Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

Program Planning Committee
Heather H. Pierce, Program Chair
Jeffrey D. Kahn
Kristen C. Kim
Kristen B. Rosati
Stephen Sencer

Program Learning Objectives
• Increase knowledge of the legal and regulatory issues unique to AMCs and teaching hospitals
• Gain a greater understanding of the strategic challenges facing AMCs and teaching hospitals
• Learn about recent legal developments, cases, and trends

Registration Fees:
Postmarked and paid on or before January 3, 2018
$750 first AHLA/NACUA/AAMC Member
$675 each additional Member
$1000 Non-Member
Postmarked and paid between January 4-18, 2018*
$875 first AHLA/NACUA/AAMC Member
$800 each additional Member
$1125 Non-Member

* Fees increase $100 after this date

Discounts
$100 off full applicable rate In-House Counsel/Solo Practitioner
$600 Government/Academician/Public Interest Professional AHLA/NACUA/AAMC Member
$700 Government/Academician/Public Interest Professional Non-Member
$375 One-Day Registration AHLA/NACUA/AAMC Member
$500 One-Day Registration Non-Member

Practice Group Luncheon
$60 Member of sponsoring Practice Group(s)
$70 Non-Member of sponsoring Practice Group(s)

Hotel Information
The Ritz-Carlton Pentagon City Hotel
1250 S Hayes Street
Arlington, VA 22202
(703) 415-5000 or (800) 241-3333
Hotel accommodations are not included in the registration fee. Call The Ritz-Carlton Pentagon City Hotel at (703) 415-5000 or (800) 241-3333 and indicate that you are attending the AHLA program. Rooms at the group rate of $199 single/double occupancy are limited and may sell out prior to the Wednesday, January 3, 2018 cut-off.

For the most up-to-date information and to register, visit our website at www.healthlawyers.org/programs
Thursday, January 25, 2018
7:00 am-5:15 pm
Registration and Information
7:00-8:00 am
Continental Breakfast, sponsored by PYA
This event is included in the program registration. Attendees, faculty, and registered spouses and guests welcome.

GENERAL SESSION

8:00-8:15 am
Welcome and Introduction
Marilyn Lamar, AHLA President-Elect
Heather H. Pierce, Program Chair

8:15-9:30 am
Institutional Resilience: Disaster Preparation and Recovery and the Role of the Lawyer
Robert Corrigan
Michele M. Garvin
• Lessons learned from a single institution (Baylor College of Medicine) across time, from Allison in 2001 to Harvey in 2017
• The roles of the general counsel and outside counsel during disaster preparation and response
• AMC considerations in disaster response beyond clinical care: Research and education
• The short-term and long-term phases of rebuilding

9:30-10:30 am
Individual Resilience: Burnout, Wellbeing, and How the Lawyer Can Help Our Providers and Institutions
Mona M. Abaza
• Increasing physician and trainee burnout is well-documented and its consequences have serious implications for the health and stability of the workforce. Institutional responses to growing concerns about health care provider stress, wellbeing, and resilience affect the overall health of the academic institution.
• What are the contributors and solutions to health care provider burnout and suicidality? How do issues of burnout and its consequences impact the institution and what is the role of institutional leadership?
• What is the role of the in-house lawyer or outside counsel and how might these attorneys help to address—or be contributors to—this situation?

CONCURRENT SESSIONS

10:45 am-12:00 noon Extended Sessions

A. Navigating New Terrain: Recent Developments in Human Subjects Research Regulation (not repeated)
Laura Odwazny
Heather H. Pierce
Kristen B. Rosati
The Feds have been busy! The past year has seen significant developments in the Federal regulation of human subjects research on multiple fronts, and at the statutory, regulatory, and policy levels. Some developments are intended to reduce burden, and others impose new or different requirements. This session will delve into the thorny issues of implementation, and identify and address the challenges involved with integrating these new mandates and flexibilities within the system of Federal human subjects research regulation. The speakers will cover the most recent hot topics, including:
• The revised Common Rule:
  – When and how will it be enforced?
  – Will there be a possible new framework to assess the “identifiability” of biospecimens, and how will that interact with HIPAA?
  – How will the exemption for activities regulated by the HIPAA Privacy Rule apply?
  – How will organizations implement “broad consent”?
  – What are other challenging issues presented by the new rule?
• FDA guidance on waiver of informed consent
• NIH Certificates of Confidentiality policy
• Part 2 regulations
• 21st Century Cures Act implementation
• Any other changes in Federal research regulation

B. The AMC Fraud and Abuse Highway: Reviewing the 2017 Potholes and Speed Bumps and Predicting the Road Ahead
Robert G. Homchick
Lisa Ohrin Wilson
• Significant law enforcement activity during 2017: FCA, criminal indictments, and more
• Fraud and abuse self-disclosure: Changes to the CMS Voluntary Physician Self-Referral Disclosure Protocol
• Managing compliance with the 60-day rule with limited resources
• Overlapping surgeries, physician compensation, research grants, and other recurring compliance nightmares

C. Structuring AMCs for Success across Three Missions: Thoughts and a Case Study
Jack M. Beal
Michael B. Lampert
Successful AMCs must coordinate across the missions of education, research, and clinical care. Each mission can strengthen the other, but getting the right balance can be hard—and it can be infinitely harder when schools of medicine, hospitals, and faculty practice plans don’t all sit under the same organizational roof.
• Various models of AMC structures and what challenges the different models can present
• Deep dive into a case study—the University of Kansas Medical Center—which has evolved through three different models over the last two decades
  – The drivers behind the most recent reorganization
  – Tools that the parties deployed to integrate more tightly the components of the AMC
• Lessons that might be drawn for AMCs in assessing their structures, their intra-AMC relationships, and what they might consider on their own campus
Continuing Education Credit Information

CLE/MCLE: AHLA will be applying for 11.75 credits (including 1.0 ethics credit) for 60-minute states and approximately 14.1 credits (including 1.2 ethics credit) for 50-minute states.

CPE: AHLA will be applying for 14.0 CPE credits.

AHLA is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Ave. North, Suite 700, Nashville, TN 37219-2417. NASBA’s website is www.nasba.org.

CBB: AHLA will be applying for 14.1 Compliance Certification Board (CBB) credits.

Participants will be given Continuing Education Request forms at the program. Forms must be completed and returned to AHLA staff to receive credit. The sessions, unless otherwise designated, are intermediate to advanced in level. This program is designed to be an update on developments in the area of teaching hospitals and academic medical centers. There are no prerequisites or advanced preparations required to register for this group live program. Those seeking accounting credits should be familiar with the basic concepts and terminology associated with health law in order to obtain the full educational benefit of this program.

Membership

Dues are $235 for those admitted to the Bar/graduated from college within the last four years; $355 for those admitted/graduated between four and seven years ago; and $400 for those admitted/graduated eight or more years ago. Dues are $120 for government employees and full-time academicians; $105 for para-legals, $125 for public interest professionals, and $100 for retired professionals. Include the applicable membership fee with your registration form and take advantage of the program registration fee for members.

12:00 noon-1:15 pm
Lunch on your own or attend the Academic Medical Centers and Teaching Hospitals and Life Sciences Practice Groups Joint Luncheon, sponsored by PYA

Topic: The Lion in the Path: Precision, Participants, and Privacy
Carrie D. Wolinetz, Associate Director for Science Policy and Acting Chief of Staff to the Director at the National Institutes of Health (NIH), Bethesda, MD

Dr. Wolinetz will highlight the exciting science and initiatives NIH is currently doing in the realm of precision medicine along with promising discoveries, engagement efforts with research participants, and the agencies processes to secure privacy and protections of participants in NIH funded clinical trials and cohort studies.

This event is not included in the program registration. Limited attendance; additional fee; pre-registration required.

CONCURRENT SESSIONS

1:30-2:30 pm
D. Project Unify: A National Model for Clinical Integration of Rural Health and Public Medical Education (not repeated)
Mary Beth Johnston (Moderator)
H. Guy Collier
Donna Gooden Payne

- The legal and transactional issues associated with the clinical integration of a state medical school faculty practice plan (East Carolina University Physicians) and the health system-affiliated group practice of its long-time hospital partner (Vidant Health)
- The legal status and governance of the corporate vehicle, which is both state university sponsored and health system controlled, created to operate this integrated practice
- Uniquely AMC issues related to maintaining medical school accreditation and the infrastructure/integrity of the academic enterprise, sponsorship of graduate medical education and expansion of clinical or academic affiliations, and faculty appointment and tenure
- Funds flow and academic mission support payments

E. Legal Ethics: Who is Your Client?
Stephen S. Dunham
Stephen Sencer

- Representing academic medical centers requires a lawyer to represent a client with multiple competing missions and/or multiple clients with interlocking finances, governance and missions
- The ethical rules and practical guidance on how in-house and outside counsel manage those relationships with integrity
- The applicable Model Rules of Professional Conduct
- Hypothetical situations involving tensions between competing missions within AMC’s

F. When Your Data Travels More Than You Do: Privacy and Security Implications of Cross-Border Data Transfers
Melissa L. Markey
Edward H. You

- What are the privacy risks to individuals of cross-border data transfer? What are strategies to minimize those risks in a transaction?
- What cybersecurity concerns are presented in cross-border transactions? What are strategies to minimize those risks in a transaction?
- What are risks and strategies related to vendors using off-shore subcontractors (and what does it mean for data to be “off-shore” when so much is in the cloud)?
- Are there national security concerns that TH-AMCs should be considering for cross-border data transfers?
- Are there export control concerns related to transactions with foreign companies that transfer specialized knowledge of biological or genetic research?
- When do foreign privacy laws apply to cross-border transactions?

2:45-3:45 pm
G. Challenges and Opportunities in “New Age” Health Care Collaborations at Home and Abroad (not repeated)
Bernadette M. Broccolo
Susan Stayn

Increasingly, AMCs are initiating, and are being sought out for participation in strategic collaborations with new players on the health industry scene—both domestic and foreign. These collaborations are often focused on development and implementation of new and innovative products and solutions in areas such as digital health, patient engagement, population health and care management, care quality/outcome improvements, payment models improvements, translational and retrospective research, and precision medicine. The participants’ cultures, approaches, goals and objectives align in some important respects, but not in others. Transactions with companies in other countries raise important and sometimes overlooked compliance considerations.

- Collaboration trends, examples, and associated
compliance and contracting planning strategies for creating a successful, sustainable, and compliant collaboration that align common interests and anticipate and manage tension points

• US laws that pose compliance challenges in collaborating with organizations new to the health care space

• The impact of the European Union General Data Protection Regulation on collaborations involving citizens from European companies

• Strategies for creating successful, sustainable, and compliant collaborations

H. Graduate Medical Education: Medicare Regulations and Policy Considerations
Tim Johnson
Lori Mihalich-Levin

• Payment for medical education
• Proposals to restructure Medicare GME payments
• New programs and CMS restrictions
• Litigation/compliance issues

J. New Models in Philanthropy to Support Medical Research
Hillary Bounds
Jake Handy
Ian Sweedler

• How funders determine the areas and types of research to support—basic research with broad application vs. targeted research
• Models for exploitation of intellectual property resulting from funded research—including ownership, licensing, revenue sharing, disclosure, and availability
• Financial considerations—project funding vs. broad funding; views on indirect costs
• Privacy concerns and use of data from research

4:00-5:15 pm Extended Sessions
K. (When) Will My Doctor Be A Robot? (not repeated)
Gary Marchant
Michael Troncoso

• How artificial intelligence (AI) is transforming and disrupting many aspects of health care and medicine
• The novel legal, ethical, and policy issues presented by AI
• Handling the legal and regulatory challenges presented by affiliated technologies, such as mobile health, wearables, and big data
• Critical issues in transactions and collaborations with industry involving AI and health care delivery

B. The AMC Fraud and Abuse Highway: Reviewing the 2017 Potholes and Speed Bumps and Predicting the Road Ahead (repeat)

C. Structuring AMCs for Success across Three Missions: Thoughts and a Case Study (repeat)

5:15-6:15 pm Networking and Diversity-Inclusion Reception, Hosted by AHLA’s Diversity-Inclusion Council, sponsored by PYA

Learn more about AHLA’s diversity and inclusion initiatives. Network with AHLA leaders and your fellow colleagues. This event is included in the program registration. Attendees, faculty, and registered spouses and guests are welcome.

Friday, January 26, 2018
7:00 am-2:45 pm Registration and Information

7:00-8:00 am Continental Breakfast, sponsored by PYA

This event is included in the program registration. Attendees, faculty, and registered spouses and guests welcome.

8:00-9:00 am The Future of Health Care and Medicine: A Washington Perspective
Karen S. Fisher

• Affordable Care Act
• Medicare and Medicaid
• Funding and regulation of Graduate Medical Education
• Funding and regulation of research
• Cmmi/alternative payment models

9:00-10:00 am The Future of the Academic Health Center
Marsha D. Rappleye

CONCURRENT SESSIONS

10:15-11:15 am
L. False Claims Act Liability Arising from Misconduct in PHS-Sponsored Research (not repeated)
Mark A. Borreilz
Gregg Shapiro

• PHS/NIH research funding processes and research integrity rules (including investigation and resolution of research misconduct)
• What constitutes a false claim in the context of federally supported research tainted by misconduct—what is a “claim” and what makes it “false”?
• Case law and recent False Claims Act enforcement activities arising from research misconduct
• The basis for institutional FCA liability in connection with research misconduct
• Preventing or reducing the risk of FCA allegations/liability

M. The Intersection of Age, Professionalism, Quality, and Law (not repeated)
Gerald B. Hickson
Charles E. Reiter

Medical leaders responding to a colleague who is thought to have diminished technical or cognitive skills and/or lapses in professionalism must balance competing interests while navigating a contradictory legal environment.

• The challenges, summarize legal concepts and research and conclude with practical tips for reaching a satisfactory resolution while minimizing the chance of litigation
• Surgeons and commercial airline pilots both accept responsibility for the safe passage of strangers, but members of only one of those professions may legally be forced to retire-pilots and chiefs of staff enjoy no such congressional protection from discrimination litigation
• The ADA, ADEA, and the Rehabilitation Act protect classes of persons from discrimination and would have protected the pilots but for Congress creating an exemption. Whether or not one thinks mandatory retirement ages are good and would have protected the pilots but for Congress creating an exemption. Whether or not one thinks mandatory retirement ages are good science or good public policy, department chairs and chiefs of staff enjoy no such congressional protection from discrimination litigation
• The HCQIA encourages and protects candid professional self-assessment but does not insulate medical leaders from discrimination claims
• Medicine is advancing at an increasing rate and the challenge of staying current has never been greater. Physician performance generally declines with age but the relationship is far from linear and mandatory age-related action may be discriminatory
Cancellations/Substitutions

Cancellations must be received in writing no later than January 15, 2018. Refunds will not be issued for cancellations received after this date. Registration fees, less a $125 administrative fee, will be refunded approximately 3-4 weeks following the program. If you wish to send a substitute or need more information regarding refund, complaint and program cancellation policies, please call (202) 833-1100, prompt #5. Please note that registration fees are based on the AHLA membership status of the individual who actually attends the program.

Special Needs

If you have needs requiring special assistance or accommodations, including special dietary needs, or have questions about accessibility issues at the program, contact our special needs coordinator, Valerie Eshleman at (202) 833-0784 or veshleman@healthlawyers.org.

Spouse/Guest Fee

For an additional $30 spouses and adult guests can register to attend the reception on Thursday evening and the breakfasts on Thursday and Friday mornings. Please sign up on the registration form. (Children are welcome to attend these events at no additional charge.)

Travel

ATC Travel Management (ATC) has negotiated discounts with Delta, Hertz, and Alamo to bring you special airfares and car rental rates lower than those available to the public. Discounts apply for travel for AHLA 2018 meetings, discounts available 3 days pre/post meeting start/end dates. Restrictions and a service fee may apply. ATC will also search for the lowest available fare on any airline.

ASSOCIATION TRAVEL CONCEPTS
1-800-458-9383
email: reservations@atcmeetings.com
http://www.atcmeetings.com/ahla

ATC is available for reservations from 8:30 am until 8:00 pm Eastern, Monday through Friday.

- Unsolicited patient complaint analysis predicts surgical outcomes, litigation risk and may identify physicians with early cognitive changes. Health care organizations need to have systems in place and processes to ensure that a fair and consistent approach is applied to all professionals within the organization

N. Traps, Tricks, and Trepidation in HIPAA and FERPA Compliance at Universities and AMCs
Marti Arvin
Kristin H. West

- Determining whether a university is a hybrid entity and what the “covered components” are that must comply with HIPAA
- Correct HIPAA “relationships” between the university’s covered components, the affiliated AMC, and the affiliated faculty practice plan or physician groups, including when an affiliated covered entity (ACE) or an organized health care arrangement (OHCA) is appropriate
- Areas of vulnerability in HIPAA compliance resulting from the university-AMC-faculty practice plan relationships, including:
  - When business associate agreements are needed between the entities
  - “Co-employment arrangements” when physicians are employees of the university when performing research and employees of the AMC/faculty practice plan when performing clinical care
  - Controlling faculty and student access to health information for research

11:15 am-12:15 pm
Lunch on your own

CONCURRENT SESSIONS

12:30-1:30 pm
O. Building a Compliant and Resilient 340B Program in the Midst of Regulatory Uncertainty (not repeated)
Richard P. Church
Donald P. Walker

Major 340B Program-related activities in the early months of the Trump administration and recent efforts in Congress to enhance program integrity and otherwise modify the 340B Program, including the impact of these developments on academic medical centers. The first months of the Trump Administration have brought flurry of activity in regard to the 340B Program, with the administration hinting at potentially major changes to come. Significant developments in this regard include the withdrawal of the controversial 340B Omnibus Guidance and the President’s budget proposal which called for new 340B Program legislation and expanded regulatory authority for HRSA. Congressional activity around the 340B Program also continues to ramp up, with lawmakers examining HRSA’s ability to protect program integrity and how covered entities use the 340B Program, among other issues

- States are now actively implementing new Medicaid MCO requirements that include better capture of rebates and increased regulatory action to eliminate duplicate discounts (e.g., Virginia’s recent prohibition on Medicaid MCO payments to contract pharmacies for 340B drugs). HRSA also has significant discretion in regard to enforcement of 340B Program requirements, and recent audit activity suggests that HRSA’s positions may be changing in certain areas

- Building a Compliant and Resilient 340B Program in the Midst of Regulatory Uncertainty: Practical steps based on experience with the 340B Program and building, maintaining, and expanding a 340B Program in a changing regulatory environment
  - Positioning the institution on 340B Program issues that remain in flux
  - Developing and reviewing an institution’s 340B Program policies and procedures
  - Adopting a comprehensive internal audit and review program to ensure ongoing compliance with the latest 340B Program guidance, identify potential compliance concerns, and take corrective action as needed
  - Training and engaging the legal and compliance teams on 340B Program issues
  - Engaging with a third party external auditor to conduct a comprehensive review of the AMC’s 340B Program
  - Handling manufacturer 340B Program inquiries/audits and HRSA audits, which have now become a routine part of the 340B Program

E. Legal Ethics: Who is Your Client? (repeat)
F. When Your Data Travels More Than You Do: Privacy and Security Implications of Cross-Border Data Transfers (repeat)

1:45-2:45 pm
H. Graduate Medical Education: Medicare Regulations and Policy Considerations (repeat)
J. New Models in Philanthropy to Support Medical Research (repeat)
N. Traps, Tricks, and Trepidation in HIPAA and FERPA Compliance at Universities and AMCs (repeat)

Adjournment
### Program Schedule

**Thursday, January 25, 2018**

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### 1:30-2:30 pm

| D. Project Unify: A National Model for Clinical Integration of Rural Health and Public Medical Education  
(not repeated) | E. Legal Ethics: Who is Your Client? | F. When Your Data Travels More Than You Do: Privacy and Security Implications of Cross-Border Data Transfers |
|-----------------|------------------------------------|-------------------------------------------------------------|
| Johnston (Moderator)  
Collier  
Payne | Dunham  
Sencer | Markey  
You |

### 2:45-3:45 pm

| G. Challenges and Opportunities in “New Age” Health Care Collaborations at Home and Abroad  
(not repeated) | H. Graduate Medical Education: Medicare Regulations and Policy Considerations | J. New Models in Philanthropy to Support Medical Research |
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Stayn | Johnson  
Mihalich-Levin | Bounds  
Handy  
Sweedler |

### 4:00-5:15 pm Extended Sessions

| K. (When) Will My Doctor Be A Robot?  
(not repeated) | B. The AMC Fraud and Abuse Highway: Reviewing the 2017 Potholes and Speed Bumps and Predicting the Road Ahead (repeat) | C. Structuring AMCs for Success across Three Missions: Thoughts and a Case Study (repeat) |
|-----------------|------------------------------------|-------------------------------------------------------------|
| Marchant  
Troncoso | Homchick  
Wilson | Beal  
Lampert |

### 5:15-6:15 pm

Networking and Diversity+Inclusion Reception, **hosted by AHLA’s Diversity+Inclusion Council, sponsored by PYA**  
(this event is included in the program registration. Attendees, faculty, and registered spouses and guests welcome)

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**Live Tweet the Program Using #AHLA18**

Will you be in Arlington, VA for Academic Medical Centers program? We encourage you to live tweet @healthlawyers so that attendees can learn from more than one session at once, and so that followers unable to attend still feel plugged in.
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The Future of Health Care and Medicine: A Washington Perspective  
Fisher  
9:00–10:00 am  
The Future of the Academic Health Center  
Rappley |
| 10:15–11:15 am|  
L. False Claims Act Liability Arising from Misconduct in PHS–Sponsored Research  
(not repeated)  
Borreliz  
Shapiro  
M. The Intersection of Age, Professionalism, Quality, and Law  
(not repeated)  
Hickson  
Reiter  
N. Traps, Tricks, and Trepidation in HIPAA and FERPA Compliance at Universities and AMCs  
Arvin  
West |
| 11:15 am–12:15 pm| Lunch on your own  |
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O. Building a Compliant and Resilient 340B Program in the Midst of Regulatory Uncertainty  
(not repeated)  
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E. Legal Ethics: Who is Your Client?  
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West |
Faculty

Planning Committee

Heather H. Pierce, Program Chair
Senior Director, Science Policy and Regulatory Counsel
Association of American Medical Colleges
Washington, DC

Jeffrey D. Kahn
Executive Vice President and General Counsel
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Phoenix, AZ

Stephen Sencer
Senior Vice President and General Counsel
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University of Colorado Denver
Aurora, CO

Marti Arvin
Vice President, Audit Strategy
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Kansas City, KS

Mark A. Borreliz
Verrill Dana LLP
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Hillary Bounds
Lead Counsel
Chan Zuckerberg Initiative
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Chicago, IL

Richard P. Church
K & L Gates LLP
Research Triangle Park, NC

H. Guy Collier
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Baylor College of Medicine
Houston, TX

Stephen S. Dunham
Adjunct Professor of Law, Vice President and General Counsel
Penn State Law
University Park, PA

Karen S. Fisher
Chief Public Policy Officer
Association of American Medical Colleges
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Michele M. Garvin
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Fenwick & West LLP
San Francisco, CA

Gerald B. Hickson
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Vanderbilt University Medical Center, Center for Patient and Professional Advocacy
Nashville, TN

Robert G. Homchick
Davis Wright Tremaine LLP
Seattle, WA

Tim Johnson
Senior Vice President
Greater New York Hospital Association
New York, NY

Mary Beth Johnston
K & L Gates LLP
Research Triangle Park, NC

Michael B. Lampert
Ropes & Gray LLP
Boston, MA

Gary Marchant
Regents’ Professor; Lincoln Professor of Emerging Technologies, Law and Ethics
Arizona State University Center for Law, Science and Innovation
Tempe, AZ

Melissa L. Markey
Hall Render Killian Heath & Lyman PC
Troy, MI

Lori K. Mihalich-Levin
Dentons US LLP
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Laura Odwazny
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