical Center in Wheeling, WV.
- In July 1992, he began working at Sanford USD Medical Center in Sioux Falls, South Dakota
- Forged a fact sheet from the Illinois Department of Corrections that falsified his criminal record
  - Changed that his felony conviction for poisoning to a misdemeanor for getting into a fistfight with a co-worker
- Attempted to join the AMA
  - Background check found the poisoning conviction
- Discovery Channel aired episode of Justice Files that included a segment of Swango
- Sanford fired Swango

Swango Case Study
- Psychiatrist residency at the SUNY at Stony Brook School of Medicine
- First rotation was internal medicine at the VA in Northpoint
- His patients began dying for no explicable reason
- Mother of Swango ex-girlfriend notified the dean at Sanford about Swango’s history
- Sanford’s Dean notified the Dean at Stony Brook
- Swango admitted he lied about his poisoning conviction
- He was immediately fired
- Under public outcry Stony Brook’s Dean and head of Psychiatry Department were forced to resign

Swango Case Study
- Dean at Stony Brook sent a warning about Swango to all 125 medical schools and all 1,000 teaching hospitals
- Since the latest Swango incident took place at a Veterans Affairs facility, federal authorities got involved
- The FBI obtained a warrant charging Swango with using fraudulent credentials to gain entry to a Veterans Affairs hospital
- Swango fled the country to Zimbabwe

Swango Case Study
- Forged documents to obtain a job at Mnene Lutheran Mission Hospital
- Patients continued to die mysteriously
- Arrested in Zimbabwe, but escaped
- Swango was formally indicted on July 17, 2000 and pleaded not guilty.
- On September 6, 2000, he pleaded guilty to murder and fraud charges to avoid the possibility of the death penalty in New York and extradition to Zimbabwe
Peer Review: Confidentiality; Discoverability; Admissibility; and Privilege *Marvin H. Firestone MD JD FCLM*
PEER REVIEW LAW

Two Competing Schools of Thought as to the Need for Statutory Protections to Guard the Peer Process:
1. Without the statutory protections, physicians would not participate in the process, thus thwarting efforts to improve quality care.
2. Protections afforded by peer review statutes are at the expense of patients.

Almost every State has enacted a peer review statute designed to protect the work of medical peer review committees.
Many States have some form of statutory privilege for medical peer review.
Interpretation of statutory privilege for peer review varies among States.

Provides peer review information shall be private, confidential and privileged.
Exceptions:
1. State agency or board which licenses the health care professional, with notice to the professional;
2. Courts will often review documents in camera to determine if the peer review privilege applies.

“... any process, program or proceeding, including a credentialing or recredentialing process, utilized by a health care entity ... to assess, review, study or evaluate the Credentials, Competence, professional Conduct or health care services of a health care professional.”
63 O.S. Sec.1-1709.1(A)(4)

Any licensed hospital or related institution;
Any licensed ambulatory surgical center;
Clinical practices of accredited allopathic and osteopathic state medical schools;
Any other entity directly involved in the delivery of health care services that engages in a credentialing or peer review process.
Meaning of “Delivery of Health Care Services”

- No Oklahoma Court has opined on its meaning.
- In Pietro v. Marriott Senior Living Services, Inc., 810 N.E. 2d 217 (Ill. App Ct.2004), the court ruled that assisted-living centers were not included as a health care facility pursuant to Illinois statute.

Who is Health Care Professional?

- “… person authorized to practice allopathic medicine and surgery, osteopathic medicine, podiatric medicine, optometry, chiropractic, psychology, dentistry or a dental specialty under a license issued pursuant to Title 59 of the Oklahoma Statutes.”
  63 O.S. Sec.1-1709.1(A)(4)

What are Peer Review Activities?

1. Any credentialing and recredentialing process.
2. Does the process actually involve the assessment, review, study or evaluation of the Credentials, Competence, professional Conduct or health care services of a health care professional?

Peer Review Activity: Some Determinative Factors

- Does the committee conducting the peer review perform multiple functions? Or,
- Is its sole purpose to conduct peer review?
- Is quality assurance the primary purpose of the committee?
- Was the investigation conducted by one person or by a committee?
- Is the investigation an internal one that is not carried out by a regularly constituted committee?
- Do non-physicians participate in the process?

More on Peer Review Activities

1. No one of the various factors is determinative;
2. The mere labeling of a committee or process as a peer review committee or process is not dispositive of the issue;
3. The primary issue is whether the activities are part of the “ordinary course of business” or in connection with formal peer review committee activities. [Columbia/HCA Health Care Corporation v. Eight Judicial District Court 936 P.2d 844 (NEV 1997)]

What Peer Review Information is Protected?

- “… all records, documents and other information generated during the course of a peer review process, including any reports, statements, memoranda, correspondence, record of proceedings, materials, opinions, findings, conclusions and recommendations, credentialing data and recredentialing data.”
  63 O.S. Sec.1-1709.1(A)(5)
Rulings: Documents Protected by Peer Review Privilege

- Committee minute records discussing hospital procedure (North Carolina 1986).
- Findings incorporated in government reports (Georgia 1996).
- Correspondence between members relating to the deliberative process and final reports (N.D. Texas 1991); and
- Peer Review committee guidelines (Illinois 2nd District 1990).

Factors Applied in Determining Protected Documents

1. Was the document generated before the peer review process started?
2. Was the document necessary to comply with quality assurance programs?
3. Is the information available elsewhere?
4. Does the document contain only a factual recitation of the occurrence?
5. Was the document created in the normal course of business and not for peer review?

Documents Specifically Excluded

1. Medical records of a patient being reviewed;
2. Incident reports and other like documents;
3. Identity of individuals who have personal knowledge of the facts and circumstances;
4. Factual statements regarding patient’s health care generated outside peer review process;
5. Identity of all documents and raw data previously created elsewhere and considered during the peer review process.
6. Copies of all documents and raw data previously created elsewhere and considered during peer review.

Discoverability of Peer Review Information in Med-Mal Action

- In a Med-Mal action, “… factual statements, presented during a peer review process utilized by such health care facility entity, regarding the patient’s health care in the health care facility entity from individuals who have personal knowledge of the facts and circumstances surrounding the patient’s health care shall not be subject to discovery.”

63 O.S. Sec.1-1709.1(C)

Discoverability of Peer Review Data in Negligent Credentialing Claim

- In a negligent credentialing/hiring claim against a health care facility, “… the credentialing and recredentialing data and the recommendations made and actions taken as a result of any peer review process utilized by such health care facility entity regarding the health care professional prior to the date of alleged negligence shall be subject to discovery …”

63 O.S. Sec.1-1709.1(D)(1)

Admissibility of Peer Review Data in Negligent Credentialing Actions

- Discovered data “… shall not be admissible as evidence until a judge or jury has first found the professional to have been negligent in providing health care services to the patient in such health care facility entity, and shall not at any time include the identity or means by which to ascertain the identity of any other patient or health care professional.”

63 O.S. Sec.1-1709.1(D)(2)
Peer Review Participant’s Protection

“... no person involved in a peer review process may be permitted or required to testify regarding the peer review process in any civil proceeding or disclose by response to written discovery requests any peer review information.”

63 O.S. Sec.1:1709.1(E)

Emerging Trends: Federal Courts

Several federal courts have found that federal law does not have a similar peer review privilege and have refused to apply the state peer review privilege.


Emerging Trends: State Courts

Several State courts have created an exception to the peer review privilege when a physician challenges his own peer review process.

Hayes v. Mercy Health Corporation, 739 A.2d 114 (PA 1999)

Some courts have given consideration to allowing the production of peer review information pursuant to a protective order.

Smith v. Deaconess Hospital LLC, No. 103,876, Decided: May 29, 2007

Issue: whether peer review actions are immune from judicial review and the participants entitled to qualified immunity (Oklahoma).

Trial court: granted defendants’ motion to dismiss on the sole ground that the defendants were entitled to qualified immunity.

Supreme Court: "Defendants are entitled to qualified statutory immunity from liability - not from suit - if they show the Board’s compliance with all the statutory conditions. That has not yet occurred." (Reversed and remanded)

Klain v. Southern Illinois Hospital Services, 2016 IL 118217

In a medical malpractice and negligent credentialing action, plaintiff requested production of:

Dr. Dressen’s three applications for hospital staff privileges, and

“...procedure summaries and case histories” that, essentially, list the various surgical procedures that Dr. Dressen performed at SIHS hospitals.
Defendant refused and maintained that:

1. any references in the applications to information reported to the National Practitioner Data Bank (NPDB) must be redacted because it is privileged under Health Care Quality Improvement Act of 1986 (42 U.S.C. § 11137(a) (2012)), and

2. information concerning medical treatment provided by Dr. Dressen to patients who are not party to this lawsuit must be redacted because it is privileged under the Credentials Act and/or the physician-patient privilege.

Circuit Court found that the documents sought in discovery by plaintiffs Klaine were not privileged and must be produced.

Appellate court affirmed.

Defendant: d/b/a St. Joseph Memorial Hospital and Memorial Hospital of Carbondale (SIHS), appealed.

Illinois Supreme Court affirmed.

"Here, plaintiffs filed a complaint against SIHS for negligent credentialing."

"Clearly, information requested to consider in determining whether to credential and recredential Dr. Dressen, would be highly relevant to the cause of action. In fact, we fail to see how a cause of action for negligent credentialing could proceed if we were to deny plaintiffs access to this information."

The appellate court held that, under Illinois discovery rules, the defendant would be “authorized, and *** in fact, required,” to produce this information with respect to the plaintiffs’ negligent credentialing claim. 2014 IL App (5th) 130356, ¶ 27.
Emerging Technology and Forensic Dentistry

Michael K. Kaner
DMD JD FAGD
February 24, 2018 ACLM

DISCLAIMER- All images herein are taken from public sources and no individual’s privacy was violated.

MORTUI VIVOS DOCENT-The Dead, They Teach The Living

- Forensic Dentistry is the use of dental and paradental knowledge to resolve civil and criminal matters.
- Malpractice case review
- Identification of human remains
- Bite mark analysis and identification of offender

Use of computers and digital technology for Forensic Dentistry

- Mass disaster identification- MFI
- 9/11
- Oklahoma City bombing
- Rhode Island Nightclub fire 2/03
- Hurricane Katrina 2005
- Haitian Earthquake- US citizen victims
- ???

Dental Identification

- DNA
- Fingerprints
- “A definitive means of positive identification of unknown human remains”

Human Dentition

- Unique
- Calcification of tooth structure
- Resistant to environmental changes
- Minimal post mortem changes
- Diamond is only thing harder than enamel
Human Dentition

- 32 teeth
- 160 individual surfaces that can be restored
- Astronomical number of permutations
- Restored with either silver, gold or composite
- Crowns
- Implants

Secondary features

- Trabecular bone patterns
- Proximity of sinuses or other anatomical features
- Endodontics
- Root curvatures
- Parafufunctional habits- grinding
- **Each set of teeth is unique even among identical twins**

History of Forensic Dentistry

- 2500 BC Giza-gold wire holding 2 teeth together
- 1776- Maj. Gen. Joseph Warren killed at Bunker Hill and buried in mass grave. Identified by his dentist, Paul Revere based on dental prosthesis made of copper wire and walrus tusk to replace missing tooth
- Bazar de la Charite Fire, Paris 1897. European aristocracy and political pressure to identify victims

Past uses of Forensic Identification

- Big Thompson Flood 1976- first use of a computer and missing persons list to ID 139.
- Guyana 1979- Jim Jones suicide and 900 victims
  - 45.1% identified by dental means (600/1300)
- Hurricane Katrina 1300+ victims identified in 2 locations

9/11 Complicating factors

- Ante-mortem dental records spread out all over the world.
- 39 states/35 Countries
- Antemortem records/limited remains
- 9/11-9/18/01 grounding of all non-military aircraft. No means of physically transferring records of victims to recovery site. (digital)

Katrina Complicating Factors

- Infrastructure destroyed
- Inability to get medical or dental records
- Alternative sources of information
- VA, prisons, insurance companies
- Hurricane Rita
- Intact HR/limited records
- Detective work
Dental Identification-How it works

- Means of communication
- Teeth Charted
- Odontogram
- Radiographs taken
- Jaw resected- Viewable?

Purpose of Positive Identification

- Death certificate
- Probate an estate
- File life insurance claim
- File wrongful death act claim
- Remarry without waiting 7 years
- Psychological- comfort & closure

Identification

- Personal effects-visual-high degree of certainty
- Not practical for trauma or decomposition.
- Fingerprints-best if possible
- DNA-lengthy, expensive. Useless if commingled or degraded.
- Dental- nearly instantaneous if records are available even on specimens decades old. Teeth and restorations are resilient.

Dental Resiliency

- Can withstand temperatures over 1600 degrees.
- Oral cavity protected by tongue, cheek, muscle mass-even in fires.
- In life, teeth susceptible to decay or periodontal disease but once a person dies, “the forces that destroy teeth don’t exist, so they provide an excellent, stable and reliable means for identifying human remains.”
- Pulp tissue is a source of DNA

Forensic Team

- Odontologist
- Pathologist
- Anthropologist
- Mortician
- Law Enforcement-evidence collection
- Radiologist
- Cadaver Dog
- Heavy Equipment Operator
- Family Assistance Center
Radiographic Evaluation

Origins of Organized Forensic Teams

- 1986 ADA Symposium recommended 50 state-run teams for mass disaster. WA and PA set up teams.
- PADIT managed 24/7 by PEMA.
- PADIT activated and judges scope of disaster
- Activates 3-40 dentists based on needed manpower.

PADIT Organization

- 6 teams
  - Antemortem procures dental records and codes for computer entry
  - Computer team enters data using WINID
  - Photography and Radiology
  - Post-mortem assists in recovery of remains
  - Comparison-uses ante and post to make match.
  - Logistics- hotel, non-professional matters

Federal Involvement

- National Model needed
- NDMS-Nat’l Disaster Medical Service under DHHS-> DHS->DHHS
- Oversees DMORT- Disaster Mortuary Operational Response Team
- Created as a result of 1996 Federal Aviation Disaster Act
- Country divided into 10 regions

DMORT Regions

NDMS Section

- MD
- NY
- Boston
- N. Carolina
- NJ
- N. Carolina
- VA
- TX
- FL
- LA
- AR
- MN
- IL
- WI
- CO
- AZ
- CA
- WA
- OR
- CA
- HI
- AL
- MS
- TN
- GA
- SC
- FL
- NC
- VA
- MD
- DC

2018 ACLM 58TH ANNUAL MEETING 307
DMORT Activated

- Boots on the ground in 12-24 hours.
- Mostly civilians with specialized training activated for 2 week assignment.
- Assist and work under local ME/Coroner in any situation that overwhelms local agency’s capacity.
- Governor requests Federal Assistance—$$$
- Trained to work with the FBI Evidence Recovery Team

DMORT Model

- 3 Teams ANTE, POST and Comparison
- ANTE
  - Collection and documentation of all records, radiographs and dentally identifying features.
  - Passenger manifests, employee records to get list of potential victims.
  - Detective work—decipher handwriting, track down specialists who may have additional information.
  - Mobile society—multiple dentists
  - HIPAA exception for disasters
  - Family release or subpoena for records if necessary

POST Team

- Collects information on unknown victims
- Chart and record existing dental structures and all restorations present as well as type of filling material used and surfaces restored.
- If severe damage, may require resection or removal of the jaw for radiographic analysis.
  - **Always done after legal authorization or permission of coroner or ME.
  - *Tipped, rotated or missing/impacted teeth listed.
  - *Unique identifiers—root canals, implants (name in denture)

Comparison Section

- Takes ante mortem of a known individual and tries to match it to an unknown victim.
- At each stage there are AT LEAST two dentists working independently and together to minimize risk of error. Often 4 or more.
  - “Only rarely does one find a perfect match of the ante-mortem and post-mortem records. More commonly, the ante-mortem chart will show only existing caries or work to be performed. The more alterations or abnormalities that exist in a given mouth, the greater the potential points of comparison. It must be remembered that a positive identification must bear no incompatibility and that any inconsistencies must be resolved to effect a perfect match between the antemortem and post-mortem data.”
  - James Cotter

Evaluation

- Ante—two surface filling
- Post—larger filling or extracted tooth is possibility
- Same tooth with no restorations post-mortem excludes that individual.
  - Teeth can’t ‘heal’ and filling can’t disappear.
  - *Unidirectional Change—once extracted, a tooth can’t later be present.

Comparison

- Use either entire mouth or whatever is available post-mortem, often less than an entire dentition.
- Even a few teeth can give enough info for
  - Age estimation
  - Smoker?
  - Oral hygiene
  - Socio-economic status
Single Tooth can be enough—If unique enough

2 planes crashed into World Trade Towers

Coverage

Summary

Flight Path
Immediate aftermath

Recovery

Team

Recovery

October walking the field

Katrina 2005
Facts

Gulfport, MS

Aerial view

New Orleans, LA

Gulfport DMORT Morgue

DMORT Flexibility
Data Collection

Factor

- Unique root formation
- Anomaly
- Root canal
- Implant
- Art and a Science - no minimal points of concordance but totality of circumstances.

Levels of Identification

- Positive Identification
- Possible/Probable
- Insufficient Data
- Exclusion

Positive

- Conclusive evidence that ante-mortem and post mortem records compare favorably with enough evidence to convince multiple odontologists of a match with no unexplained inconsistencies.
- Only level accepted legally
- Considered as absolute certainty

Probable or Possible Identification

- Odontologists believe that there is a consistency between the ante mortem and post mortem records but without further evidence, they will not 'sign off' as to positive identification.
- Often occurs if only a small fragment was recovered but not enough to convince of identity.

Insufficient Data

- Overlaps Possible/Probable
- Often if recovered remains with no restorations and bone or tooth structure is common enough to warrant further investigation, but insufficient to warrant a conclusion.
Exclusion

- Inconsistency that can’t be explained.
- Person with history of extensive dental work (restorations/bridgework) could be excluded from a post mortem victim with no dental work.
- Discrepancy-explained and unexplained
- Explained-change in form from time of ante until post mortem. Filling enlarged or extracted
- Unexplained-force exclusion.
* Tooth missing ante mortem but present post mortem.

Means of Comparison

- Pre-computers-walking the tables
- Ante mortem charts placed in a long row and same for post mortem.
- Still ideal for small identification (< 50)
- Logistical nightmare if used for 9/11
- WINID

Computerization and Dental Forensics

- CAPMI-Computer Aided Post Mortem Identification used by military for Korean era and Vietnam MIAs.
- Algorithm in DOS-based program to coordinate data and allow searches of limited nature. Limitations were inability to link graphics or type of information that could be coded.

NCIC

- NCIC-Nat’l Crime Information Center used as repository of criminal records and dental information on missing individuals.
- Limitations were difficult coding system and redundant codes. Usually entered by law enforcement with limited dental knowledge—high error rate.
- Only 3% of missing persons have dental data in NCIC while 50% of unidentified persons recovered have dental data usable for comparison.

WinID

- Dr. Jim McGivney—computer science major in college and forensic dentist
- Windows-base using best of CAPMI and added to it.
- Simple and uniform coding system
- DMD can compare ante and post with high degree of certainty and confidence
- Odontogram-visual presentation of teeth with fillings for easier comparison
- Allows for linkage of graphics
Linkage of graphics

- Dentist can scan ante mortem and post mortem radiographs and perform split screen search without having to open each case file or look at files individually.
- In a large disaster, a dentist who finds a unique post mortem remains may come up with 30 possible matches. Using graphics, they could access radiographs of all 30 and review them in 10 minutes, a task that would have taken hours previously.

WinID Advantages

- Dual input screens (one for ante-mortem and one for post mortem) minimizing error.
- Ability to search for specific restorations.
- Ex: lower right second premolar found with three surface amalgam restoration.
  #28-MOD. Can search any ante mortem records with that restoration filtering possible field of matches.

WinID Match feature does NOT make an identification, it just filters.

- Filters using most common features between ante mortem and post mortem but also the least number of mismatches or inconsistencies
- Some inconsistencies could be caused by missed coding or transcription error.
- Missing premolar in post-orthodontic patient coded as first premolar when it’s second premolar

Uses of Win ID

- Egypt Air 1999
- Guam plane crash 2000
- DMORT uses it because of ease in use and training.
- Can code subcategories-pins, posts
- Can code and search by non-dental features-tattoos, scars, DOB, sex, hair color, artificial joints

Exit Button

Clicking the Exit Button will exit the operator from WinID and save the additions and changes made to the database since the last save or the last time this particular database was opened. If you wish to preserve the original database without any changes, go to the File Menu and use the “Save Database As” command and save the newly changed database under a different name.

See Slide 7-8 of this module to review the “Save Database As” command.

To minimize error, avoid Distractions. Or, the number 1 reason to have a warranty.
Level Needed for an Identification

- There are no minimal number of points needed like fingerprints.
- A single tooth can be sufficient for positive ID if enough features exist while a full set of radiographs may be insufficient.
- Discretion of identification lies with odontologist who must be prepared to justify their conclusions in court.

WinID

- Available to anyone at www.winid.com
- Standard program-DMORT, NYC OCME and military
  *Used to separate 9/11 identifications and American Airlines #587 crashed in Rockaway Queens on 11/12/01 killing 246 people on plane and ground.
  *DM-disaster Manhattan
  *DQ-disaster Queens

AA #587

- Identifications completed in 1 week due to up and running infrastructure at ME’s office and cooperation from government and dentists in NYC and Dominican Republic.

Alternative Computerized Systems

- At present there are 12 different systems used to number teeth throughout the world. In US, a universal system facilitates transfer of information.
- DAVID-Disaster and victim Identification Used in Australia to account for different numbering systems.

Forensics-Ideal and Reality

- Ideally- everything coordinated to help identify the victims in a quick orderly fashion
- Reality- ID process is same as that in routine comparative dental ID but the inherent dental problems are magnified. Problems of body fragments, mutilation, commingling and incineration, idiosyncratic dental records from numerous regions, poor working conditions and psychological stress confound the ID process.

Psychological Implications

- Not any dentist or dental student with some training can practice forensic dentistry.
- Stress of dealing with human remains can have long-lasting effects on the unprepared.
- US Air #427- Pittsburgh 1994- dental students used to comb the wreckage as a ‘learning experience’.
- Follow-up studies by mental health workers detailed increased levels of psychosomatic illnesses even years later particularly among the students.
The Future

- Computer Technology boon for forensic dentistry.
- FBI is considering development of a high speed dental identification system akin to its AFIS system for fingerprint recognition to compare thousands of records and rank matches.
- Post 9/11, without computers, digital technology or WinID, identification would have been nearly impossible.

Attention to Detail and Your Forensic Reputation

Once lost, it can never be regained. The margin of error is zero.

Thank you

Questions ???
SATURDAY, FEBRUARY 24

COLONIAL | 3:45 pm - 5:00 pm

GENERAL SESSION II: Physician/Attorney Financial Planning, Business and Asset Protection
Moderator: Raymund King, MD, JD, FCLM

• 3:45 PM - 4:15 PM Retirement and Asset Protection Trusts, Mark Monasky, MD, JD, FCLM
• 4:15 PM - 4:45 PM Winding Up and Practice Transfers, Mark Monasky, MD, JD, FCLM
• 4:45 PM - 5:00 PM Q & A General Session II
Sample Forensic Identification

The Future

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Thank you

Questions???
What is asset protection planning?

- Planning strategies which place assets beyond the reach of future creditors
- Does not protect against present or reasonably foreseeable future creditors
- Best AP planning is not AP planning at all

Why asset protection planning?

- Many lawsuits not covered by insurance
- Expanding theories of liability
- U.S. allows lawyers to accept cases on contingency fee
- Result-oriented judges and juries
- Deep pocket syndrome
- Divorce
- Bankruptcy

ASSET PROTECTION IS NOT ABOUT

- Hiding assets
- Avoiding taxes
- Fraudulent transfers
- Avoiding taxes
- Moving assets overseas
- Being irresponsible

BASICS OF ASSET PROTECTION

- Insurance
  - Auto, home, disability, malpractice, E & O, life, umbrella
  - Reduce risk
  - Qualified retirement Plans & IRAs
- Change ownership
  - Business entities: partnership, LLC, corporations
  - Trusts
Is asset protection planning legal?

The U.S. Supreme Court in the 1999 case, Grupo Mexicano de Desarrollo, stated that “there is absolutely nothing new about debtors trying to avoid paying their debts or seeking to favor some creditors over others – or even about their seeking to achieve these ends through sophisticated strategies” and went on to say that the transfer of a debtor to avoid creditors in pursuing their own interest “is entirely proper and predictable.”

ASSET PROTECTION REQUIRES MULTIPLE SKILL SETS

- Estate planning
- Tax law: income, gift, estate, GST
- Real estate law
- Trusts
- Probate
- Business law
- Federal and state law
- Retirement plans, ERISA
- Bankruptcy law
- Creditor – debtor law

BUSINESS ENTITIES

- Corporation, C-corp or S-corp
- Partnerships
  - General, LP, LLP, LLLP
  - LLC
  - Sole proprietorship

Planning With LPs and LLCs

- Charging Order Protection
  - A charging order gives the creditor the rights of an assignee of a partnership interest
  - The creditor does not receive any management or voting rights.

- Veil Piercing
  - Reverse Veil Piercing
  - Constructive Trust
  - Alter Ego

TRUSTS

- Revocable
  - Historically no asset protection, against public policy
  - Incomplete gift, doesn't matter who beneficiaries are
  - RLT (revocable living trust)

- Irrevocable – third party beneficiary
  - Great asset protection
  - Complete gift
  - Traditionally all trusts other than revocable trusts

- Irrevocable – settlor is beneficiary
  - DAPT (domestic asset protection trust)
  - Historically no asset protection, against public policy

FRAUDULENT TRANSFER

- UFTA (UNIFORM FRAUDULENT TRANSFER ACT)
- UVTA (UNIFORM VOIDABLE TRANSFER ACT)
- Statute of Elizabeth
  - Delay, hinder, or defraud
  - Actual or constructive
  - Existing and future creditors
BADGES OF FRAUD

- a) Transfer to an insider
- b) Debtor retains possession or control
- c) Concealment
- d) Lawsuit commenced prior to transfer
- e) The transfer involved substantially all of debtor’s assets
- f) Debtor absconded
- g) Concealment of assets
- h) Consideration received by debtor less than value of asset
- i) Debtor was insolvent or became insolvent shortly after transfer

DAPT - OVERVIEW

- Self-settled irrevocable trust where settlor is discretionary beneficiary
- Directed trust statute
- Hybrid DAPT
  - Irrevocable third party trust where trust protector has power to add grantor as discretionary beneficiary
  - A DAPT that moves offshore when a creditor threat arises

DAPT - ADMINISTRATION

- Administrative trustee
- Investment Trustee
- Distribution Trustee
- Trust protector

TRUST PROTECTOR

- Amend trust
- Terminate trust
- Decant to another trust
- Removal and replacement of trustees
- Direct investments
- Modify withdrawal rights
- Approve or reject trustee accounting
- Construe terms of trust
- Limit information to beneficiaries
- Refuse a contribution

CONSTITUTIONAL ISSUES

- Supremacy Clause
- Full Faith and Credit Clause
- Contract Clause

DAPT – CONFLICT OF LAWS

- Location of assets
- Domicile of beneficiary
- Venue of cause of action
- Governing law of trust
- Domicile of trustee
- Always have at least 3 out of 5 factors in your favor
- Public policy and real property exceptions
DAPT — GRANTOR AS BENEFICIARY

- Estate tax inclusions theories
  - 2036, 2038
  - Creditor’s rights
  - Implied agreement
  - Grantor trust
- Incomplete v. Complete gift

WHY A RETIREMENT TRUST?

- Why not name beneficiary directly (other than spouse)?
- Stretch distributions decided by beneficiary, not you
- The issue was whether an inherited IRA retains its character as a "retirement account" in the setting of bankruptcy. The Court ruled NO.
  - No protection in bankruptcy
- Alternatives that provide asset protection
  - Retirement trust
  - Trusteed IRA

RETIREMENT TRUSTS

- Apply only to inherited retirement plans (i.e. at owner’s death)
- Only the individual owner of the plan (not a trust) can receive RMDs while living
- Primary beneficiary is spouse, secondary beneficiaries are separate retirement trusts for each child
- Qualified retirement plans are trusts by definition under the IRC, so a qualified plan or IRA can never be placed into a trust

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RETIREMENT TRUSTS

- Conduit
  - RMDs paid out of trust directly to beneficiary
  - Trustee may mandate beneficiary take stretch distribution
  - Assets lose protection once paid out of trust
  - Taxed at beneficiary’s tax rate
- Accumulation
  - May accumulate assets in trust if beneficiary has creditors
  - Trust taxed at higher tax rate
  - Works best for Roth IRA beneficiaries

Practical Applications

<table>
<thead>
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<th>Conduit</th>
<th>Accumulation</th>
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<tbody>
<tr>
<td>&quot;Perfect&quot; Child</td>
<td>Trusteed Child</td>
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<td>Substance Abuse</td>
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<td>Marital Issues</td>
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<td>No Spenderthrift Issues</td>
<td>Professional Issues</td>
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<td>Strong Marriage</td>
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<td>Non-exempt GST Planning</td>
<td>Spendingthrift</td>
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<td>Order remainder beneficiaries</td>
<td>Exempt GST Trust</td>
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</tbody>
</table>
| Roth IRA | }
Advantages of Conduit Trust

- Certainty – supported by Treasury Regulations
- Greatest flexibility for remainder and contingent beneficiaries
- Easiest to achieve desired distribution pattern
- Best used for IRAs with low basis, i.e. traditional IRAs

Advantages of Accumulation Trust

- Trustee discretion maintained
- Asset Protection
- Substance or spendthrift Issues
- Incentive Trust provisions
- Best use for inherited Roth IRAs

GSTT Issues

- Normally allocating GST exemption to trusts designed to be funded with IRAs is not an efficient use of GST exemption because it is an item of IRD
- Roth IRAs an exception

MD Wealth Protector

A niche law firm

MD Wealth Protector, LLC
A NICHÉ LAW FIRM

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MRPC Rule 1.17 Sale Of Law Practice

- A lawyer or a law firm may sell or purchase a law practice, or an area of law practice, including good will, if the following conditions are satisfied:
- (a) The seller ceases to engage in the private practice of law, or in the area of practice that has been sold, (in the geographic area) (in the jurisdiction) (a jurisdiction may elect either version) in which the practice has been conducted;
- (b) The entire practice, or the entire area of practice, is sold to one or more lawyers or law firms;

Rule 1.17 Sale Of Law Practice

- (c) The seller gives written notice to each of the seller's clients regarding:
  - (1) the proposed sale;
  - (2) the client's right to retain other counsel or to take possession of the file; and
  - (3) the fact that the client's consent to the transfer of the client's files will be presumed if the client does not take any action or does not otherwise object within ninety (90) days of receipt of the notice.

If a client cannot be given notice, the representation of that client may be transferred to the purchaser only upon entry of an order so authorizing by a court having jurisdiction. The seller may disclose to the court in camera information relating to the representation only to the extent necessary to obtain an order authorizing the transfer of a file.

- (d) The fees charged clients shall not be increased by reason of the sale

CLOSING A MEDICAL PRACTICE

- Relocation, retirement, disability, or death
- Variations in state law
- Patient notification: 2-3 months
- Employees: notify early, offer incentives to stay until end
- Insurance carriers: Medicare, Tricare, Medicaid, Private
  - Beware contract terms and payment cycles for capitated contracts, HMOs, PPOs
CLOSING A MEDICAL PRACTICE

- Licensing agencies
- Malpractice carriers: tail insurance
- Notify referring physicians
- Landlord
- Medical Societies

MEDICAL RECORDS

- Ownership:
  - Physical record, paper or electronic, property of practice
  - Information in record property of patient
- Retention: How long?
  - 10 years or until statute of limitations expires
  - Patient notified prior to destruction
  - Children, age of majority + statute of limitations
  - State law or insurer requirements
- Transfer
  - Written authorization by patient
  - Guaranteed access by you for liability purposes

MEDICAL RECORDS

- Storage
  - Secure (whether physical or electronic) from loss, tampering, unauthorized access
  - State law
- Destruction
  - Use professional destruction service
  - Obtain certificate of destruction
  - Incineration, shredding, pulverization, reformatting, demagnetization
  - HIPAA
  - Retain documents for 6 years

ACCOUNTS RECEIVABLE

- Single large asset of most practices
- Need to continue collection efforts after practice closed
- Sell to a factoring company
- Often most important factor in determining severance pay

BUY-SELL AGREEMENTS

- Does not apply where professional (usually a physician) is merely an employee and has no ownership interest in organization
- Usual rules don’t apply
- State law restricts ownership to licensed professionals

BUY-SELL AGREEMENTS

- Closely interrelated with employment contract
- In most cases, provisions normally found in buy-sell agreement for a nonprofessional entity are often placed in employment contract (or partnership agreement or Operating Agreement in the case of partnerships or LLCs)
- Most equitable way is to coordinate buy-in with buy-out
**Valuation**

- Work in progress
- Accounts receivable
- Hard assets
- Going concern
- Goodwill
- Contractual relationships

**Triggering Events**

- Retirement
- Disability
- Death
- Loss of license
- Reduced workload
- Termination
  - Voluntary
  - Involuntary, for cause and not for cause
- Sale of practice
- Divorce, marital or business

**PAYMENT STRATEGIES & TAX CONSEQUENCES UNDER BUY-SELL**

- Accounts receivable
- Going concern/goodwill
- Covenant not to compete
- Basis in stock, partnership or membership interest
- Consulting agreements
- Severance pay
- Nonqualified deferred compensation
- Real estate

**SPECIFIC STRATEGIES – low price stock buy-in**

- Professional buying-in purchase stock at low price (avoids purchasing stock with after-tax dollars, thus increasing basis in stock)
- New shareholder essentially acquires interest in entity with pretax dollars
- This allows older shareholders to avoid reduced salaries as they are not subsidizing new shareholder
- If significant portion of buy-in through salary reduction, then buyout best done through severance pay (which is tied to outstanding accounts receivable of retiring professional)
- Pre-tax buy-in, pay ordinary tax at buy-out

**SPECIFIC STRATEGIES – high price stock buy-in**

- Professional buying-in purchase stock at high price (purchase accounts receivable with after-tax dollars, thus increasing basis in stock)
- New shareholder acquires interest in entity with after-tax dollars
- Existing shareholders do not receive reduced salaries as they are not subsidizing new shareholder
- If significant portion of buy-in through high price stock, then buyout done by older shareholder selling stock to new buying shareholder, with resultant capital gains tax
- After-tax buy-in, pay lower capital gains tax at buy-out

**OTHER FACTORS IN BUY-SELL**

- Length of service
- Special expertise or national prominence
- Severance pay
  - Cautions must be taken so IRS does not reclassify severance pay as deferred compensation
  - Deferred comp subject to ERISA, and FICA tax (payable by both professional and corporation) due upon deferral (as opposed to receipt of funds)
  - Must not be contingent upon employee retiring
  - Payments no longer than two years
  - Must not exceed twice the annual compensation for previous 2 years
  - Still subject to IRC 409A Nonqualified Deferred Compensation
SEVERANCE PAY – DETERMINING AMOUNT

• Percentage of accounts receivable and work in progress
  • Bad debt, collection costs, reduced payments (managed care contracts)
  • Amount actually collected
  • Endpoint
  • Percent of compensation over 1-3 year periop prior to retirement
  • Additional amount to compensated for nonvested retirement monies (be careful to avoid ERISA violations)

ACCOUNTS RECEIVABLE

• Along with work in progress, represent bulk of assets of professional practice
• Fully deductible to organization if paid out to professional
• Ordinary income to professional
• FICA applies
• Taxed at 21% if retained in corporation

Retirement/Reduced workload

• On call issues
• Phase-in of stock repurchase and buy-sell agreement
• Age discrimination issues
• Of Counsel in law firms

COVENANT NOT TO COMPETE

• Very prevalent in professional organizations
• State laws vary considerably as to enforceability
• Payments to physician/attorney generally deductible by organization
• Ordinary income to professional
• FICA taxes at individual and corporate level
• IRS will scrutinize closely
  • Professional must be in good health and available
  • Covenant must not be illusory

STOCK OR PARTNERSHIP OR MEMBERSHIP INTEREST

• Basis
• Capital gains
• Selling professional pays capital gains
• Not deductible to purchasing corporation

Consulting agreement

• Common in nonprofessional organizations
• May violate fraud and abuse and antikickback laws
• Generally deductible to organization
• Ordinary income to professional
• FICA taxes
SATURDAY, FEBRUARY 24

GOLD  |  7:30 pm - 9:15 pm

ANNUAL AWARDS BANQUET (Ethics credit)
Age Friendly Cities: Promoting, Health, Ethics and Justice
Presenter: Anabel Pelham, PhD
World Health Organization’s Age-Friendly Cities Initiative

“...to engage cities to become more age-friendly so as to tap the potential that older people represent for humanity.”

Creating Caring Communities

Gerontologists continue to make major contributions to our understanding of aging and quality of life.

The Ecological Model of Aging: CONTEXT MATTERS to health, wellness, independence, life satisfaction, and more.

Eight Domains of Livability

- Outdoor spaces and buildings
- Transportation
- Housing
- Social Participation
- Respect and Social Inclusion
- Civic Participation and employment
- Communication and Information
- Community Support & Health Services

In 2050, older adults will represent 22% of the world’s population.

Two-thirds of these will live within city limits.

World Health Organization

Age Friendly Network Founded in 2005
Currently 541 cities in 37 countries. 179 million people worldwide (2018).
CAFE: Advancing Inclusive Communities

Anabel Pelham, Ph.D. Professor
Center for Age Friendly Excellence (CAFE)

World Health Organization’s Age-Friendly Cities Initiative

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- Civic Participation and employment
- Communication and Information
- Community Support & Health Services
Examples: Outdoor Spaces and Buildings

- Clustersed shopping & services
- Elevators and ramps
- Traffic islands
- Public toilets
- Non-slip walkways
- Rest areas
- Lighting
- Stair railings
- Easy-to-read signs
- Law enforcement
- Public seating
- Green spaces
- Extended time at pedestrian crossings

Outdoor Spaces and Buildings

2020 Trees by 2020 Challenge

3-year CIP between Grassroots Ecology & Town of Los Altos Hills to provide community engagement & walking habitat enhancement at 3 local Open Space Preserves

Mobility

- Pedestrian
- Bicycles
- Public Transportation
- Automobiles
- Self driving cars

San Jose, California

Lincoln Avenue Road Diet: Removing vehicle lane to add a bike lane & a two-way left-turn lane

Los Altos Hills, California

Senior Friendly Pathways Walk
Housing

- Location
- Structure
- Design
- Choice
- Availability
- Accessibility

Housing

Helping residents of mobile homes avoid displacement

San Jose, California

Housing

The Bay Area Senior Health Policy Coalition is hosting this event next month in South SF!

Initiatives and Innovative Housing Models Addressing the Needs of the Aging Population

How Do You Finance Housing for Seniors and What Are the Policy Solutions to Address Housing?

Social Participation

- leisure,
- social,
- cultural,
- spiritual, and
- family activities

Social Participation

Happy Hollow Park & Zoo offers free admission & parking exclusively for those age 50+

San Jose, California

Respect, Social Inclusion

From family, community, service providers.

San Jose, California
Respect, Social Inclusion

El Toro Social Club: The Prime Lifers (the new term for Active +50 Adults)
Morgan Hill, California

Civic Participation/Employment

- Volunteerism
- Paid employment
- Entrepreneurism
- Social perception of older workers

South County Lifelong Learning (SCLL): classes, lectures & discussions for 50+
Morgan Hill, California

Civic Participation/Employment

A free education series via Los Altos Forward with experts about ways to enhance downtown Los Altos. 2018 is a focus on housing and transportation for older persons.
Los Altos, California

Communication/Information

Information & social inclusivity
Staying linked to people and events
Los Altos, California
“Blazing Trails” Active Aging Video Clip: in honor of Older American Month
https://youtu.be/y1eaaLA41Oo

Morgan Hill Life Newspaper & Senior Advisory members column

High-quality, available, appropriate, and accessible services

City of San Jose opens its first Vietnamese American Community Center (VACC)

Community Services on Wheels is “a mobile social service agency, providing a food pantry, emergency financial assistance & supportive services to homeless and low-income residents/seniors of Saratoga, Los Gatos & West San Jose

A Five Year Commitment
• Planning (Year 1-2)
• Implementation (Year 3-5)
• Progress Evaluation (End of Year 5)
• Continual Improvement
Global Network of Age-Friendly Cities

Network Membership
Cities participating in a global network commit to a cycle of continually assessing and improving their age-friendliness.

An Age-friendly city generates:
• Economic Benefits
• Social Capital
• Infrastructure Innovations
• Healthy Communities

What we do: First Steps
• Organize an age-friendly taskforce
• Assessment
• Focus groups
• Surveying
• Develop project ideas to meet needs
• Mayor signs application
• Submit application to WHO

Age Friendly Initiative
All Santa Clara County cities have applied to become World Health Organization-designated Age Friendly Cities

An Age-friendly city is an inclusive and accessible urban environment that promotes active aging

A Holistic Model

“We must be Age-Friendly in our policies, priorities and resources for sure we are well prepared and trailblazers in creating a livable Santa Clara County for the 8 to 60 year olds.”
SUNDAY, FEBRUARY 25

COLONIAL | 7:45 am - 9:30 am
GENERAL SESSION III: Hot Topics in Health Law and Legal Medicine
Moderator: Robert Bitonte, MD, JD, FCLM
• 7:45 AM - 8:15 AM America Gone to Pot: The Medical Legal Impact of Recreational Marijuana Legalization Paul Blaylock, MD, JD, FCLM
• 8:15 AM - 8:45 AM Top Regulatory and Billing Risks Facing Dentists and Dental Practices Robert Liles, JD
• 8:45 AM - 9:15 AM The Lumbar Spine: Preexisting Condition, New Injury or Aggravation? What Does Science Tell Us? Marjorie Eskay-Auerbach, MD, JD, FCLM
• 9:15 AM - 9:30 AM Q&A General Session III

COLONIAL | 9:30 am - 10:30 am
GENERAL SESSION IV: Student Writing Awards
Moderator: Robert Buckman, PhD, FCLM, President, ACLM Foundation
(This Session made possible by an ACLM Foundation Grant.)
• 9:30 AM - 9:50 AM Student Writing Awards – Hirsh Award
• 9:50 AM - 10:10 AM Student Writing Awards – Orr Award
• 10:10 AM - 10:30 AM Student Writing Awards – Gene Basanta Poster Award

COLONIAL | 10:45 am – 12:30 pm
GENERAL SESSION V: Daubert at 25: Where Have We Come?
Moderator: Leon Aussprung, MD, JD, FCLM
• 10:45 AM - 11:15 AM Daubert and Expert Witnesses: A Historical Perspective Jack Snyder, MD, JD, FCLM
• 11:15 AM - 11:45 AM Daubert: Plaintiff’s Counsel’s Perspective François Blaudeau, MD, JD, FCLM
• 11:45 AM - 12:15 PM Daubert: Defense Counsel’s Perspective Joe Piorkowski, MD, JD, FCLM
• 12:15 PM - 12:30 PM Q&A General Session
SUNDAY, FEBRUARY 25

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  Robert Liles, JD

• 8:45 AM - 9:15 AM The Lumbar Spine: Preexisting Condition, New Injury or Aggravation? What Does Science Tell Us?  
  Marjorie Eskay-Auerbach, MD, JD, FCLM

• 9:15 AM - 9:30 AM Q & A General Session III
"America Gone To Pot: Medical Legal Impact of Recreational Marijuana Legalization"

ACLM 2018 CHARLESTON, S.C.

5. MYTH: Marijuana is a gateway drug to more use. Pre-teen advocates claim it as an "easy" drug planted. FACT: CDC reports that 20% of opiate users begin with pot use. High school students lie in their drug use reports.

6. MYTH: Pot does not have any immediate effects on the brain. FACT: Medical studies show an immediate effect of marijuana on the human brain's processing of emotions, behavior, digestion, if altered space perception, it's psychomotor activity, it lowered reaction time, it impaired judgment/motor skills, it caused delusions, and it caused personal and social problems.

7. C. F. T. Energy brain function is not susceptible to neurological impairment than in adults. FACT: 60% of high school students who use marijuana regularly have a compromised attention span and impaired judgment/motor skills. difficulty with concentration, increased risk of death, and more.

8. B. A. A. Belief that chronic use of marijuana is not habit forming in addiction. FACT: Recent studies show that marijuana affects a person's behavior and functioning in a way that is similar to the way alcohol affects a person. It is the most widely used illegal substance in the U.S. and is controlled in 29 states.

9. E.M.Y.: Chronic pot use does not increase likelihood of use of other forms of substance. FACT: Early results show increased use in psychiatric behavior in age 10-21.

Fact: It is illegal to drive under the influence of marijuana in every state. The question is how do you prove the driver was under the influence and impaired?

Fact: It is clear from early data from the earliest legalization states (Colorado, Washington, and Oregon), that the injury/accidens/fatality impact is escalating. Which should give other states eyesing legalization pause... but... America continues to go to pot!
CONCLUSIONS / PREDICTIONS

1. Lack of public education about the marijuana effect on driving skills is a major problem. LeVeon Bell, All Pro Pittsburgh running back told the police: “I didn’t know you could get a DUI for being high.” He learned it with a suspension, fine, and community service. Another example of ignorance is when a Oregon football player was pulled over at 100 mph. As the heavy smoke billowed out his car window, he told the cop “he was sorry, but we smoked it all”…thinking he couldn’t be cited if no joints found. As I said, most drivers still believe you can’t prove impairment.

2. As of Jan. 1, 2018, eight (8) states have legalized recreational marijuana (Oregon, Washington, California, Alaska, Maine, Massachusetts, Nevada, and Colorado).

3. Americans are conducting a big experiment with marijuana, which is having a physiologic impact on young brains in our country. I coined the phrase 2 years ago “Drug Concussed Driving”!

   a. My advice if you live in a legalized state, assume the guy in front, beside, and behind you is “buzzed.” Educate your children to avoid rides with buzzed drivers.

   b. Remember: 1) Slow Reaction Time; 2) Poor Concentration; 3) Impaired Peripheral Vision are not a good combination for a driver.

   c. Welcome to the “Stoned Age”… America is going to pot… & that’s not fake news!
I. Overview of the Current Enforcement Landscape

Expenditures for Dental Services

• The Centers for Medicare and Medicaid Services (CMS) estimates that in 2016, health care spending increased 4.3% and cost approximately $3.3 trillion. Notably, approximately 4% of this $3.3 trillion was spent on dental services. The amount of money spent on dental services is more than what is spent on home health services and more than twice what is spent on durable medical equipment each year.

• Based on spending alone, you would think that law enforcement would have dedicated significant investigation and prosecution resources to this specialty area long ago. In years past that hasn’t been the case, likely due to the fact that most dental services are not covered under Medicare. However, over the last three years, we have seen a resurgence in state and federal prosecutions of dental fraud.

Federal Efforts

• Notably, health care enforcement efforts are not limited to only Strike Force territories. Each of the 94 U.S. Attorneys Offices around the country have dedicated civil and criminal prosecutors investigating health care fraud and abuse matters.

• During FY 2017, the federal government won or negotiated over $3.7 billion in judgments and settlements under the False Claims Act. Of this total, $2.4 billion came from individuals and entities in the health care industry.

• This is the eighth consecutive year that the department’s civil health care fraud settlements and judgments have exceeded $2 billion.

• During FY 2017, 674 qui tam (whistleblower) cases were filed and the DOJ recovered approximately $3.4 billion in connection with these whistleblower actions brought under the False Claims Act. Of this amount, approximately $393 million was awarded to the whistleblowers.

• In contrast, during FY 2017, 125 non-qui tam cases were brought under the federal False Claims Act.

• Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than $56 billion.

Impact of the “Yates Memo”

On September 9, 2015, Deputy Attorney General Sally Yates issued a memorandum entitled “Individual Accountability for Corporate Wrongdoing.” This important document instructs DOJ prosecutors to stop resolving corporate cases that release individuals from personal liability, (in the absence of extraordinary circumstances).
I. Overview of the Current Enforcement Landscape

Targeting

• How are state and federal law enforcement agencies (and private payor SIUs) identifying improper dental billing patterns? Auditors have developed several measures, in consultation with experts at state Medicaid agencies, CMS, ADA, and the AAPD, to identify providers with billing patterns that are noticeably different than their peers.

• What measures are typically reviewed? Law enforcement and private payor SIUs use measures designed to analyze dental claims in order to identify:
   Dentists who received extremely high payments per patient;
   Dentists who rendered an extremely large number of services per day;
   Dentists who provided an extremely large number of services per patient per visit;
   Dentists who provided services to an extremely large number of children and other patients;
   Dentists who provided certain selected services to an extremely high proportion of children, i.e., pulpotomies and extractions.

II. Dental Cases Brought Under the False Claims Act.

Provisions of the False Claims Act? Simply put, the federal civil False Claims Act (FCA) imposes civil monetary penalties and damages on any person who knowingly submits, or causes to be submitted, a false claim to the government for payment.

• The term “knowingly” does not merely mean “actual knowledge,” the term also includes reckless disregard and deliberate ignorance. 31 U.S.C. § 3729-3733.

• Approximately 30 states, along with the District of Columbia and some municipalities also have laws similar to the federal False Claims Act.

II. Dental Cases Brought Under the False Claims Act.

Statute of limitations, damages and penalties under the False Claims Act.

• Generally, the False Claims Act has a six-year statute of limitations that can be tolled (under certain circumstances) up to a maximum of ten years from when the government knew, or reasonably should have known, that the violation occurred. 31 U.S.C. § 3731(b).

• The penalties for violations of the False Claims Act have been raised effective February 3, 2017:
   Treble damages plus
   $10,957 and $21,916 per false claim or statement.

Health care reform changes to the False Claims Act.

• The Affordable Care Act included a number of changes to the False Claims Act. Under the statute, the term “overpayments” was defined as “any funds that a person receives or retains” under Medicare or Medicaid, to which they are not entitled.

• The Affordable Care Act further provides that all overpayments must be reported and refunded within 60 days of being identified.

• Moreover, the legislation made it clear that a repayment retained by a person after the deadline for reporting and returning the “overpayment” qualifies as an “obligation” for purposes of the False Claims Act.

The bottom line is clear – should you identify an overpayment, it must be repaid within 60 days or the provider may be liable under the False Claims Act.

II. Dental Cases Brought Under the False Claims Act.

Recent dental cases brought under the False Claims Act

• January 2018. DOJ prosecutors announced it had settled False Claims Act allegations against a dental management company and more than 130 of its affiliated dental clinics for $23.9 million in connection with false Medicaid claims filed for pediatric dental services. Allegations included billing Medicaid for medically unnecessary services and for services not rendered, The government also alleged that the defendant’s routinely pressured and incentivized dentists to meet production goals through a system that disciplined unproductive dentists and awarded productive dentists with substantial cash bonuses. Moreover, the defendants ignored complaints from their own dentists regarding overutilization.

• September 2017. Connecticut Attorney General brought a state False Claims Act case against a Fairfield dentist alleging that $900,000 billed to the state Medicaid program for elderly Medicaid patients in assisted living facilities were not provided. Services billed for multi-surface restorations, repairs for dentures and sets of dentures were allegedly not provided. The state also noted that services performed on dentures for the same teeth that cavities were supposedly filled were also billed to Medicaid.
II. Dental Cases Brought Under the False Claims Act.

- Recent dental cases brought under the False Claims Act:
  - December 2017: NEVS federal prosecutors sought an FCA case against a
    Texas-based, managed care, 10 affiliated dental practices, their owners
    and marketing chief for $64.7 million. The government alleged that dental
    clinics in 17 states submitted false claims for:
    - Submitting claims to Medicaid for dental services that were not
      provided.
    - Paid kickbacks to Medicaid beneficiaries and their families, marketers
      and marketing entities in violation of the Anti-kickback statute.
    - Used erroneous Medicaid provider numbers misrepresenting the
      dentists performing pediatric dental procedures.

III. Criminal Cases Brought Against Dentists and Dental Entities.

- Penalties under the Anti-Kickback Statute can include:
  - A fine up to $25,000.
  - Exclusion from participation in federal and state health care benefit programs.
  - Civil monetary penalties (CMPs) of up to $25,000 per violation and
    assessments equal to not more than three times the amount of remuneration
    paid under the arrangement.

-More and more prosecutors are including a charge of
  Improperly using a patient’s identity.

- Failure to properly document opioid medical necessity

- This change is noteworthy. It effectively lessens the requirements needed
  for the government to bring a criminal case under the anti-kickback
  statute.

- Under § 6402(f)(2) of the Affordable Care Act:
  - Codified at 42 U.S.C. § 1320a–7b(b), the federal anti-kickback statute was
    simply enacted in 1972. Under this statute, it is a crime to
    knowingly and willfully a means of identification of another person, shall, in additional to the
    predicate offense
    subsection (c) 
    government. Under this statute, whoever during and in relation to any felony enumerated in
    "aggravated identity theft (18 U.S.C. § 1028A)
    in health care fraud cases brought by the
    Improperly using a patient's identity.

- Notably, the 9th Circuit also follows the "one purpose test." See U.S. v. Davis, 132
  F.3d 1062 (9th Cir. 1998).

III. Criminal Cases Brought Against Dentists and Dental Entities.

- The Anti-Kickback Statute is an intent-based statute.

- A violation of this statute can also result in Civil Monetary Penalties,
  civil assessments and exclusion from participation in federal and state
  health benefit programs.

- The Anti-Kickback Statute is a criminal statute that can
  result in fines up to $25,000 per violation and up to 5 years in prison per
  violation.

- Under the Affordable Care Act, a violation of the Anti-Kickback Statute
  can also be pursued as a violation of the civil False Claims Act.

- A violation of this statute can also result in Civil Monetary Penalties,
  civil assessments and exclusion from participation in federal and state
  health benefit programs.

Emerging Arguments Relied on by DOJ

- Other take away is to keep in mind:
  - Penalties under the Anti-Kickback Statute.
  - "Prescriptions of opioids that are outside of usual medical practice and
    without a legitimate medical necessity;" Several of the recent criminal
    prosecutions involved situations such as this.

- "Prescriptions of opioids that are outside of usual medical practice and
  without a legitimate medical necessity;" Several of the recent criminal
  prosecutions involved situations such as this.

- Examinations using a patient’s identity: More and more prosecutions are including a charge of
  Improperly using a patient’s identity.

- Examples of the 9th Circuit's inclusion:
  - 18 U.S.C. § 1001 (relating to mail fraud).
  - 18 U.S.C. § 1035 (relating to false statements relating to health care matters),
  - 18 U.S.C. § 1001 (relating to false statements or entries generally),
III. Criminal Cases Brought Against Dentists and Dental Entities.

Criminal cases brought against dentists and dental entities.

• December 2017: The local news in Anchorage, Alaska spotlighted the fact that a local dental who had been charged with Medicaid fraud went to trial. At the conclusion of the trial, the jury returned a verdict of guilty on five counts of fraud.

• November 2017: Michigan’s Attorney General announced that his office had successfully apprehended a fugitive dentist that had been wanted by the state regulatory entity for over a year due to non-payment of taxes.

IV. Common Errors Identified in GAP Analyses of Dental Claims

• Failure to comply with state and / or contractual documentation requirements. The state of California has been cited in numerous GAP analyses for failure to comply with state and / or contractual documentation requirements empowers the state to perform audits and will likely be subject to close scrutiny in an audit.

• Failure to provide a complete medical history for each pediatric patient.

• Failure to sign dental treatment notes. Dentists failed to include any observations or interpretations on radiographic exposures and the dentist’s interpretations.

• Failure to record observations from x-rays. The dental notes did indicate, for most patients, findings: medical conditions and / or illness; name and telephone number of primary and specialty care providers; medications; allergies / reactions to medications; other allergies / sensitivities; immunizations status; review of systems; family history; and social history.

• Missing dental treatment plans / consent forms.

• Completed dental treatment plans and consent forms.

• Billing for services not rendered.

*In 2018 58TH ANNUAL MEETING*
IV. Common Errors Identified in GAP Analyses of Dental Claims

A. Unlicensed individuals found to have performed dental procedures. Generally speaking, we have seen two categories of cases where this has occurred, one which is truly egregious and one which is less egregious.

B. Unlicensed personnel providing care as a result of an administrative error. This typically occurs when a license fails to be timely renewed by state board. If you are performing dental procedures and your license has not been timely renewed, the state board may take disciplinary action against you.

IV. Common Errors Identified in GAP Analyses of Dental Claims

Other Potential Risk Areas

• Billing Medicaid for substantiated work.
• Billing Medicaid for multiple cleanings within a six month period.
• Too many or too few X-rays. In some cases, the X-rays have been taken incorrectly, taken for no indication, or taken at the wrong time.
• Inappropriate use of protective stabilization devices. For example, using a “papoose board” to immobilize the children, regardless of whether or not restraint was necessary.
• Concealing other available coverage. The failure to identify and bill additional dental care, coverage for which the patient may be eligible, is problematic.
• Misreporting of dates in an effort to evade calendar year maximums or time restrictions. Billing more than $1.3 million for those procedures. He further admitted that if those restrictions were not met, revenue would have been less.

V. Final Thoughts

Reducing Risk

Background Checks + Exclusion Screening

• Background checks. Criminal history services; Federal / DEA controlled substances. Many states allow you to check an individual’s criminal history in the government’s online databases.
• Have a few minutes, check out:
  • www.crimewatch.com “Job References” “Instant Degrees”
  • www.policedetectives.com “Fictitious References” “White Lies” “Alibis”
  • Bottom line: Exercise care when relying on a “background check.”

IV. Common Errors Identified in GAP Analyses of Dental Claims

7. Misreporting or Failing to Collect Co-Payments and Deductibles. At the outset, it is worth noting that the ADA Principles of Ethics and Code of Professional Conduct specifically address the waiver of co-payments in the November 2016 edition. The ADA guidance does not make a distinction between whether routine co-payments are paid by Medicaid recipients or not. If a provider fails to collect co-payments, the provider is not in violation of the Federal Medicare / Medicaid Anti-Kickback Statute, and exposes you and your practice to potential civil liability. (See HHS-OIG’s 1994 Fraud Alert).

8. Unbundling. Billing for a dental service or procedure at a higher level than was actually provided is known as “unbundling.” An example of unbundling has been illustrated by the August 2017 prosecution of a dentist out of Connecticut, who handled Medicaid payments on a bundling basis. According to the United States Attorney’s Office, the defendant dentist was paid $54,863,408 for services between January 1, 2014 and December 31, 2016. The defendant was alleged to have charged Medicaid for services that were either not provided or were not performed at the higher level. The defendant was sentenced to 3 years in prison and was ordered to pay $172,363,157 in restitution.

V. Final Thoughts

Reducing Risk

• Ensure that dental practices have an effective Compliance Program in place. This would include an approach to conduct periodic internal audits of claims to ensure that the services have been properly documented, and medically necessary and were coded / billed properly. When the last time you conducted an internal dental claims audit and examined whether the services you are providing fully reflected medical necessity requirements, were documented to meet the requirements of the payor, and are properly reimbursed?

• Be sure and engage any outside dental consultant? Be sure and engage any outside dental consultant through legal counsel.

• Ensure that the dental practices comply with the minimum professional standards of dentistry. For example, in one recent case, a dentist was alleged to have engaged in the performance of patient care that did not conform to minimum professional standards of dentistry (regardless of whether actual injury to the patient occurred).

• Dental providers should screen their applicants, clinical staff, administrative staff, contractors, vendors and agents on a regular basis. At this time, there are a total of 46 different databases that need to be checked. These 46 databases include:
  • (1) List of Excluded Individuals and Entities (LEIE). Maintained by HHS-OIG.
  • (2) System for Award Management (SAM). Maintained by the General Services Administration.
  • (3) 38 State Medicaid Exclusion Registries. Maintained by either the State Attorney General’s Office or the State Medicaid Fraud Control Unit (MFUC)

Questions

This outline is provided as general information only. It does not constitute legal advice and should not be used as a substitute for seeking legal counsel.

Robert W. Liles is an attorney with the firm of Liles Parker, PLLC. He may be contacted at (205) 209-6700 or by e-mail at: rliles@lilesparker.com

2018 ACM 58TH ANNUAL MEETING
THE LUMBAR SPINE: PREEXISTING CONDITION, NEW INJURY OR AGGRAVATION? CAUSATION AND LOW BACK PAIN

19TH CENTURY APPROACH TO LBP

- Back pain was attributed to spinal trauma
- The pathology of “spinal irritation” was never demonstrated and the diagnosis disappeared, but the idea that the spine could be a source of pain and that it must be irritable remains.

SPINAL PAIN

- First attributed to injury or trauma in the Victorian era, with the rise of a diagnosis of “railway spine,” attributed to the excessive speed achieved by steam engine trains.
- This occurred in parallel with the rise of the worker’s compensation system in England

X-RAYS

- Visualization of the spine became an opportunity to explain both back pain and sciatica
  - Lumbosacral anomalies (Adams 1910, Danforth & Wilson 1925)
  - Facet joint degeneration (Goldthwaite 1911, Putty 1927)
  - SI disease (Goldthwaite and Osgood 1905)
- Surgeries were designed to correct these
  - SI joint fusion, lumbar fusion, etc.
  - Failed to resolve the problem

WW I & II

- Large number of casualties led to focus on injuries, fractures in particular
- Greater emphasis on back pain as an injury and part of orthopedics

“BACKACHE”

- Edwin Smith papyrus from 1,500 BC ends in the middle of a description of an acute back strain
- Degenerative changes have been found in the earliest human remains (Neandertal man)
APPLICATION OF ORTHOPEDIC PRINCIPLES

• 1900 – two to six weeks strict bedrest for acute LS pain (Bradford & Lovett 1900)
• Contrary to previous recommendations of mobilization, the notion that LBP and sciatica were due to traumatic inflammation gained ground
• CLBP would develop if primary injury was not treated properly with rest (Love 1938)


BACK PAIN WAS MEDICALIZED

• Back pain became a disease, the sufferer was a patient
• Rest removed the patient from everyday life and involved disability


AND IATROGENIC....

Number of surgical spine procedures that were performed in the US

CAN DOCTORS ACCURATELY ASSESS CAUSATION IN CASES WITHOUT MAJOR OBVIOUS TRAUMATIC INJURY?

• Most physicians are NOT trained in this.
• Many treating physician practices use a PA or NP to do the initial visit assessment, and PAs and NPs are NOT Trained in this.

CAUSATION: TWO WAYS TO THINK ABOUT IT

1. Could this exposure or risk factor cause or be part of the cause of the condition?

2. In this particular person, did this exposure ACTUALLY cause or contribute to this condition?

HILL'S CRITERIA FOR CAUSATION (IN GENERAL)

1. Strength of the association (epidemiology)
2. Temporality
3. Consistency among studies
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5. Experimental evidence
6. Plausibility of a biologic mechanism
7. Coherence of evidence
8. Analogy to a similar effect, from a similar agent
CAUSATION: WORK RELATED?

- Many physicians jump to conclusions about causation, and, therefore, Work Risk, using “common sense” or experience.
- Thinking ONLY about 2 of the 9, (temporality and plausibility, the two that do NOT require a knowledge of the medical literature) is not sufficient to establish causation.

LOW BACK PAIN AND “INJURY”

PRE-EXISTING CONDITIONS IN THE LUMBAR SPINE (IMAGING)

- Degenerative disc disease is a spectrum and findings on imaging include:
  - HNP and annular fissures
  - Facet hypertrophy, spondylosis
  - Spinal Stenosis
  - Degenerative spondylolisthesis

BACK PAIN AND HEAVY WORK: WADDELL
THE BACK PAIN REVOLUTION, 2nd EDITION 2004

- “Most episodes of back pain probably start spontaneously or while doing an everyday activity that we have done many times before.”
- “We must recognize that these are simply patients’ attempts to explain their pain. The answers tell us more about how people think about back pain than about what really causes it.” p. 117

HOW TO MEDICALLY DETERMINE CAUSATION IN A SINGLE PERSON

- NIOSH:
  - Modified slightly by ACOEM for its Occupational Medicine Practice Guidelines
PAIN - DEFINITION

- **Due to Definition**, the definition of pain is important with respect to assessing studies
- Eg. Low back pain rather than normal aches and pains vs. pain in the back.
- Cultural factors may influence reporting
- **Different target populations**
  - Point prevalence 15-30%
  - 1 month prevalence of 19-43%
  - Lifetime prevalence of 60-70%


WHY DOES IT MATTER?

- Causation issues are rare in cases with short duration MSK symptoms.
- The disputes arise over cases in which new onset MSK pain is allegedly related to a risk factor/incident and results in persisting pain with disability


DOES AN INJURY CAUSE OR ACCELERATE DEGENERATIVE DISC DISEASE?

- Identical twin studies have shown that after controlling for major environmental factors, about 50% of IVD degeneration is associated with genetic factors
- This decreases to 35% in the lower lumbar spine of men


CHANGING VIEWS

- Genetic factors and psychosocial considerations in biopsychosocial model


A DIFFERENT MODEL

Mechanical factors and an injury model VS. Genetic factors and psychosocial considerations in biopsychosocial model
**DOES DDD EXPLAIN LBP??**

- Epidemiology of disc degeneration and associated pathology DO NOT explain symptoms of LBP and disability
  - Eg. Degenerative changes in women lag behind those in men by 10 years, but
  - There is no statistically significant association between age or gender and incidence of low back pain
  - No consensus between DDD on imaging and LBP sx
  - Pathology on MRI has shown little relationship to sx or disability

**IS IT A DISEASE?**

- Epidemiology of disc degeneration and associated pathology DO NOT explain symptoms of LBP and disability
  - Pathology on MRI has shown little relationship to sx or disability
  - Studies have failed to show that the appearance of degenerative changes could be used to predict subsequent development or worsening of symptoms.

**IMAGING AS A CLINICAL TOOL**

- MRI-identified disc abnormalities do not reliably predict the need for back pain-related medical consultation and resultant work incapacity.
  - Physical job characteristics and psychological aspects of work are a more powerful


**DEGENERATIVE DISC DISEASE**

- Describes common findings on imaging
  - Is a pre-existing condition
  - Genetically predetermined
  - Unrelated to trauma
  - Not accelerated by trauma
  - It is not an injury and its presence does not predict the incident of low back pain after an event.

**NON-SPECIFIC BACK PAIN**

- Most authors today agree that despite modern medicine, the pain-generating structure for most adults with LBP cannot be reliably scientifically established.
  - There are published articles on facet pain, disc pain, SIJ pain, etc., however, these are not agreed upon by most authors. Pain syndromes can be reliably diagnosed and most of the low back literature uses the terms “nonspecific low back pain” or “low back pain.”

**IS IT THE DISC? DISCOGENIC LBP**

Diagnostic criteria and treatment of discogenic pain: a systematic review of recent clinical literature

Khalid M. Malik, MD,*, Susan P. Collier, MD,†, David R. Wukas, MD,‡, Brian M. Bacon, MD

CONCLUSION: Suspected discogenic pain, despite its extensive affirmation in the literature and enormous resources regularly devoted to it, currently lacks clear diagnostic criteria, terminology and treatment.
PATIENT HISTORY OF LOW BACK PAIN

- The best single predictor of future back pain is a previous history of back pain; this has been consistent demonstrated and substantially outweighs any other predictor


WITH THAT IN MIND...

- Can we accurately identify a new injury?
- Can we accurately identify an aggravation
  - Aggravation leads to a permanent worsening of an underlying or pre-existing condition. Alteration or acceleration essentially determined.
  - Exacerbation is a temporary worsening of symptoms, such as pain, that does not change an individual’s underlying condition.

INDIVIDUAL RISK FACTORS FOR LBP

- Results have generally been inconsistent for predicting low back trouble
  - Height
  - Weight
  - Flexibility
  - Fatigability
  - Fitness
  - Back muscle strength and general level of fitness appear to be of little significance


EPIDEMIOLOGY

WHAT ARE THE RISK FACTORS?

- Age and Onset of LBP
  - Strong evidence of association
- Obesity
  - Insufficient and conflicting evidence
- Smoking
  - Insufficient evidence
- Sleep Disturbances
  - Conflicting and insufficient evidence
- Physical Activity
  - Strong evidence of association

- There is moderate evidence that examination findings including in particular height, weight, lumbar flexibility and SLR may have predictive value for future LBP on disability
- There is limited and contradictory evidence that attempting to match physical capability to job demands may reduce future LBP and work loss

INDIVIDUAL FACTORS - LBP

- History of low back pain
  - Strong evidence that a history of LBP is a risk factor for LBP in an occupational setting

Melhorn JM, Talmage JB, Ackerman WE, Hyman MH, AMA Guides to the Evaluation of Disease and Injury Causation, Second Ed., 2014, Chapter 8

OCCUPATIONAL / PHYSICAL RISK FACTORS

- Roffey and Wai systematic reviews used Bradford–Hill criteria for determining a causal relationship
- Final conclusions:
  - Physical stressors were not independently causative agents
  - It is difficult to implicate physical occupational exposures as a major independent cause of LBP,
  - With the corollary that simply reducing physical exposures is unlikely to have a widespread preventive effect.


HEAVY PHYSICAL WORK

- Limitations in studies
  - Many studies have been limited to specific groups
    - Scaffolders or health care workers
  - Some studies addressed sick leave for low back pain, rather than onset of LBP
- Conclusion: There is insufficient evidence for heavy work as a risk factor for LBP

IMA Guides to the Evaluation of Disease and Injury, 2nd Ed.

OCCUPATIONAL / PHYSICAL RISK FACTORS

- A prospective study showed little correlation between perceived “minor trauma,” subsequent back pain and changes in spinal pathology; suggesting that psychosocial factors and compensation claims were better predictors of future back pain.


HEAVY PHYSICAL WORK: LIFTING STUDIES - LBP

- Increased sick leave for LBP
  - Handling heavy objects 5x or more/shift
  - Lifting loads of any weight into those respondents
  - Neither #frequency nor #load caused # of days

WARNING
Lifting hazard. Single person lift could cause injury. Use assistance when moving or lifting.
HEAVY PHYSICAL WORK - LBP

- A number of studies reported no statistically significant association between heavy work and LBP, and many weak associations were reported
- Statistically significant associations are limited
  - High manual handling of materials in scaffolders
  - Lifting and standing in smokers

There is insufficient evidence for heavy work as a risk factor for LBP

HEAVY WORK DUTCH SYSTEMATIC REVIEW

- Spine 2009; 34 (8): E281-E293
- 12 studies reporting on 34 exposures.
- 5 studies found an association, but
  - 1 only in smokers,
  - 2 only in men,
  - 1 only in women
- 7 studies found no statistical association

Conclusion: Conflicting Evidence

OTHER FINDINGS

- Heavy lifting + standing was a strong predictor of LBP in smokers
  - Heavy work, either standing or lifting was not
  - Same association was not present in non-smokers

OTHER FINDINGS

- No statistically significant association between workers’ physical capacity and exposure (high or low)
- No statistically significant association between lifting or carrying with one or two hands

OCCUPATIONAL/ PHYSICAL EXPOSURES AS A RISK FACTOR

- Increase in the # of physical exposures (heavy lifting, awkward trunk postures, whole body vibration) increased from 0-3
  - Statistically significant increase in the incidence of low back pain for those <40 yrs, those 40-49 yrs
  - Association was not significant in those >50 yrs

OCCUPATIONAL BENDING/ TWISTING

- Trunk flexion and LBP or twisting and LBP
  - No statistically significant association with LBP
  - Strong evidence for an association with work absence
- It may be that trunk flexion and rotation do not cause back pain, but if back pain develops, those with greater ergonomic demands have more difficulty and are more likely to miss work
SITTING, STANDING AND WALKING

- Occupational sitting
  - Sufficient evidence for no association
- Standing and Walking
  - Strong evidence for no association

PSYCHOSOCIAL FACTORS AT WORK

- Injury model alone does not explain the incidence of low back pain at work; psychosocial factors have been thought to contribute
- 1991 Boeing study – importance of non-physical factors
  - Strongest predictor of acute back injury claims and chronic disability was unsatisfactory employee appraisal ratings by an immediate supervisor within 6 months before a back injury claim

PSYCHOSOCIAL FACTORS AT WORK - LBP

- Multiple primary studies have arrived at conflicting results and there is some disagreement among systematic reviews with respect to their conclusions
- Transition to chronicity does not have a psychosocial component, including first provider

- Awkward occupational postures
  - Insufficient evidence
- Trunk flexion or rotation/LBP absence
  - Insufficient evidence
- Frequent bending
  - Strong evidence No association
- Standing
  - Some evidence No association
- Standing and walking < 2 hours
  - Strong evidence No association
- Standing and walking > 2 hours
  - Strong evidence No association

SUMMARY

<table>
<thead>
<tr>
<th>Age</th>
<th>Weak evidence</th>
<th>Strong evidence</th>
<th>No evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obesity</td>
<td>Weak evidence</td>
<td>Strong evidence</td>
<td>No evidence</td>
</tr>
<tr>
<td>Smoking</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Past history of LBP</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Sports, Exercise, and Leisure Activity</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Job satisfaction</td>
<td>Weak evidence</td>
<td>Strong evidence</td>
<td>Positive association</td>
</tr>
<tr>
<td>Organizational aspects</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Social support</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
<td>Insufficient evidence</td>
</tr>
<tr>
<td>Work stress</td>
<td>Strong evidence</td>
<td>Positive association with absences for LBP</td>
<td>No evidence</td>
</tr>
</tbody>
</table>

PAIN AND DISABILITY VS. ANATOMIC FINDINGS OF INJURY

- The epidemiological studies available for review had pain and disability as their main outcomes, rather than objectively demonstrable injury or damage
- The correlation between symptomatology and pathology is inconsistent

There is insufficient scientific evidence to conclusively establish that any occupational or ergonomic risk factor is actually a medical cause of working-age adult LBP.


What is the structural damage that occurs with new onset low back pain?

• Degenerative changes on imaging are pre-existing
• Does minor trauma cause structural changes?

MINOR TRAUMA AND SERIOUS LOW BACK ILLNESS
• 200 subjects interviewed every 6 months
• Serious trauma: high energy trauma resulting in serious visceral injury, proximal long bone, pelvic, or spinal fracture, or dislocation.
• Minor trauma (all other trauma)
  • Perceived injury to the low back area with pain ≥ 2 (out of 10) for at least 48 hours, but not meeting the definition of major trauma.
  • Included: “injuries” occurring during lifting, sports, motor vehicle accidents, falls.

Carragee et al; Does Minor Trauma Cause Serious Low Back Illness? Spine 2006; 31 (25): 2942-2949 AND Are first-time episodes of serious LBP associated with new MRI findings? TSJ 2006; 6: 624-635

• 200 subjects
• 170 reported 652 minor traumatic events.
• 323 episodes of serious low back pain
• Minor trauma was only associated with serious low back pain in a compensation setting.

Carragee et al; Does Minor Trauma Cause Serious Low Back Illness? Spine 2006; 31 (25): 2942-2949 AND Are first-time episodes of serious LBP associated with new MRI findings? TSJ 2006; 6: 624-635

LOW BACK PAIN AND DISABILITY
• Minor trauma had no independent association with progression to serious low back pain
• Spinal structural abnormalities (MRI and discography) had only a weak association with serious back pain and no association with disability or medical utilization
• Predictors of adverse outcome
  • Baseline history of depression, somatization, chronic (usually neck) pain, or a workers’ compensation claim.
  • Current smoking

Carragee et al; Does Minor Trauma Cause Serious Low Back Illness? Spine 2006; 31 (25): 2942-2949 AND Are first-time episodes of serious LBP associated with new MRI findings? TSJ 2006; 6: 624-635

Disability was predicted by an abnormal psychometric profile and previously disputed compensation claims.
• predicted 93% of episodes.
• Prediction was NOT improved by adding minor trauma to ANY of the models.

Carragee et al; Does Minor Trauma Cause Serious Low Back Illness? Spine 2006; 31 (25): 2942-2949
LOW BACK PAIN AND DISABILITY

• The "injury model" has transformed a largely benign symptom into a dire illness.
• "Our findings do not support the concept that serious low back pain and disability stem from minor trauma, structural problems, or the combination of the two."

Carragee et al; Does Minor Trauma Cause Serious Low Back Illness? Spine 2006; 31(25): 2942-2949

Are first-time episodes of serious LBP associated with new MRI findings? The Spine Journal 2006; 6: 624-635

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1. Could this exposure or risk factor cause or be part of the cause of this condition in any person?

2. In this particular person, DID this exposure ACTUALLY cause or contribute to this person’s condition?

HILL’S CRITERIA FOR CAUSATION (IN GENERAL) PROC R SOC MED 1965; 58: 293-300

1. Strength of the association (epidemiology)
2. Temporality
3. Consistency among studies
4. Biologic Gradient
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7. Coherence of evidence
8. Analogy to a similar effect, from a similar agent

CAUSATION: WORK RELATED?

• Many physicians jump to conclusions about causation, and, therefore, Work Risk, using "common sense" or experience.

• Thinking ONLY about 2 of the 9, (temporality and plausibility, the two that do NOT require a knowledge of the medical literature) is not sufficient to establish causation.

HOW TO MEDICALLY DETERMINE CAUSATION IN A SINGLE PERSON

• NIOSH:
  • Modified slightly by ACOEM for its Occupational Medicine Practice Guidelines

NIOSH/ACOEM STEPS TO DETERMINE RELATEDNESS

| Table 3-2 National Institute for Occupational Safety and Health/American College of Occupational and Environmental Medicine Steps for the Determination of Work-Relatedness of a Disease |
|---|---|
| 1. Identify evidence of disease | 2. Review and assess the available epidemiologic evidence for a causal relationship |
| 3. Obtain and assess the evidence of exposure | 4. Consider other relevant factors |
| 5. Judge the validity of epidemiology | 6. Make an opinion about the work relatedness of the disease in the person undergoing evaluation |

STEP 1: DOES THE PERSON HAVE THE DISEASE?

1. Evidence of disease.
   - What is the disease? Consider symptoms vs. condition
   - Is the diagnosis correct?
   - Does the evidence (eg, history, physical examination findings, and results of diagnostic studies) support or fail to support the diagnosis as present in this person?


STEP 2: EPIDEMIOLOGY

2. Epidemiological data.
   - What is the epidemiological evidence for the disease or condition?
   - Does quality data support a relationship with work?
   - To what extent is the condition idiopathic?
   - Is the prevalence/incidence in the general population KNOWN?

STEP 3: EXPOSURE

3. Evidence of exposure.
   - What evidence, predominantly objective, is there that the level of occupational environmental exposure (eg, frequency, intensity, and duration) could cause the disease?
   - Employer supplied job description, video, industrial hygiene reports, etc. CORRELATED with Employee history of exposure.

STEP 4: OTHER RISK FACTORS

4. Other relevant factors (think comorbidities)
   - What other relevant factors are present in this case?
   - Are there individual risk factors other than the occupational environmental exposure that could contribute to the development of the disease?
   - For example, if the diagnosis is carpal tunnel syndrome, is the worker pregnant, obese, or hypothyroid, diabetic?

STEP 5: VALIDITY OF EVIDENCE

5. Validity of evidence.
   - Are there confirming or conflicting data to suggest that information obtained in the assessment is inaccurate?
   - Are other opinions in the case inaccurate?
   - Is the hx consistent throughout? Is the hx provided by anyone other than the individual?
   - (Carragee, Validity of Patient History)

STEP 6: CONCLUSION(S)

   - Do the data obtained in the preceding assessment support the presence of a work-related disease?
   - After assessing the factors previously mentioned, is the available information sufficient to support a causal relationship between the event and the complaints.
MOST IMPORTANT UPDATED HILL CRITERIA-FRAMEWORK FOR ANALYSIS

- Reversibility: reduction preceded the disease
  - Did the incident result in expected symptoms in a timely manner?
- Exclusion: necessary to exclude other possibilities
  - Could the described incident cause the condition?
- Dose-response relationship
  - More exposure → more disease; what if you remove the exposure?
- Consistency
  - Same results in different populations w/ same or similar exposure and same disease

DETERMINING WORK-RELATEDNESS

- Are the findings of the condition (disease/injury) compatible with the work of the agent or injury to which the person was exposed?
- Is sufficient exposure present to have caused the disease?
  - Eg. Lumbar sprain/strain vs. Degenerative disc disease
  - Differentiation between symptoms and diagnosis
- Does the weight of evidence support the disease as having an occupational rather than a non-occupational origin?
  - Low back pain vs. degenerative disc disease

IDENTIFY EVIDENCE OF DISEASE

- Symptoms
- Physical Examination Findings
- Testing – EMG/NCV, imaging
- Differential diagnoses – likelihood
- Does the evidence support a particular disorder?

REVIEW AND ASSESS THE AVAILABLE EPIDEMIOLOGIC EVIDENCE

- Is there epidemiologic (EB literature) supporting the condition on an occupational or traumatic basis?

CONSIDER OTHER RELEVANT FACTORS

- Are there risk factors? Consider age related changes
- History of prior injury?
- Other diseases or exposures?

Patients with newly symptomatic knees and shoulders are more likely to have age related changes than acute injuries.
JUDGE THE VALIDITY OF TESTIMONY

- Is info about date of injury, complaints, mechanism or prior injury status consistent?
- Who has determined the causal relationship? Based on what?
  - ER provider
  - Treating physician – consider relationship with “patient”
  - Injured worker/ Plaintiff?

SUMMARY

- Can the claimed symptoms/injuries be reasonably attributed to the event, and if not, why not?
  - Are there objective findings of structural injury? or only symptoms
  - Is there a temporal relationship?
  - Could the event have caused the injury or symptoms?
  - What is the natural history of the injury?

Table 6.1 The Forensic Causality Evaluation

<table>
<thead>
<tr>
<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td>The history of the injury in the individual was reworded or placed in quotation marks. This is self-reported history. Evaluating physician making statements or affirmations as to any actual knowledge of the incident, exposure, or individual job duties be direct observations.</td>
</tr>
<tr>
<td>Length of employment</td>
</tr>
<tr>
<td>Recent work history or job history of current employment</td>
</tr>
<tr>
<td>Determine what, if anything, was different about the job task on the day of the alleged exposure or incident.</td>
</tr>
<tr>
<td>Equipment involved, duration of exposure to risk factors, equipment malfunction.</td>
</tr>
<tr>
<td>Observations at the workplace such as any report change in hours, supervision, quality, staffing.</td>
</tr>
<tr>
<td>Recent performance review.</td>
</tr>
<tr>
<td>If “positive trauma” is the alleged mechanism, what happens when no longer performing the “positive trauma” activity.</td>
</tr>
<tr>
<td>If an exposure is the alleged mechanism, what happens when the exposure ceased or was removed?</td>
</tr>
</tbody>
</table>
SUNDAY, FEBRUARY 25

COLONIAL | 9:30 am - 10:30 am

GENERAL SESSION IV: Student Writing Awards
Moderator: Robert Buckman, PhD, FCLM, President, ACLM Foundation
(This Session made possible by an ACLM Foundation Grant.)

- 9:30 AM - 9:50 AM Student Writing Awards – Hirsh Award
- 9:50 AM - 10:10 AM Student Writing Awards – Orr Award
- 10:10 AM - 10:30 AM Student Writing Awards – Gene Basanta Poster Award
2018 Student Writing Competition in Law Medicine and Bioethics

4452 Words

Mark Fadel
MD/JD Candidate Class of 2019
The University of Toledo College of Medicine and College of Law
Mark.Fadel@rockets.utoledo.edu
(440) 665-2125
I. INTRODUCTION

The first recorded measles outbreak struck the United States in 1657 during colonial settlement in Boston, Massachusetts. By 1912, measles became a nationally notifiable disease, with over 6,000 measles-related deaths reported in the first decade alone. Vaccine development for the measles virus began in 1954 at Boston Children’s Hospital when Dr. Thomas Peebles first isolated the virus. After researchers proved its safety and efficacy, the Food and Drug Administration (“FDA”) licensed the vaccine for administration to the American public.

To curb the spread of vaccine-preventable, communicable diseases, states began passing compulsory vaccination laws for school children. The United States Supreme Court upheld these vaccination mandates as a condition of entry to schools by relying on states' police power in protecting public health and safety. Despite this broad authority, many state mandates included exemptions that permitted people to refuse vaccination for nonmedical reasons, like religious, philosophical or personal beliefs. Over the past few decades, rates of these exemption

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1 The first report in the United States was written by John Hull in his diary. C. OF PHYSICIANS OF PHILA., HISTORY OF VACCINES, http://www.historyofvaccines.org/timeline#EVT_100503.
3 C. OF PHYSICIANS OF PHILA., supra note 1.
4 Nearly 19 million doses were administered in the first twelve years. Id. The Biologics Control Act of 1902 authorized the federal government to regulate the sale of biologics. PUB. L. No. 57-244, 32 Stat. 728 (1902). Later, the enactment of the Public Health Service Act revised and recodified the Biologics Control Act, thereafter empowering the FDA to regulate the marketing of vaccines. 42 U.S.C. § 242(a)-(b) (2012).
5 The spread of smallpox in the 19th century triggered states to pass these mandates for school children. C. OF PHYSICIANS OF PHILA., GOV’T REGULATION, https://www.historyofvaccines.org/content/articles/government-regulation (last updated Apr. 5, 2017).
6 Jacobson v Massachusetts, 197 U.S. 11 (1905) (upholding the authority of states to compel vaccination under the exercise of a proper police power).
7 C. OF PHYSICIANS OF PHILA., VACCINATION EXEMPTIONS, https://www.historyofvaccines.org/content/articles/vaccination-exemptions (last updated Apr. 19, 2017).
claims have increased and fears of measles spread have re-surfaced. In 2011, Justice Antonin Scalia blamed this phenomenon on vaccines emerging as “victims of their own success.” The elimination of these vaccine-preventable diseases caused less public concern for the actual disease, and more for the “risk of injury from the vaccines themselves.”

A spectrum of these mandates currently exists, ranging from California's current ban of all nonmedical claims to Ohio's extremely permissive law. This legal-medical connection can guide state legislatures in formulating uniform laws that restrict access to nonmedical exemptions by considering public health and safety paramount to any other policy factor.

II. MEASLES BACKGROUND

Measles poses a serious threat to public health. Its contagious nature spreads to any vulnerable individual in close contact with an infected person. The greatest risk of susceptibility results from not receiving the vaccination, a proven efficacious and safe method of protecting against this potentially fatal disease.

A. Signs and Symptoms

This virus commonly infects susceptible patients via direct or airborne contact. Viral particles can spread to 90% of the people close to an infected individual, proving its highly

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8 In a meta-analysis of 18 published measles studies, this article concluded that “[t]he phenomenon of vaccine refusal was associated with an increased risk for measles among people who refuse vaccines and among fully vaccinated individuals.” Varun K. Phadke, et al., Association Between Vaccine refusal and Vaccine-Preventable Diseases in the United States: A Review of Measles and Pertussis, 315 JAMA 1149, 1149 (2016).

9 Bruesewitz v. Wyeth, 562 U.S. 223, 226 (2011) (finding that the National Childhood Vaccine Injury Act shields vaccine manufacturers from product liability lawsuits in state court because the federal law already provides means to obtain compensation).

10 Id.

11 CAL. HEALTH & SAFETY CODE § 120325(c) (West 2016).

12 OHIO REV. CODE ANN. § 3313.671(B)(4) (LexisNexis 2016).

13 See infra., Part I.A.

14 Id.

15 See infra., Part I.B.

contagious nature.\textsuperscript{17} After seven to fourteen days from exposure, individuals typically present with a high fever, cough, runny nose, and watery eyes.\textsuperscript{18} The characteristic rash presents a few days after the onset of fever and most often starts on the face, then spreads down the neck to the extremities and lower trunk.\textsuperscript{19}

While this common presentation of measles seems tolerable, complications occur in about 30% of cases and can lead to serious consequences.\textsuperscript{20} Measles has the potential of causing a transient suppression of immune defenses, increasing a person's susceptibility to subsequent bacterial and viral illnesses.\textsuperscript{21} While diarrhea remains the most common complication, pneumonia and encephalitis cause the most deaths.\textsuperscript{22} One of the most serious complications of measles, subacute sclerosing panencephalitis ("SSPE"), may not present until seven to ten years after an ostensibly full recovery.\textsuperscript{23} It usually develops in those infected with measles at an early age and can result in seizures, dementia, and ultimately, death.\textsuperscript{24} The relationship between measles and SSPE highlights the essential reason for vaccination.\textsuperscript{25}

\textbf{B. The MMR Vaccine and Herd Immunity}

In 1971, the US licensed the measles, mumps, and rubella combination vaccine ("MMR") to provide triple coverage against these three highly contagious viruses.\textsuperscript{26} As a live-attenuated vaccine, immunity develops from the weakened viral strains causing a harmless infection that the

\textsuperscript{17} CTRS. FOR DISEASE CONTROL & PREVENTION, TRANSMISSION OF MEASLES, https://www.cdc.gov/measles/about/transmission.html (last updated Mar. 3, 2017) (noting that measles "lives in the nose and throat mucus" and can "spread to others through coughing and sneezing").
\textsuperscript{18} Id.
\textsuperscript{19} Id.
\textsuperscript{20} Id.
\textsuperscript{21} Id.
\textsuperscript{22} Id.
\textsuperscript{23} Id.
\textsuperscript{24} Id.
\textsuperscript{25} Id. ("The risk of SSPE following vaccination is $\leq$ one-twelfth the risk of SSPE following infection.").
\textsuperscript{26} Researchers found that the MMR vaccine induced immunity to measles, mumps and rubella in 96%, 95%, and 94% of vaccinated children, respectively, with no greater adverse effects than each single vaccine. Id.
patient's immune system fights.\textsuperscript{27} The body raises an army of specific antibodies to combat any future exposure to the viral particles, resulting in lifelong immunity.\textsuperscript{28} The current CDC guidelines recommend two doses, one at 12 to 15 months of age, and the second at four to six years of age.\textsuperscript{29}

Those with contraindications, like immune-suppressed or severely allergic individuals, have an increased risk of exposure and subsequent infection that exceeds the rest of the population due to the physical inability to safely receive a vaccination.\textsuperscript{30} The concept of herd immunity lends protection to this population by limiting the possibility of a susceptible patient from coming into contact with a contagious individual.\textsuperscript{31}

A contributing factor to the spread of measles results from the clustering of unvaccinated individuals based on a variety of factors, including ethnicity, socioeconomic status, religious beliefs, and educational level.\textsuperscript{32} In a study of preschool age children, researchers found that despite a greater population density that presumably increases the risk of transmission, “modestly increased immunization levels remained strongly correlated with decreased” measles

\textsuperscript{28} Id.
\textsuperscript{29} However, the second dose could be given as early as 28 days after the first dose. Id. Two doses are recommended because some children may not have an antibody response to the first dose, in which case, the second dose will nearly always induce immunity. Gans & Maldonado, supra note 16.
\textsuperscript{31} Herd immunity is accomplished when a “large enough proportion of the population is immune, transmission cannot occur and any remaining susceptibles will be protected.” Herd immunity is especially important for measles because “humans are the only natural host; infection usually results in highly characteristic disease and is followed by solid, lifelong immunity; and spread occurs largely by relatively direct contact.” John P. Fox, Herd Immunity and Measles, 5 N ENGL J MED 463 (1983).
\textsuperscript{32} Id. at 464–65.
infection rates. Additionally, scientists have found that vaccination rates maintained above 91 to 94 percent may suffice to sustain the herd immunity effect.

Through the efforts of public health officials, the medical community, and municipalities enforcing vaccination mandates, the CDC declared measles eliminated from the US in 2000. However, the celebratory reduction in the incidence of this vaccine-preventable and potentially fatal disease brought with it a public misperception that the disease itself no longer posed a threat. This shifted the public sentiment from praise of the vaccine to concern over its minimal adverse effects, resulting in a lack of urgency associated with its administration. As the saying goes, however, just because you cannot see it, does not mean it's not real. An increase in vaccine refusal, subsequent erosion of herd immunity and intermittent resurgence of measles followed.

III. SPECTRUM OF NONMEDICAL EXEMPTION LAWS

States vary in the exemptions they permit parents to claim for their children. All fifty states permit exemptions for medical reasons. Differences exist in the permissiveness of

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33 The data showed that reaching a herd immunity threshold has realistic benefits and immunization coverage in preschool aged children in urban communities of at least 80% may be sufficient to prevent measles outbreaks. Id. at 826.


36 Saad B. Omer et al., Vaccine Refusal, Mandatory Immunization & the Risks of Vaccine-Preventable Diseases, 360 N. ENG. J. MED. 1981, 1981 (May 2009) (stating that "[a] reduction in the incidence of a vaccine-preventable disease often leads to the public perception that the severity of the disease and susceptibility to it have decreased"); see also supra, Part I (citing Bruesewitz, 562 U.S. at 226).

37 Id.

38 Saad B. Omer et al., Vaccine Refusal, Mandatory Immunization & the Risks of Vaccine-Preventable Diseases, 360 N. ENG. J. MED. 1981, 1981 (May 2009) (“Multiple studies have shown an increase in the local risk of vaccine-preventable diseases when there is geographic aggregation of persons refusing vaccination.”); see generally Fox, supra note 31 (explaining how herd immunity protects a community).


40 Id.
nonmedical exemptions, like personal beliefs and religious reasons. Some states have an outright ban, like California, and others simply allow parents to submit a signed formed, like Ohio. This spectrum may contribute to the persistence of measles in the US, as discussed below.

A. California

California once had a broad exemption law but restricted it following a nationally publicized measles outbreak in 2015. The new law bans the use of nonmedical exemptions, serving as the most restrictive vaccination law. Furthermore, its scope extends to public and private schools, making it the most expansive law as well.

The California Department of Public Health ("CDPH") received five reports of suspected measles cases on January 5, 2015. All patients had visited Disneyland theme parks in Orange County, California between December 17-20. California published data regarding the confirmed measles cases broken down by county, reflected in Table 1, below. Among those

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41 § 120325(c) (allowing only “[e]xemptions from immunization for medical reasons”).
42 § 3313.671(B)(4) (“A pupil who presents a written statement of the pupil's parent or guardian in which the parent or guardian declines to have the pupil immunized for reasons of conscience, including religious convictions, is not required to be immunized.”).
43 Scott Neuman, California Lawmakers Vote to Remove Vaccine Exemptions for Schoolchildren, NAT’L PUB. RADIO (June 25, 2015, 3:27 PM), http://www.npr.org/sections/thetwo-way/2015/06/25/417492698/california-lawmakers-vote-to-remove-vaccine-exemptions-for-schoolchildren (“The bill is aimed at increasing immunization rates following a serious measles outbreak in December that was traced back to Disneyland and that sickened dozens.”).
44 CAL. HEALTH & SAFETY CODE § 120335(b) (West 2016) (“The governing authority shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center . . . .”).
45 CTRS. FOR DISEASE CONTROL & PREVENTION, MORBIDITY AND MORTALITY WEEKLY REPORT, MEASLES OUTBREAK – CALIFORNIA, DECEMBER 2014-FEBRUARY 2015 (2015), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a5.htm?s_cid=mm6406a5_w.
46 Id.
with clear vaccination documentation, 57 patients were unvaccinated and only 25 had one or more doses of the MMR vaccine.48

The data collected from this outbreak indicated an association between geographical proximity to Disneyland, vaccination status, and personal belief exemption rates. Every county bordering Orange County reported cases,49 and most of the others came from counties around the San Francisco50 and Sacramento area.51 The focus of the disease around cities related to the herd immunity phenomenon: as the number of contacts with susceptible individuals increased, the serial transmission rate increased.52 Most of those infected never received the vaccine, and further analysis by the CDC showed that the majority of that subpopulation chose to opt out because of personal beliefs.53

According to Table 1, of the counties with confirmed cases, three of the top four counties had >3% exemption rates in child care facilities while those counties with only one case had much lower exemption rates.54 While this shows no formal relationship, the statistics indicate a noteworthy observation that caught national attention.55 With low vaccination rates partly to

48 Id.
52 See generally Fox, supra note 31 (explaining the concept of herd immunity).
53 CTRS. FOR DISEASE CONTROL & PREVENTION, MORBIDITY AND MORTALITY WEEKLY REPORT, MEASLES OUTBREAK – CALIFORNIA, DECEMBER 2014-FEBRUARY 2015 (2015), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a5.htm?s_cid=mm6406a5_w. (“Among the 110 California patients, 49 (45%) were unvaccinated . . . .”).
blame for the outbreak, California's public health officials took advantage of the momentum and national attention to change their vaccination mandate.

In February 2015, two senators introduced Senate Bill 277, seeking to eliminate the nonmedical exemptions altogether.\textsuperscript{56} The reason for its introduction stemmed partly from the Disneyland outbreak.\textsuperscript{57} Governor Edmund Brown signed the bill into law in June 2015, making California the third state to eliminate all forms of nonmedical exemptions.\textsuperscript{58} The new law simply deleted the language, "or because of personal beliefs," from the original text.\textsuperscript{59}

Shortly after enactment, challengers filed a motion for preliminary injunction in a federal district court, alleging constitutional violations.\textsuperscript{60} The judge denied the motion, citing ample Supreme Court precedent.\textsuperscript{61} The equal protection argument failed because allowing vaccinated children to attend school while excluding those with personal belief exemptions rationally relates to the same legitimate interest in public health and safety.\textsuperscript{62} The court rejected the substantive due process claim because "[u]questionably, imposing a mandatory vaccine requirement . . . is well within [the State's] power to condition school enrollment on vaccination."\textsuperscript{63} Finally, the

\begin{itemize}
\item \textsuperscript{57} Hearing on S.B. 277 Before Assemb. Comm. on Health, 2015 Leg. 11 (June 9, 2015) (“The authors point to an outbreak of measles linked to Disneyland in in December 2014 as one of the reasons for the introduction of this bill.”).
\item \textsuperscript{59} Compare CAL. HEALTH & SAFETY CODE § 120325(c) (West 2014) (amended 2015), with CAL. HEALTH & SAFETY CODE § 120325(e) (West 2016) (now allowing only “[e]xemptions from immunization for medical reasons”).
\item \textsuperscript{60} Whitlow v Cal. Dep't of Educ., 203 F. Supp. 3d 1079 (S.D. Cal. 2016).
\item \textsuperscript{61} Id. at 1092.
\item \textsuperscript{62} 203 F. Supp. 3d at 1087–88 (“Plaintiffs have failed to show that children with [personal belief exemptions] . . . are members of a suspect class. Plaintiffs have also failed to show that these classifications burden a fundamental right. Thus, these classifications would be subject to rational basis review, not strict scrutiny.”).
\item \textsuperscript{63} Id. at 1089 (citing Zucht v. King, 260 U.S. 174 (1922) (due process challenge of a city ordinance failed when plaintiff student was rejected from private and public school for refusal to be vaccinated)).
\end{itemize}
California Constitution delineates a fundamental right to education and the plaintiffs argued that absent any actual outbreak, the state does not have a "compelling reason to enact a vaccine mandate." The court rejected this contention because "the State's interest in protecting the public and health safety . . . does not depend on or need to correlate with the existence of a public health emergency." The plaintiffs have not appealed this decision.

California likely will see vaccination rates steadily increase as implementation continues. Unfortunately, the change in law resulted from a reactive and not proactive approach. Nevertheless, California’s experience and legislative response may serve as a valuable lesson to other states and encourage them to follow California’s example.

B. Ohio

Unlike California, Ohio has the broadest exemption law. Furthermore, the vaccination mandate only applies to public schools, excluding private school children from its reach. This section discusses the relationship between an easy exemption process and a magnified risk of measles transmission.

Ohio has a relatively easy process of obtaining an exemption. The guardian must "present a written statement" declining immunization “for reasons of conscience, including religious

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64 203 F. Supp. 3d at 1089 (citing Butt v. California, 842 P.2d 1240 (Cal. 1992) (holding education is a “fundamental interest”)).
65 203 F. Supp. 3d at 1090.
66 203 F. Supp. 3d at 1091 (“Conditioning school enrollment on vaccination has long been accepted by the courts as a permissible way for States to inoculate large numbers of young people and prevent spread of contagious diseases.”); see generally Jacobson, 197 U.S. at 11 (“If vaccination strongly tends to prevent the transmission or spread of this disease, it logically follows that children may be refused admission to the public schools until they have been vaccinated.”).
68 CAL. DEP'T PUB. HEALTH, CALIFORNIA'S KINDERGARTEN VACCINATION RATES HIT NEW HIGH (Apr. 12, 2017), https://www.cdph.ca.gov/Programs/OPA/Pages/NR17-032.aspx.
69 § 3313.671(A) (stating that the law only applies “to an elementary or high school for which the state board of education prescribes minimum standards.”).
convictions . . . .” Therefore, parents need to only write either their religious denomination or some personal cause for exempting their child without any input from a health care provider. This makes Ohio citizens most at risk for not only an outbreak, but one that spreads to the largest number of people. Accordingly, an Amish community in Ohio recently experienced the largest measles outbreak since 1996.71

The Amish religion does not expressly prohibit vaccination, but its followers generally reject preventive health care for cultural reasons.72 As a result, the communities have low immunization rates.73 Upon returning from the Philippines, two unvaccinated Amish men arrived in Knox County, Ohio in 2014 with early symptoms of measles.74 This led to the exposure of measles among one of the largest Amish settlements in the US.75

Before the outbreak began, 340 out of the 383 total confirmed cases were unvaccinated.76 Pursuant to CDC guidelines, the counties affected increased their vaccination efforts to contain the spread.77 At that time, less Amish people opposed vaccination, resulting in administration of the MMR vaccine to over 10,000 people in the community.78 Ultimately, this outbreak

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70 § 3313.671(B)(4).
72 Paul A. Gastanaduy et. al., A Measles Outbreak in an Underimmunized Amish Community in Ohio, 375 N ENGL J MED 1343, 1343 (Oct. 6, 2016).
73 Id.
74 Id.
75 This Amish community had an estimated population of 32,630 persons centered in Holmes County. Gastanaduy, supra note 72.
76 Id.
demonstrated the relationship between permissive nonmedical exemption laws, clustering of unvaccinated individuals and a higher disease incidence resulting in an outbreak.79

IV. CONSTITUTIONAL AND FUTURE CONSIDERATIONS

Courts still stand by the precedent established over a century ago under Jacobson v. Massachusetts.80 This authority affords states the ability to compel vaccination without offering nonmedical exemptions.

The rejection of all claims in the most recent challenge to California's elimination of nonmedical exemptions provides a modern application regarding their constitutionality.81 The most protected "fundamental" rights require a "strict scrutiny" analysis that depends on a "compelling state interest" and a law "narrowly tailored" to its purpose.82 Parental rights and the choices regarding rearing one's children require this form of heightened analysis.83 Two cases challenging compulsory vaccination laws afforded broad discretion to states in creating laws that protect the public health yet restrict parental choice.84 Furthermore, in another landmark case, the Court stated that even the free exercise of religion does not serve as a shield against these laws.85 Subsequent challenges based on religious and parental rights have failed, thus favoring the interest of public health over individual liberty in this context.86

80 197 U.S. at 27; see Part IV.
81 See Whitlow, 203 F. Supp. 3d at 1085–91.
82 Id.
83 Meyer v. Nebraska, 262 U.S. 390 (1923) (striking a Nebraska law that restricted teaching foreign languages to children because it infringed upon parents’ control of their child's education as protected by the Due Process clause of the Fourteenth Amendment).
84 Jacobson, 197 U.S. at 27; Zucht, 260 U.S. at 177.
85 Prince, 321 U.S. at 166–67 ("[H]e cannot claim freedom from compulsory vaccination for the child more than for himself on religious grounds. The right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death.").
Eliminating nonmedical exemptions serves as an obvious solution, but this method often faces the fiercest opposition amongst anti-vaccine groups, which could impact an elected officials' re-election. Alternative methods apply incremental changes to state laws that slowly burden the exemption process over time. For example, education components, as required in Washington and Oregon, compel parents to make an informed choice, instead of conveniently signing a document. Ultimately, the collaboration of the medical and legal communities in all states to produce innovative and uniform resources that elucidate the fatal consequences of measles and its safe prevention can have a sweeping impact on the incidence of the disease nationwide.

V. CONCLUSION

State-based school immunization laws form the bedrock of compulsory vaccination efforts in the US. However, a spectrum of these mandates permitting exemptions has been shown to contribute to measles incidence. Therefore, a widespread migration toward more restrictive procedures for obtaining nonmedical exemptions can help maintain herd immunity by limiting the number of unvaccinated individuals susceptible to transmitting measles. Judiciously settled constitutional permission for this progression already exists. Now states must act within that authority to safeguard against the persistence of this potentially fatal disease.

exercise of religion claim because plaintiff's beliefs did not exempt her from a state's ability to mandate vaccinations) (citing Jacobson, 197 U.S. at 26).
87 Douglas S. Diekema, Personal Belief Exemptions from School Vaccination Requirements, 35 ANN. REV. PUB. HEALTH 275, 280 (Mar. 2014) ("Laws that do not allow some degree of conscientious objection can further inflame anti-vaccination groups, leading to increased resistance to these laws.").
88 Id.
89 Id. ("Although such measures are unlikely to change the decision of the most resistant parents, they would eliminate many exemptions sought because of convenience rather than conviction.") (citing Douglas S. Diekema, Improving Childhood Vaccination Rates, 366 5 N ENGL J MED 391 (2012)).
91 See Part II.B.
92 197 U.S. at 25; 260 U.S. at 176.
List of Tables

1. Table 1

<table>
<thead>
<tr>
<th>County</th>
<th>Total Number of Confirmed Cases(^{93})</th>
<th>Personal Belief Exemption Rate of Child Care Facilities(^{94})</th>
<th>Personal Belief Exemption Rate of Kindergarten(^{95})</th>
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</table>

Table 1. The number of cases per county during the Disneyland outbreak compared to the personal belief exemption rate reported by all child care centers during the 2014-2015 school year.

\(^{93}\) California Measles Surveillance Update, supra note 47.
\(^{94}\) 2014-2015 Child Care Immunization Assessment Results, supra note 54.
2018 Student Postdoctoral Writing Contest
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Word Count: 5000
I) Introduction:

Cosmetic surgery is rapidly increasing in popularity and being sought out in rising numbers by youth in Canada, USA, UK and Australia. The concept of cosmetic surgery was once taboo but has now become commonplace with reality TV shows and celebrities normalizing the practice.

There is considerable debate in the feminist literature about the concept of cosmetic surgery often framed by juxtaposing issues of consent, self-determination, and bodily integrity against the continued oppression of the patriarchy and the domination of the female body. The debate over cosmetic genital surgeries brings these issues to the forefront. Further it can be asserted that Western female cosmetic genital surgeries are no different than the almost universally condemned practice of female genital mutilation in terms of their respective societal roles. These procedures exist on the same continuum of domination of the female body and control of female sexual capacity.

Female Genital Mutilation (FGM) is illegal in Canada under Criminal Code s 268, in the USA under Federal Code § 116, and in the UK under the Female Genital Mutilation Act, 2003. Cosmetic genital surgeries are regulated like other medical procedures. These cosmetic surgeries are tacitly accepted as valid exercises of autonomous self-determination, while FGM is prohibited as “barbaric” and oppressive.

This paper is the first in a series in which I argue that cosmetic genital surgery operates on a continuum of domination of the female body with FGM. In this paper, I argue that rather than being regulated like other elective surgeries, cosmetic genital surgeries performed on girls under the age of 18 in Canada should be subject to sections 268(3) and 268(4) of the *Criminal Code*. Both the text and underlying purpose of these provisions should read to capture parents and healthcare providers who consent to and perform elective cosmetic genital surgeries on minors.

It is a generally accepted principle of Canadian statutory interpretation that the words of an Act are to be “read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament”. This is often referred to as the purposive approach to interpretation. In order to appropriately interpret section 268, I will first explore and define in Part II the practice of female cosmetic surgery and that of FGM. Part III then considers the history, object, and intent of the 1997 revisions to s. 268 of the *Criminal Code*. In Part IV, I apply this understanding of the intent and object of s. 268 to the legal and ethical concepts of substitute decision-maker consent and the ethical Zone of Parental Discretion to assert that the current provision of cosmetic genital surgeries to girls under the age of 18 is aggravated assault under section 268. I conclude with arguments for the social utility of prosecuting the provision of cosmetic genital surgeries to minors under section 268.

**II) What is Female Cosmetic Genital Surgery (FGCS)?**

Cosmetic genital surgery encompasses a wide range of surgical procedures aimed at changing the appearance of the female vulva. These include labioplasty procedures which involve excising part of the labia, clitoral hood reduction, surgical and laser vaginal tightening, hymenoplasty, and “G-spot” injections. Cosmetic labioplasty in particular is rapidly increasing in popularity. The number of procedures rose 23% in the USA between 2015-2016 making it the

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9 *Canada*, supra
fastest growing cosmetic surgical procedure\textsuperscript{13}. Of these, 559 labioplasty surgeries were performed on girls under age 18 (5% of total labioplasties performed in the USA)\textsuperscript{14}. This same trend of adolescent girls seeking cosmetic genital surgery is being seen across Western nations including Canada, the UK, and Australia\textsuperscript{15}.

It is important to distinguish cosmetic labioplasty performed purely for aesthetic reasons from reconstructive vulvar surgeries for congenital anomalies resulting from genetic syndromes,\textsuperscript{16} post-traumatic reconstructive surgeries, cancer surgeries or gender reassignment surgeries. Cosmetic procedures are performed on normal vulvar anatomy to “improve” aesthetics only.

Labia reduction is the most common FGCS\textsuperscript{17}. This procedure first appeared in the surgical literature in the mid-1970s and was associated with the sex work/pornography industry.\textsuperscript{18} It remained a niche market, fringe procedure existing outside of “mainstream” surgery until recently; it did not appear on the American Society of Aesthetic Plastic Surgeons yearly statistics for cosmetic procedures until 2007.\textsuperscript{19} But since 2007, these procedures have been the most rapidly increasing cosmetic procedures performed in North America\textsuperscript{20}.

Amidst this increase, adolescent girls have emerged as key targets of this cosmetic surgery market. A speaker at the 2013 meeting of the American Society of Aesthetic Plastic Surgeons, presenting on the topic of labioplasty, suggested that the procedures should be proactively offered to adolescent girls “prior to having a partner make a disparaging remark about

\textsuperscript{14}Ibid
\textsuperscript{16}It should be noted that the practice of reconstructing the genitalia of infants born with intersex syndromes is itself controversial and arguably unethical
Adrienne Carmack, Lauren Notini and Brian Earp (2016) “Should surgery for hypospadias be performed before an age of consent? Journal of Sex Research, 53(8), 1047-1058
\textsuperscript{17}ASAPS stats, Supra
\textsuperscript{18}Radman HM Hypertrophy of the labia minor” Obstet Gynecol 1976; 48 (Suppl 1) 78s-79s
\textsuperscript{19}ASAPS Stats, Supra
\textsuperscript{20}Ibid
the appearance of their genitalia.”

Rather than sparking outrage in the room of (almost entirely male) surgeons, the recommendation was generally met with approval or at least little disapproval. The purported benefit of offering the surgery to adolescent girls was to save them the psychological harm and embarrassment of their partner making demeaning remarks. There was no discussion of the ethics of this suggestion or the underlying socio-political framework that would socialize a male partner to make such comments. There was also little discussion of the potential complications of these procedures.

This lack of concern about the potential health consequences for girls and women is troubling. The complications of the labioplasty procedure include wound dehiscence, hematoma, urinary retention, infection, and pain. The end point of labia growth is not well understood and the long term impacts on sexual functioning and pregnancy have not been studied in the context of adolescent labial surgery. Unfortunately, the popularity of the procedure is rapidly increasing without the long term impacts being well understood.

II) What is Female Genital Mutilation (FGM)?

The World Health Organization (WHO) defines female genital mutilation as “all procedures involving partial or total removal of the external female genitalia or injury to the female genital organs for non-medical reasons.” There are several terms used to describe the alteration of female genital organs. Female circumcision is a term commonly used by communities in which these procedures are practiced, but is generally avoided in the Western literature as it is felt to equate the procedures to male circumcision and in doing so minimize the harm caused by the procedure. Female genital cutting is considered a value-neutral term that is medically correct and culturally sensitive and has been adapted by many of the Gynaecology

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21 Annual Meeting of the American Society of Aesthetic Plastic Surgery, April 2013, New York, New York, USA
22 Personal experience of the author, to avoid personal professional repercussions I am not naming the speaker who made these comments or the name of the session
26 Although male circumcision remains a contentious topic with many advocating for male genital procedures to also be illegal
associations and international health organizations.\textsuperscript{27} The WHO\textsuperscript{28} and the UN\textsuperscript{29} maintain the use of the term “mutilation” to purposely call attention to the gravity and harm caused by the act and is intentionally value-laden language. FGM will be used in this paper in reference to these practices.

The WHO has classified the procedures of FGM into varying levels of invasiveness and destructiveness.\textsuperscript{30} As a generalization, the procedures are often performed in non-sterile environments, without anesthesia and by non-medical practitioners, often family or community members\textsuperscript{31}. There are significant immediate and long term risks as a result of these procedures, including immediate death from hemorrhage, infection, difficulty with bowel/bladder control, and trauma during childbirth.\textsuperscript{32}

The practice of FGM has been condemned by the WHO, the UN General Assembly,\textsuperscript{33} the American Medical Association\textsuperscript{34}, the College of Physicians and Surgeons of Ontario\textsuperscript{35}, and the American College of Obstetrics and Gynaecology\textsuperscript{36}. The risk of FGM has been accepted as a

\textbf{WHO Modified Typology 2007}

Type I: Partial or total removal of the clitoris and/or the prepuce (clitoridectomy)
- Type Ia) removal of the clitoral hood or prepuce only
- Type Ib) removal of the clitoris with the prepuce

Type II: Partial or Total removal of the clitoris and the labia minor, with or without excision of the labia major (excision)
- Type IIa) Removal of the labia minora only
- Type IIb) partial or total removal of the clitoris and labia minora
- Type IIc) partial or total removal of the clitoris, the labia minora, and the labia major

Type III: Narrowing of the vaginal orifice with the creation of a covering seal by cutting and appositioning the labia minora and/or the labia majora, with or without excision of the clitoris (infibulations)
- Type IIIa) removal and apposition of the labia minora
- Type IIIb) removal and apposition of the labia majora

Type IV: unclassified, all other harmful procedures to the female genitalia for non-medical purposes (eg pricking, piercing, incising, scraping and cauterization)


\textsuperscript{28} WHO, Supra
\textsuperscript{29} Ibid
\textsuperscript{30} WHO Modified Typology 2007
\textsuperscript{31} Ibid
\textsuperscript{32} Ibid
\textsuperscript{34} AMA Policy on Female Genital Mutilation H-525.980, A-06 Modified, 2016
\textsuperscript{35} CPSO Policy Statement #2-11 Female Genital Cutting (Mutilation), 2011 Dialogue 3
\textsuperscript{36} American College of Obstetricians and Gynecologists Committee on Gynecologic Practice, Female Genital Mutilation, ACOG Comm Opin 1995
ground for refugee status, and recent criminal charges laid against an American physician prove that girls continue to be subjected to these procedures even after immigration to North America.

FGM involves cutting of the vulva with immediate risk of serious complications and lifelong changes to the anatomy impacting sexual functioning, child-bearing and menstruation. It is performed to uphold external standards of a perceived societal norm about feminine and masculine sexuality. Cosmetic genital surgery also involves cutting of the vulva with lifelong changes to anatomy and immediate risk of infection, bleeding, and death and long-term risk of impact on sexual functioning, child-bearing and menstruation. It is performed to uphold external standards of a perceived societal norm about feminine and masculine sexuality. These procedures exist on the same continuum of domination of the female body. They are two sides of the same coin. There is no justification for differing legal standards to the regulation of these procedures.

III) Canadian Criminal Code Provisions Against FGM: Section 268 (3) and (4)

The approach to criminalizing FGM has varied across the Western world. The UK, and the USA chose to enact specific Acts aimed directly at the practice. Canada chose instead to modify existing provisions in the Criminal Code for clarity, while maintaining that FGM was already prohibited under the pre-existing provisions in order to avoid a legal vacuum during the revision process.

Section 268 of the Canadian Criminal Code expressly criminalized female genital mutilation after revisions introduced in 1997 and reads as follows:

Section 268 (1) Aggravated assault - Everyone commits an aggravated assault who wounds, maims, disfigures, or endangers the life of the complainant

2) Punishment - Everyone who commits an aggravated assault is guilty of an indictable offence and liable to imprisonment for a term not exceeding fourteen years

3) Excision - For greater certainty, in this section, “wounds” or “maims” includes to excise, inflate or mutilate, in whole or in part, the labia majora, labia minora, or clitoris of a person, except where

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37 Latif v Canada (2015), 2015FC1408, 262ACWS(3d) 186
39 UK, supra
USA, Supra
40 Testimony of Mr Yvan Roy, Senior General Counsel, Criminal Law Policy, Department of Justice to the Standing Committee on Justice and Legal Affairs, Oct 1, 1996 [Roy]
a) a surgical procedure is performed, by a person duly qualified by provincial law to practice medicine, for the benefit of the physical health of the person or for the purpose of that person having normal reproductive functions or normal sexual appearance or function; or

b) the person is at least eighteen years of age and there is no resulting bodily harm

4) Consent - For the purposes of this section and section 265, no consent to the excision, infibulation, or mutilation, in whole or in part, of the labia majora, labia minora or clitoris of a person is valid, except in the cases described in paragraphs (3)(a) and (b).  

I will use the purposive interpretation approach to argue that cosmetic genital surgery on minors is currently prohibited under Section 268(3) and (4).

Bill C-27 “An Act to Amend the Criminal Code with respect to child prostitution, child sex tourism, criminal harassment and female genital mutilation” was tabled together with a private member’s bill Act C-235, “An Act to Amend the Criminal Code with respect to genital mutilation of female persons”. The Standing Committee on Justice and Legal Affairs heard evidence regarding the proposed revisions in 1996. At this time, cosmetic genital surgery remained a fringe procedure in plastic surgery and was not widely sought or on the radar as a potential public issue.

Bill C-27 was introduced by the Minister of Justice in response to the UN Convention on the Rights of the Child, the 1993 UN Declaration of the Elimination of Violence Against Women, and the 1996 World Congress Against Commercial Sexual Exploitation of Children. The aim of the bill was to revise the Criminal Code with respect to four identified areas: child prostitution, child sex tourism, criminal harassment, and female genital mutilation, with the explicit intention to clarify that female genital mutilation is an offence under section 268 of the Criminal Code. The object was to afford children special protection against abuse and exploitation.

The Minister argued for inclusion of the medical exception out of recognition that there would be situations in which cutting the genitals of minors would have to be done for medically

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41 Canada Criminal Code, RSC, 1985, c. C-46 [Criminal Code]
42 Shaughnessy Cohen, Chair, Standing Committee of Justice and Legal Affairs, Oct 1, 1996 [Standing Committee]
43 Standing Committee, Supra
44 Testimony of MrYvan Roy, Senior General Counsel, Criminal Law Policy, Department of Justice to the Standing Committee on Justice and Legal Affairs, Oct 1, 1996 [Roy]
necessary or “reasonable” purposes. By including the reference to both the individual being a medically qualified practitioner and the need for a medical reason, the Minister was attempting to protect against the situation in which a physician would collude with a family to perform the procedures on a child without a valid medical reason, while allowing physicians to be protected from prosecution for performing medically necessary procedures. In particular, there was the intent to only allow procedures for reasons that are, according to Mr. Yvan Roy, Senior General Counsel, Criminal Law Policy, Department of Justice, “socially redeeming. The objective [of which] is to protect the person from illness”.

For further clarification of the scope of medically justified and social redeeming genital cutting of minors, Dr. Andre Lalonde (Society of Obstetrics and Gynaecology of Canada) and Dr. Gillian Oliver (Head of Paediatric and Adolescent Gynaecology at the Hospital for Sick Children, Toronto) clarified the various types of FGM and the known short and long term complications of the procedures. They identified specific medical conditions that they believed should be exempted from the criminal provisions. Dr. Oliver was clear that the medical definition of normal anatomy should apply:

> “the idea of a normal anatomy is very clear, it is what it is supposed to look like, and whether you are Japanese, Ethiopian, or North American, your genitals basically follow the same pattern. It is not a cultural definition”

Dr Lalonde was concerned about leaving a loophole by using the word “normal”:

> “We are concerned that someone could ask for such a procedure because they feel this is a normal sexual appearance or function according to their culture and that being the culture of the physician and the culture of the patient. We believe this would then create a possible loophole.”

Both physicians testified that surgery on the genitals of minors would only be acceptable to create genitals that in either function or appearance fall within the range of medically normal

46 Ibid
47 Ibid, p 1720
48 Evidence of the Standing Committee on Justice and Legal Affairs, November 19, 1996
49 Testimony of Dr Gillian Oliver, before the Standing Committee on Justice and Legal Affairs, November 19, 1996, [Oliver] p 1140
50 Testimony of Dr Andre Lalonde, before the Standing Committee on Justice and Legal Affairs, November 19, 1996, [Lalonde] p 1120
They did not address the possibility of requests for cosmetic genital surgery explicitly; likely because cosmetic surgeries were not widespread in 1996. The content of their presentations can be extrapolated to condemn cosmetic genital procedures, given that they were asking for an exception to operate only on pathologically abnormal genitals and not culturally abnormal genitals. This supports my contention that s. 268 currently captures cosmetic genital surgery on adolescent girls. To emphasize, in 1996, cosmetic genital procedures were not widespread nor within the scope of consideration of the Standing Committee, but both Dr. Oliver and Dr. Lalonde, specifically address surgery for aesthetic reasons as being unacceptable in all cases.

In reading the plain language text of the definition of excision under 268(3) (“wounds” or “maims” includes to excise, inflate or mutilate, in whole or in part, the labia majora, labia minora, or clitoris), the definition describes the cosmetic labioplasty and clitoral hood procedures. The remaining cosmetic procedures can justifiably be read into the language in the context of the evidence of the Standing Committee on Justice and Legal Affairs. The medical exemption was explicitly intended to cover only reconstructive procedures with a socially redeeming purpose. On this interpretation, adolescent cosmetic genital procedures are currently prohibited under the provisions section 268 of the Criminal Code.

V) The Concept of Consent

In FGM, it is not difficult to see how socialization and cultural norms impact on women’s choices over the procedure and parental choice to pursue the procedures for their daughters, I contend that similar Western forces of socialization and cultural norms are driving the trend of cosmetic genital procedures on adolescent girls and lead to parental consent for these procedures. Evidence shows that teenage girls who exhibit extreme adoration of celebrities are most likely to seek cosmetic surgery of all types and exposure to internet pornographic images of digitally

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51 Oliver, supra
Lalonde, supra
52 Oliver, supra
Lalonde, supra
altered genitalia led to decreased self-esteem of adolescent girls and led them to identify normal vulvar anatomy as abnormal\textsuperscript{54}.

The objective of the provisions in s 268(3)(a) and (4) is to protect girls from the indisputable harms of FGM. Subsection (4) explicitly disallows consent by a third party aimed at vitiating any parental rights to consent to female genital mutilation on behalf of their minor children. Since conceptually there is little difference between the external coercive forces leading to FGM and those cosmetic genital surgery, by extension the provision in s 268 (4) should be interpreted as prohibiting parental consent to minors undergoing cosmetic genital surgery.

We accept that there are legal limits to the control parents are allowed to exert over their children’s healthcare decision making.\textsuperscript{55} In Ontario, the \textit{Health Care Consent Act}\textsuperscript{56} section 21(2) states that a substitute decision maker must always act in the patient’s “best interests”. In two recent cases, \textit{R v Stephan}\textsuperscript{57} and \textit{R v. Lovett}\textsuperscript{58}, both parents had their children’s “best interests” in mind when they chose to pursue naturopathic remedies instead of seeking proper medical attention for their children due to their strongly held social convictions. In both cases the parents were found criminally liable for the death of their children. Deeply held philosophical beliefs and a desire to fit into a perceived social norm is not justification for inflicting harm on a child, even when the parental intentions are within their concept of the child’s “best interests”. A family’s desire to pursue FGM for their children in order to fit a social norm of their country of origin is explicitly prohibited by s268(4). Ethical debate surrounds the appropriate limitations to be placed on parental decision making\textsuperscript{59}. A useful analytical tool is the concept of the Zone of Parental

\begin{flushright}
\textsuperscript{55} Ney v. Canada (Attorney General) 1993 CarswellBC 113, [1993] 6 W.W.R. 135
\textit{R v Lovett} 2017 CarswellAlta 2449, 2017 ABQB 703 \textit{[Lovett]}
\textit{Health Care Consent Act,} 1996 S.O. 1996, c 2 Schedule A
\textit{Stephan, supra}
\textit{Lovett, supra}
\textsuperscript{58} LF Ross. “Children, families and healthcare decision-making” New York: Oxford University Press, 1998,
F Shoeman. “Parental discretion and children’s rights;background and implications for medical decision-making” J Med Philos 1985, 10:45-6 \textit{[Shoeman]}
R Rhodes and IR Holzman.”The not unreasonable standard for assessment of surrogates and surrogate decisions” Theor Med 2004; 25: 367-85 \textit{[Rhodes]}
\end{flushright}
Discretion\textsuperscript{60}. This combines the concepts of “Best Interests” and The Harm Principle\textsuperscript{61}. This Zone of Parental Discretion asserts that it is ethically permissible for parents to make decisions that fall into the moral gap below the optimal best interests of their child and the cut-off point of what will cause harm to their child if the parents’ decision is followed. Although ethicist\textsuperscript{62} argue for slightly different considerations and standards when deciding when to override parental autonomy, there seems to be a consensus that parents do not need to maximize condition of their child, but they are not allowed to cause foreseeable harm to their child and parents may not use their personal beliefs systems to justify allowing foreseeable harm to come to a child. The decisions in \textit{R v Stephan}\textsuperscript{63} and \textit{R v Lovett}\textsuperscript{64} are legal confirmation of the concept of the Zone of Parental Discretion and place clear legal limits on the rights of parents to make choices regarding their child’s bodily integrity when influenced by cultural desires to conform.

I conclude that the desire to have their children conform with a Western societal “norm” of genital appearance via cosmetic genital surgery does not fall within the ethically permissible Zone of Parental Discretion and is not compatible with case law. In reading the provisions of s 268(3) and (4) as a whole and in the historical context of the intention of parliament, cosmetic genital surgery on girls under 18 should be interpreted as prohibited under s 268 (3)(a) and (4) in all cases.

\textbf{IV: Prosecution is Justified}

The question remains if the goal of protecting girls from harmful cultural practices furthered by criminal prosecution, and if so which parties should be prosecuted?

During the standing committee hearings, there was intense discussion about whether criminal law was the correct vehicle to condemn FGM and protect children\textsuperscript{65}. One recurring

\begin{flushright}
\textsuperscript{61} DS Diekema “Parental Refusals of Medical Treatment: the Harm Principle as Threshold for State Intervention” Theor Med Bioeth 2004; 25: 243-64. [Diekema]
\textsuperscript{62} Ross, supra, Shoeman, supra, Rhodes, supra, Kipnis, supra, Diekema, supra
\textsuperscript{63} Stephan, supra
\textsuperscript{64} Lovett, supra
\textsuperscript{65} Testimony of Michelle Williams, Policy Researcher and Analyst, African Canadian Legal Clinic, Evidence of the Standing Committee on Justice and Legal Affairs, November 26, 1999 [Williams]
\end{flushright}
theme of concern was the unintended consequences of prosecuting and convicting parents who would otherwise be fit parents and were acting out of cultural beliefs and a desire for their child to conform to a cultural norm. There may be further damage to the child’s personal development if the parents serve a long prison sentence. The debate focused on the need for the criminal law to serve deterrent, educational and punitive functions while avoiding inflicting further harm on the already victimized child. It was suggested that there be a more severe sentence for health care providers\textsuperscript{66} because physicians should “know better than to perform FGM….so their degree of responsibility is heightened in this regard”, reflective of s718.1 Fundamental Principle “a sentence must be proportionate to the gravity of the offence and the degree of responsibility of the offender”\textsuperscript{67}. To date, no Canadian health care providers have been charged under s 268. In the USA, Dr Jumana Nagarwala is currently facing a life sentence under US federal law prohibiting FGM\textsuperscript{68} for allegedly performing FGM procedures on two girls in Michigan.

In considering cosmetic genital surgery, the parallel arguments could be asserted. Health care providers should “know better” than to harm the genitals of minors for cultural motivations and held to account for their actions. The promotion of the subjugation of women and girls in Canada through the coercive dominance of their bodies for profit is counter to the principles of equality and the spirit of the \textit{Charter of Rights and Freedoms}\textsuperscript{69}. Cosmetic genital surgery does not fall into the category of socially redeeming genital surgery qualifying for the medical exemption under s268(3)(a). The prosecution of healthcare practitioners performing these procedures would serve a deterrent purpose and signal that cosmetic genital procedures are an expression of the same societal harms that lead to FGM. The prosecution of offenders under s 268 will ultimately serve as recognition of the subversive undermining of the development of the authentic self in Western women and girls through our dominant socio-political paradigm.

\textbf{V: Conclusion}

Cosmetic genital surgeries exist on the same continuum of domination of the female body as female genital mutilation. Both serve to surgically manipulate the female genitalia to conform

\textsuperscript{66}Williams, supra
\textsuperscript{67} \textit{Criminal Code} s 718.1
to the dominant societal norm. By using purposive interpretation it can be concluded that cosmetic genital surgeries on girls under 18 years are currently prohibited by the Canadian Criminal Code. Prosecution of healthcare practitioners providing these services would serve to recognize the forces leading to non-authentic choice in Canadian women and girls and further the spirit of equality of the Charter of Rights and Freedoms.
SUNDAY, FEBRUARY 25

COLONIAL | 10:45 am – 12:30 pm

GENERAL SESSION V: Daubert at 25: Where Have We Come?
Moderator: Leon Aussprung, MD, JD, FCLM

• 10:45 AM - 11:15 AM Daubert and Expert Witnesses: A Historical Perspective
  Jack Snyder, MD, JD, FCLM

• 11:15 AM - 11:45 AM Daubert: Plaintiff’s Counsel’s Perspective
  Francois Blaudeau, MD, JD, FCLM

• 11:45 AM - 12:15 PM Daubert: Defense Counsel’s Perspective
  Joe Piorkowski, MD, JD, FCLM

• 12:15 PM - 12:30 PM Q & A General Session
Daubert v. Merrell Dow Pharmaceuticals: A Historical Perspective

Jack Snyder, MD, JD, PhD, FCLM
57th Annual Meeting of the American College of Legal Medicine
February 25, 2018

Treatises on Experts

How to Be An Expert
Today's Challenge

**Daubert, or Not Daubert**

*Does it Make a Difference?*

Experts Before 1923

- If “qualified,” then “entitled”
- Is subject matter “beyond range of knowledge of average juror”?
- Success, prosperity, commercial value - marketplace test defines expertise
- Test doesn’t distinguish expert from expertise, presupposes expertise exists without determination of its validity

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**Frye v. United States**

293 F. 1013, 1014 (1923)

- Systolic blood pressure deception test
- Novel technology
- No “marketplace acceptance”
- New test for admissibility needed

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**Frye v. United States**

293 F. 1013, 1014 (1923)

“Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.”
Frye v. United States
293 F. 1013, 1014 (1923)

- General acceptance within its field
  - (? astrology)
- Separates expert from expertise
- Moves to “intellectual marketplace”
- Replaces buyers of knowledge with sellers
  of knowledge
- Deals with new knowledge that lacks
  established clientele

Problems with Frye

- Vagueness
- Not necessarily related to reliability
- Imposes waiting period for GA
- Time of onset of GA rarely clear
- No std for defining “particular field” (how
  many noses to count?)
- Less rigorous field may be less scrutinized
  by court


- Exposure to Bendectin alleged to have caused limb
  reduction birth defects
  TC & 9th Cr. reject animal studies, structure-activity
  analyses, and statistical reanalysis of EPI studies by ¶’s
  experts, citing lack of general acceptance (Frye)
  5th Cr. remands and says FRE supersedes Frye
  Judge (gatekeeper) determines admissibility based on
  reliability (scientific knowledge) and relevance
  (helpfulness or “fits the facts”)
  9th Cr. rejects ¶’s experts again on remand

Daubert Admissibility

- Gatekeeping implies affirmative
  obligation (¶ Rule 104a hearing or just
  a “record”)?
- Proponent has burdens of production
  & persuasion (FRE 702) by
  preponderance

Daubert Admissibility

- FRE 402 Relevance = Fit plus
  helpfulness
- FRE 702 requires FRE 402 Relevance
  PLUS Reliability (Knowledge based on
  Qualifications plus Validity)

Foundation of Expert Opinion

- Expert can rely upon:
  - Personal knowledge or first-hand observation
  - Facts made known at trial
  - Inadmissible facts if of a type reasonably relied
    upon by expert and his peers (many courts make
    independent determination of trustworthiness)
  - Courts determine adequacy of factual foundation
    as a matter of law
Qualifications

- Necessary but not sufficient?
- What sort of qualifications?
- Need for credentials in appropriate specialty?

Qualifications

- Knowledge, skill, training, experience, OR education – wide latitude among courts
- Judge must address Q in abstract as well as Q to testify about subject relevant to issues at bar
- Typically matter of weight rather than admissibility

Qualifications of Experts

- Knowledge, skill, experience, training, or education - for most courts, just need one of these
- Typically must be licensed physician familiar with problem or procedure in order to testify on medical (usually nat’l) std of care (but see medical device cases)
- Non-physicians frequently testify about causation
- Labels are not as important as competence for EWs

Daubert: 50-State Overview

- https://jurilytics.com/50-state-overview
- Daubert and Frye propose two different standards of admissibility in expert testimony. Frye evaluates the “general acceptance” of the testimony in the field from which it comes, while Daubert tasks judges to evaluate the “methods and principles” upon which the expert opinions are founded. Many state courts have expressed that Daubert constitutes a more liberal standard for admissibility than Frye. On the flip side, some courts have found that Daubert in practice actually constitutes a more restrictive test.

Frye vs. Daubert

- Frye looks at whether expert knowledge is “generally accepted.” Therefore, expert evidence that is generally accepted but has weak scientific foundation can be admitted.
- Conversely, Daubert inspects the “methods and principles” underlying expert opinion. As a result, opinions that have strong scientific foundation, but have not been generally accepted, can be admitted. In many cases, the two are consistent. But in some cases (e.g., bitemark evidence), the two can diverge.

Comparing Frye and Daubert in Florida as of 2015
### Simplistic Comparison of Frye/Daubert

<table>
<thead>
<tr>
<th>Daubert Scientific Foundation Strong</th>
<th>Daubert Scientific Foundation Weak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frye General Acceptance</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Both Admit</td>
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<tr>
<td>Low</td>
<td>Frye Excludes Daubert Admits</td>
</tr>
<tr>
<td></td>
<td>Both Exclude</td>
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</tbody>
</table>

### General Electric Company v. Joiner

*118 S. Ct. 512 (1997)*

- Exposure to PCBs alleged to have caused ¶’s lung Ca
- TC rejects animal studies cited by ¶ due to wrong dose, wrong tumor, wrong route of exposure; lack of fit with the facts; & lack of justification for extrapolation
- TC rejects EPI studies since authors denied causation; correlations were not statistically significant; different types of chemicals were involved (D msj granted)
- 11th Cir. reverses, applying a “stringent standard of review to the trial judge’s exclusions...”

### General Electric Company v. Joiner

*118 S. Ct. 512 (1997)*

S.Ct. holds “abuse of discretion” std. applies - Ct.App. shouldn’t reverse unless TC ruling “manifestly erroneous” & Ct.App. “may not categorically distinguish between rulings allowing ET & rulings which disallow it”

¶ “claims that because [TC’s] disagreement was with the conclusion that the experts drew from the studies, the [TC] committed legal error...But conclusions & methodology are not entirely distinct from one another. Trained experts commonly extrapolate from

### Appellate Review

- Matters of law – typically de novo review
- Matters of fact – “abuse of discretion” deference
- “Trans-case” (less deference) vs. “case-specific” (more deference) facts
- High vs. low level of “abstraction”

### Kumho Tire Co., Ltd. v. Carmichael

*119 S. Ct. 1167 (1999)*

Tire defect alleged to cause blowout which caused MVA
TC says ¶’s expert can’t testify because analytic methods were unscientific (D msj granted)
11th Cir. remands & says Daubert doesn’t apply Breyer/Scalia say trial judge must perform gatekeeping adequately but has great latitude to apply Daubert to determine reliability & validity - failure to apply Daubert may be abuse of discretion in some cases
Outcome: No error by TC - Daubert stds can be applied to non-scientific expert, so D wins
Technical or Other Specialized Knowledge

- FRE 702 does not distinguish scientific from technical or other specialized knowledge
- Does testimony have reliable basis in the knowledge and experience of the relevant discipline?
- Will methods for testing reliability (methods) vary excessively?

- Kumho as “wake-up” call for defense bar?
- Police officers
- Forensic scientists
- Social scientists
- Whether courtroom expert “employs same level of intellectual rigor that characterizes practice of an expert in the relevant field? – undesirable end-around Daubert?


- Defective home heater caused fire/death by CO
- Fire investigators and metallurgist as experts – TC admitted testimony – plaintiff prevails
- 8th Cir. reversed, remanded, TC told to enter J as matter of law for defendant
- S.Ct. upholds, Ginsburg says Ct. App. can rule that plaintiffs don’t get “second bite of the apple”

Confusion of Terminology

- Scientific Reliability means reproducibility, consistency
- Scientific Validity means accuracy (does it show what it purports to show?)
- Court says “evidentiary reliability is based on scientific validity”

Daubert Standards for Validity

- Four Non-Exclusive Factors
  - Testability (Falsifiability, Refutability, Testable & Adequately Tested)
  - Error Rate
  - Peer Review & Publication
  - General Acceptance

Subject Matter of Expert’s Opinion

- Factors that Help Courts ID Scientific Knowledge
- Whether the theory or technique can be or has been tested in accordance with scientific methods
- Whether it has been subjected to peer review and publication
- Known or potential rate of error and stds controlling a technique’s operation
- Degree of acceptance of theory or technique within the relevant scientific community
Falsifiability - Testability
- Most important factor
- Principles/Methodology (Judge)-Conclusion (Jury) Paradox
- Analytical Gap: ipse Dixit of Expert not enough to connect Method with Conclusion (some conclusions permitted, some are not)
- Switch to General Causation v. Specific Causation (must prove GC to get to SC)

General v. Specific Causation
- Should judges rule on general causation while juries determine specific causation?
- If judges don’t rule on GC, then aren’t we allowing the expert to speculate?

Error Rate(s)
- False negatives
- False positives
- Random v. Systematic (recall bias) errors
- Should tolerable rates be based on cost of mistakes or being wrong?
- If ER only slightly better than coin flip, good enough?

Peer Review and Publication
- Submission to scrutiny indicates “good science”
- Want to detect serious flaws in study designs and methodology
- Peer review occurs before and after publication

Role of General Acceptance of Scientific Evidence (Frye)
 Civil or criminal matter?
 State or Federal court?
 What is relevant scientific community?
 What is the measure of general acceptance?
 Causation or methodology or both?

“A reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community...Widespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique that has been able to attract only minimal support within the community...may properly be viewed with skepticism.”
Other Factors To Consider

- Whether the method consists of a testable hypothesis
- Whether the method has been subject to peer review
- The known or potential error rate
- The existence and maintenance of standards controlling the technique’s operation
- Whether the method is generally accepted
- The relationship between the technique and methods established to be reliable

Other Factors To Consider

- The qualifications of the expert
- The non-litigation uses for the method or technique
- Falsifiability or amenability of method or technique to empirical testing
- Logical consistency (both internally & externally)
- Consistency with accepted theories
- Precision and accuracy of the method or technique
- Degree to which conclusions are based on generalizations or information of unverifiable origin

Federal Rule of Evidence 403

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

Amended FRE 701

If the witness is not testifying as an expert, the witness’ testimony in the form of opinions or inferences is limited to those opinions or inferences which are (a) rationally based on the perception of the witness and (b) helpful to a clear understanding of the witness’ testimony or the determination of a fact in issue, and (c) not based on scientific, technical or other specialized knowledge.

Amended FRE 702

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise, provided that (1) the testimony is sufficiently based upon reliable facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.
Amended  
FRE 703

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted. If the facts or data are otherwise inadmissible, they shall not be disclosed to the jury by the proponent of the opinion or inference unless their probative value substantially outweighs their prejudicial effect.

Federal Rule of Evidence 704

(a) Except as provided in subdivision (b), testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.

(b) No expert witness testifying with respect to the mental state or condition of a defendant in a criminal case may state an opinion or inference as to whether the defendant did or did not have the mental state or condition constituting an element of the crime charged or of a defense thereto. Such ultimate issues are matters for the trier of fact alone.

Federal Rule of Evidence 705

The expert may testify in terms of an opinion or inference and give reasons therefor without first testifying to the underlying facts or data, unless the court otherwise requires. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

Federal Rule of Evidence 706

The court may on its own motion or on the motion of any party enter an order to show cause why EWs should not be appointed, and may request the parties to submit nominations. The court may appoint any EWs agreed upon by the parties, and may appoint EWs of its own selection. An EW shall not be appointed by the court unless the EW consents to act. An EW so appointed shall be informed of duties by the court in writing, or at a conference in which the parties shall have the opportunity to participate.

A witness so appointed shall advise the parties of the witness' findings; if any, the witness' deposition may be taken by any party, and the witness may be called to testify by the court or any party. The witness shall be subject to cross-examination by each party, including a party calling the witness.
Daubert: 25 Years Later
Sunday, February 25, 2018
American College of Legal Medicine

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Daubert: Defense Counsel’s Perspective

Two representative cases illustrating differing approaches to Daubert – rigorous versus lenient

Milward v. Acuity Special Products Group (1st Cir. 2011)

High water mark for appellate courts that follow a lenient standard with respect to admissibility of expert testimony

The Daubert standard "is not monolithic: within it, embedded findings of fact are reviewed for clear error, questions of law are reviewed de novo, and judgment calls are subjected to classic abuse-of-discretion review."

Relevant inquiry: In reaching opinion, did expert apply methodology with the same level of intellectual rigor he used in his scientific practice?

- Less inquiry into whether that methodology was itself intellectually rigorous

Milward v. Acuity Special Products Group (1st Cir. 2011) (continued)

Trial court rejected expert testimony because he assigned weight to evidence that should not have been considered reliable – “at best a plausible hypothesis.”

First Circuit reversed, approving of expert’s weight-of-the-evidence approach.

Ipse dixit: This evidence has weight because I am ascribing it weight.

But Joiner directed courts to reject testimony when there is "too great an analytical gap between evidence and conclusion."

First Circuit said the gap was of the court’s own making.
C.W. ex rel. Wood v. Textron, Inc. 
(7th Cir. 2015)
Toxic tort suit: plaintiffs sued after their home's well was contaminated with vinyl chloride, a toxic gas. Plaintiffs' infant children experienced some acute symptoms and neurological issues. Defendant, which operated a nearby plant that released vinyl chloride, successfully moved to exclude Plaintiff's experts on causation.
◦ The trial court rejected a post hoc ergo propter hoc methodology: cannot conclude causation because illness occurred after levels exceeded regulatory requirements.
◦ Similarly, ruling out alternatives is not a reliable methodology to show causation.

Bases of Successful Daubert Challenges

Ipse Dixit:
◦ Latin meaning: “He himself said it”
◦ Actual meaning: “Because I said so”
◦ Conclusory opinions that are unsupported by scientific reasoning

Analytic Gaps:
◦ Similar to Ipse Dixit, but more reasoning articulated by expert.
◦ Reasoning contains serious gaps in logic
◦ Basing opinion/calculation on erroneous predicate facts
◦ Failing to exclude alternative explanation/rule out alternative causes
◦ Selectively choosing to rely on studies that support expert’s opinion while ignoring contrary studies with no reasoned basis

Bases of Successful Daubert Challenges

Ipse Dixit (example):
◦ Issue: whether damage to property was caused by wind (covered by policy) or rain (not covered by policy)
◦ Expert opined “within a reasonable degree of engineering certainty” that the roof and flashing were first damaged by wind and that the water penetration and damage followed the wind damage
◦ Court found the proffered testimony of plaintiff’s expert inadmissible because expert “does not mention the type of material used in the flashing or attempts to approximate the wind speeds necessary to cause the flashing to peel back. This reviewer finds plaintiff’s expert’s testimony speculative. Second, while plaintiff’s expert did state his conclusion was based on the premise that the roof was not damaged before a storm, he completely ignored any evidence of damage from prior damage or rain damage prior to the storm. Third, that expert did not examine the roof in person until May 17, 2012 — eight months after the damage allegedly occurred and after repairs had been completed — calls into doubt the reliability of his testimony given the absence of a clear methodology or relevant data.”

Analytic Gaps (examples):
◦ Expert based used assumptions for calculations that were inconsistent with factual record
◦ Expert failed to validate his results against other studies
◦ C.W. ex rel. Wood v. Textron, 807 F. 3d 827 (7th Cir. 2015) 2015)
◦ Expert relied on studies that were too attenuated with respect to injuries being claimed by plaintiffs
◦ Expert failed to “connect the dots”
Bases of Successful *Daubert* Challenges

**Misapplication of Scientific Principles to Case at Hand:**

- Scenario starts with scientific principle or opinion that is reliable and generally accepted but attempts to extrapolate to facts of individual case when principles do not apply.
- Represents a distinct subtype of gaps in scientific reasoning.
- Example is *Tillman v. C. R. Bard, Inc.* 96 F. Supp 3d 1307 (M.D. Fla. 2015)
  - Products liability case involving IVC filter.
  - Expert’s analysis and methodology focused on design defect or manufacturing defect that resulted in failure of IVC filter.
  - Case at hand involved filter that had tilted and migrated, but not fractured.
  - Disconnect between expert’s opinions about product defect and facts of case.

Overview of State Law

- 29 states apply *Daubert* or a similar test.
- 17 states continue to apply *Frye* in at least some circumstances.
- Some degree of overlap with *Daubert* states.
- 6 states have not rejected *Frye*, but apply *Daubert* factors.
- 4 states have developed their own tests.

Questions/Discussion
Thank You

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