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MEDTECH | PHARMA

US Health Care Compliance Update

Thursday, November 7, 2019
Noon – 1 PM EST
11 AM – noon CST
10 AM – 11 AM MST
9– 10 AM PST

Presented by
Mark Gardner, M.B.A., J.D., President, Gardner Law
Amanda Johnston, J.D., R.A.C. Sr. Attorney, Gardner Law

The Depot, Minneapolis, Minnesota

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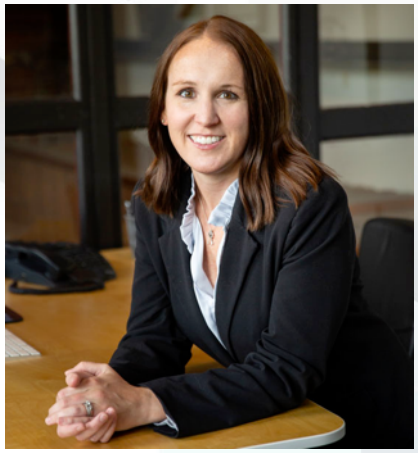
Agenda

- Speaker bios
- 2020 AdvaMed Code revisions
  - Overview
  - New additions
  - Notable updates
- Transparency reporting changes
  - Federal “Sunshine Act” reporting
  - State transparency reporting
  - Transparency best practices
- Recent settlements
- Compliance program auditing and monitoring best practices

Speaker bios

Mark Gardner, M.B.A., J.D.
President

- Former product manager
- Adjunct professor of law
- 20+ years in health care
- Former MedTox Laboratories, Celleration, ev3



Amanda Johnston, J.D., R.A.C.
Senior Attorney

- Former compliance officer
- Regulatory Affairs Certification
- 9+ years in health care
- Former United Health Group, Medtronic, Coloplast

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2020 AdvaMed Code Changes

AdvaMed Code – Overview

- Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals (AdvaMed Code)
  - AdvaMed Code was previously updated in 2009
  - 2020 revision goes into effect on January 1, 2020
- Several state laws require compliance with industry codes
  - CA, NV, and CT
  - MA and VT have stricter laws modeled after the Code
- Updates:
  - New sections
  - Updates to address evolving nature of HCP interactions
  - Improved readability, ease of use
  - Revised examples

New “Additions” to the AdvaMed Code

- New section: Jointly-Conducted Education and Marketing Programs
  - Outlines principles that companies should follow when conducting joint education or marketing programs
- New section: Communicating for the Safe & Effective Use of Medical Technology
  - Outlines principles that companies should follow when communicating truthful and non-misleading information about off-label or unapproved uses

New “Additions” to the AdvaMed Code

- New section: Demonstration, Evaluation, and Consigned Products
  - Outlines principles for company to follow for consigned product arrangements
- New section: Company Representatives Providing Technical Support in the Clinical Setting
  - Outlines principles that apply to company representatives in the clinical setting

Notable "Updates" to the AdvaMed Code

- Updates: Consulting Arrangements with HCPs
  - Detail on what constitutes legitimate need for consulting arrangement
  - More detail on objective valuation methods for FMV, conflict of interest
- Updates: Educational & Research Grants, Charitable Donations, and Commercial Sponsorships
  - Checklist added to aid in review of requests for third-party support, new defined terms
- Updates: Travel & Lodging: Venue
  - More guidance on location selection criteria and when companies can provide reasonable travel and lodging to HCPs
- Updates: Providing Modest Meals and Refreshments to HCPs
  - Consolidated and clarified HCP meal guidance, policies and controls

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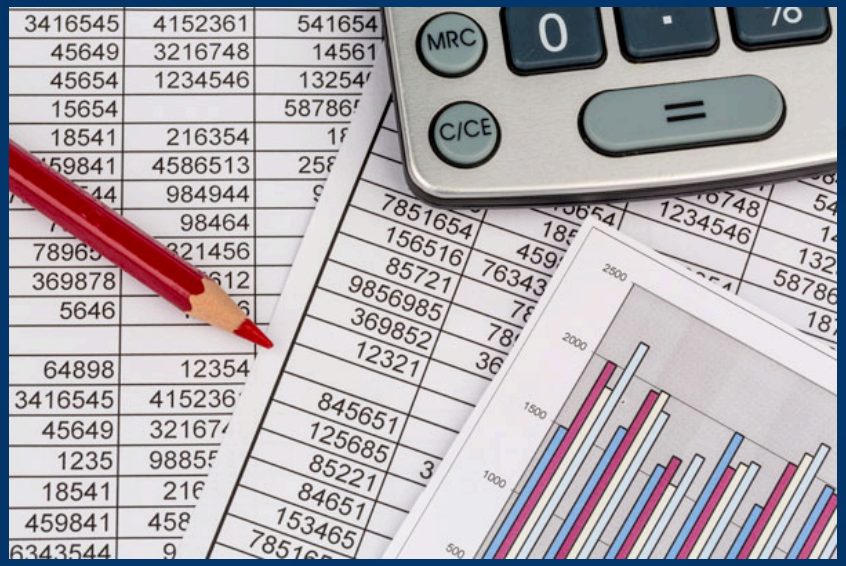
See our June Regulatory Alert for more info:
https://gardner.law/2019/06/june-2019/

PhRMA Code

- Pharmaceutical Research and Manufacturers of America (**PhRMA**) Code on Interactions with Health Care Professionals
- Updated September 2019
- Revisions were minor
  - The following clarifying language highlighted in yellow was added to sections 5 and 7 and is not a significant change:
    - Section 5: "A conference or meeting is any activity, held at an appropriate location (typically limited to the health care professional's country of practice unless there are security or logistical concerns, which would include international scientific congresses and symposia), where (a)…"
    - Section 7: "Speaker training sessions should be held in venues and locations (typically limited to the speaker's country of practice unless there are security or logistical concerns) that are appropriate and conducive to informational communication and training about medical information; specifically, resorts are not appropriate venues."

Transparency Reporting Changes



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Sunshine Act Updates

- Federal Physician Payments Sunshine Act ("Sunshine Act")
  - Annual submission March 31 to CMS through Open Payments system
  - Must report:
    - Payments greater than or equal $10.97 or more than $109.69 annually (for calendar year 2020) to physicians and teaching hospitals
      - Thresholds are adjusted annually based on CPI
    - Research payments and transfers
    - Ownership and investment interests
- CMS has disclosed 64+ million records since August 2013

Sunshine Act Updates

- New: Per SUPPORT Act of 2018, starting in January 2021, definition of “covered recipient” will be expanded to also include:
  - Physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives
  - Start tracking nurses for federal purposes January 1, 2021 for reporting in 2022
- New: 2019 Teaching Hospital list released by CMS
  - https://www.cms.gov/OpenPayments/About/Resources.html

Sunshine Act Updates

- New: November 1, 2019, CMS issued its final 2020 Physician Fee Schedule
  - New: Modified payment categories
    - Consolidated two categories for continuing education programs
    - Added three new categories: debt forgiveness, long-term medical supply or device loan, and acquisitions
  - New: Standardized data on reported medical devices
    - CMS proposes that ”DI” (fixed, mandatory) portion of UDI be reported starting on January 1, 2021. CMS will issue guidance on this.
  - New: As noted, definition of “covered recipient” expanded (as required by the SUPPORT Act)

Sunshine Act Trends

- More companies opting for automated systems (Porzio, MediSpend) vs. manual tracking and reporting
  - How are you tracking?
- Failure to report payments was cited by the government in Life Spine case
  - Will there be more enforcement in the future?
- Some vendors have started offering electronic sign-in sheet technology to automate tracking

Summary of state deadlines:

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Beware of International Transparency Requirements

- Australia
- Belgium
- Brazil
- Canada
- Colombia
- Croatia
- Cyprus
- Czech Republic
- Denmark
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Indonesia
- Ireland
- Israel
- Italy
- Japan
- Latvia
- Lithuania
- Malta
- Medicines for Europe
- MedTech Europe
- Middle East
- Netherlands
- Norway
- Philippines
- Poland
- Portugal
- Romania
- Russia
- Serbia
- Slovakia
- Slovenia
- South Korea
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- United Kingdom

State Updates

- New: New Jersey recently finalized its gift ban amendments (drug only)
  - Meal limits for promotional activities ($15 for breakfast and lunch; $30 for dinners) but not “education events”
  - $10,000 bona fide services cap
  - Changes to definitions for “education event,” “prescriber,” and “research”

- New: Colorado law requires drug companies to provide pricing and generic information to prescribers (drug only)
  - Must provide the wholesale acquisition cost of a drug, in writing, when they are providing “information concerning the drug to the prescriber”
  - Must also provide the names of at least three generic prescription drugs from the same therapeutic class, or if three are not available, as many as are available for prescriptive use.

Transparency Reporting Best Practices

- Implement policies and procedures to help keep track of and comply with state and federal transparency requirements
- Train affected staff
- Implement tracking and reporting system
  - Manual tracking or third-party reporting software/tools
- Use your QMS to track reporting and registration requirements to ensure deadlines are not missed and information is reported properly
- Don’t forget state requirements
- Consider international transparency reporting requirements

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See our July Regulatory Alert for more info:
https://gardner.law/2019/07/july-2019/

Recent Settlements

Life Spine

- $5.99 million settlement reached in October 2019
- Alleged Anti-Kickback Statute & False Claims Act violations
- CEO and VP of of Business Development also named as defendants
- Alleged conduct:
  - Paid millions of dollars to HCPs in exchange for purchasing products
    - 10% of total sales revenue
  - Life Spine did not report all payments to CMS per Sunshine Act
  - Aggressively recruited potential high-volume surgeons to enter into consulting arrangements
  - Recruited HCPs to transfer IP to Life Spine in exchange for payments and promised support to develop products
  - Payments to HCPs were tied to the their usage of Life Spine products
  - Expected HCP consultants to fulfill their “commitments”
  - Performed ROI calculations on HCP consultant agreements
  - HCP consultants accounted for 50% of Life Spine’s domestic sales

Mallinckrodt

- $15.4 million settlement announced in September 2019
- Alleged Anti-Kickback Statute & False Claims Act violations
- Mallinckrodt (formerly Questcor) allegedly provided illegal remuneration to HCPs by “wining and dining” them to induce prescriptions
  - Lavish meals and entertainment

Covidien

- $17 million settlement announced in March 2019
- Alleged Anti-Kickback Statute & False Claims Act violations (qui tam)
- Alleged conduct:
  - Paid HCPs for services that exceeded fair market value or were not performed
  - Provided free or discounted marketing staff who were tasked with driving referrals to customers
  - Drafting free marketing plans
  - Providing meals to referral HCPs with the intent to drive referrals to customers
  - Providing improperly structured discounts and free product
  - Promoting off-label use of products

Novartis

- In July 2019, Novartis reported that they have set aside $700 million to settle a kickback case
- Alleged conduct:
  - Providing remuneration in the form of lavish dinners, fishing trips, and other social events for HCPs to induce prescriptions
  - Paid for HCP speaker programs that did not occur
  - Violated Novartis internal policy that required speaker programs to have a legitimate educational purpose

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See our July Regulatory Alert for more info:
https://gardner.law/2019/09/sept-2019/

Compliance program auditing and monitoring best practices

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Auditing and monitoring

- Compliance program auditing/monitoring is #5 of the 7 elements of the OIG Compliance Program Guidance (CPG)
- Adoption of the CPG is required by California and Connecticut
- Auditing is also required by law in Massachusetts and Nevada under penalty of perjury

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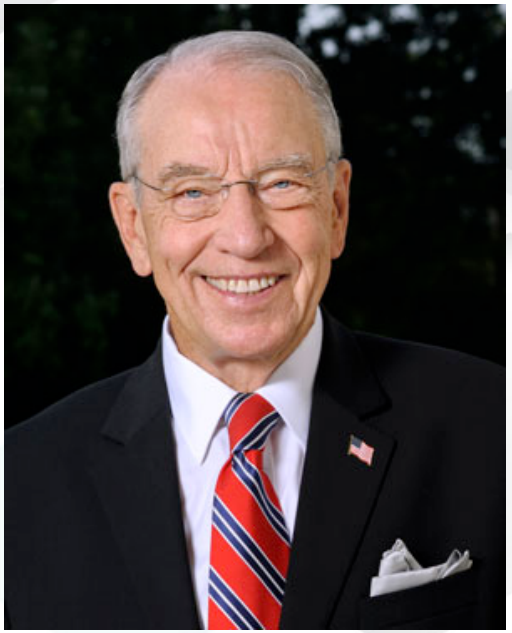
Is the government slowing down?

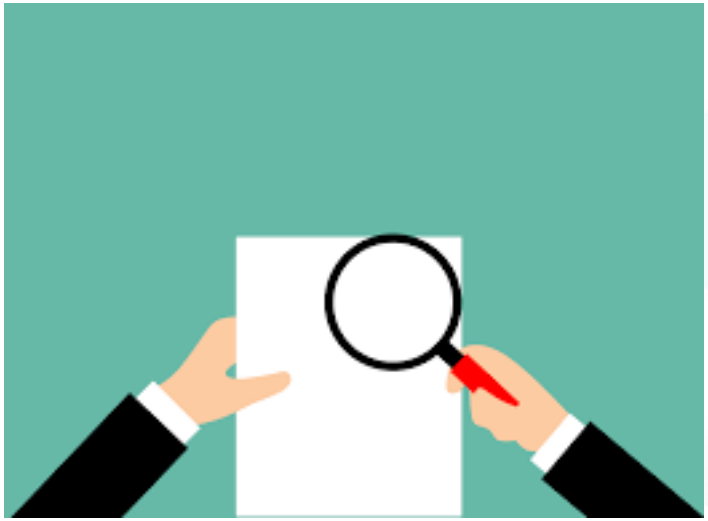
- Since fiscal year 2004, the OIG has reported over $53 billion in “expected investigative recoveries” in cases alleging health care fraud
- Sen. Charles Grassley (R-IA) complained on September 4, 2019 to U.S. Attorney General William Bar that the DOJ is dismissing whistleblower cases without appropriate consideration
- We predict an increase in whistleblower, a.k.a., “qui tam” or “relator” lawsuits alleging violations of the Anti-Kickback Statute and False Claims Act due to waning interest in prosecuting off-label promotion



“The qui tam provisions have reinvigorated an Act which had been mostly left for dead after the 1940s. In order for the law to continue working, DOJ must let the qui tam provision work the way it was intended and allow relators to proceed with litigation on their own.” – Sen. Charles Grassley (R-IA)

Best practices to mitigate risk

- Begin by auditing your compliance program and conducting monitoring activities
- Incorporate the CPG, AdvaMed/PhRMA, ACCME guidance into your policies, procedures, and training



What is auditing?

- Also known as a “gap assessment”
  - A compliance audit is a more formal and systematic examination of company behavior applied against legal, regulatory and industry best practices and company rules set forth in the compliance program
- Audits are often conducted under privilege
- Focus is directed towards company interactions with those in a position to purchase company products and/or influence prescribing behavior

How do I audit?

- During an audit, functions that interact with HCPs and health care entities are interviewed
- Documentation is reviewed
  - e.g., consulting and grant agreements, transparency reports, job descriptions, commercial plans, policies and procedures, promotional materials, among other things
- Testing is performed in order to determine whether rules are being followed
  - For example, reviewing how HCPs are being paid or transfers of value are tracked and reported for sunshine

What is the scope of a typical audit?

- The scale of an audit is largely driven by the size of an organization and commercial activities
- Some organizations choose to have their entire compliance program audited while others focus on auditing specific activities
- The output of an audit includes a report and action plan for remediation as necessary

What standards should I audit against?

- Best practice is to audit the compliance program against the CPG, internal policies and procedures, the PhRMA Code for drug makers and the AdvaMed Code for device makers, and ACCME guidance
- The following laws are also audited against:
  - Anti-Kickback Statute
  - False Claims Act
  - HIPAA
  - Physician Payments Sunshine Act
  - Food, Drug & Cosmetic Act

FDA

PhRMA
AMERICA'S BIOPHARMACEUTICAL COMPANIES

AdvaMed
Advanced Medical Technology Association

Accreditation Council for Continuing Medical Education
A·C·C·M·E

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Typical “auditing” activities

- Speaker bureaus
- HCP consulting arrangements
- Provision of meals to HCPs
- Promotional materials, including social media
- Transparency reporting and gift-ban law adherence
- Provision of health economic and reimbursement information
- Provision of reimbursement support for patients and customers
- Discounts, rebates and free product programs
- Compliance training
- Scientific exchange
- Provision of grants and charity
- Collaborative marketing with customers
- Research activities
- Distributor practices
- Educational and training programs
- Privacy
- General commercial staff adherence to Compliance Program policies and procedures

What is monitoring?

- Monitoring is less intensely focused and involves ongoing day-to-day compliance management and oversight of activities and processes
- Taking corrective action to address audit observations
- This involves addressing questions from staff and issues as they surface
- Examples of monitoring:
  - addressing staff providing inappropriate reimbursement advice
  - responding to a question from sales asking if they can discount product
  - addressing an expense report violation
  - staff paying an HCP to speak when they are not under a contract
  - addressing a salesperson making a homemade sales presentation
  - staff promising an HCP a grant before staff have vetted the request
  - a sales person promising a customer a lucrative consulting job in order to gain their loyalty

Do I need a dedicated resource for monitoring?

- Ideally, yes
- Manufacturers should embed compliance support into day-to-day operations
- A compliance point person needs to be available to answer questions
- Absent one, employees will make their own decisions without guidance—which is risky, especially in a high-pressure environment

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Typical “monitoring” activities

- Ride-alongs in the field with commercial staff
- Holding periodic Compliance Committee meetings to discuss hot spots
- Having a promotional review committee consisting of qualified Medical, Legal (compliance) and Regulatory professionals who review all promotional materials and advertising prior to use
- Systematic grant review by a Grant Committee
- Annual needs assessment for consultants
- Establishing and enforcing a robust speaker bureau procedure
- Periodic Board reporting about compliance
- Qualifying and performing background checks on HCP consultants before they are hired
- Reviewing hotline reports
- Taking corrective action to address audit observations
- Monitoring consultant compensation caps

Benchmarking

- As part of ongoing monitoring, a manufacturer may also consider periodically comparing its Open Payments data with competitors and industry averages
- A great way to do this is using publicly available Open Payments/Sunshine data

EXAMPLE 2018 REVENUE V. GENERAL PAYMENTS

	YOUR COMPANY	COMPETITOR A	COMPETITOR B	COMPETITOR C
Total Revenue	$30,000,000	$100,000,000	$1,000,000,000	$10,000,000
Total General Payments	$2,000,000	$5,000,000	$30,000,000	$1,000,000
Revenue after General Payments	$28,000,000	$95,000,000	$970,000,000	$9,000,000

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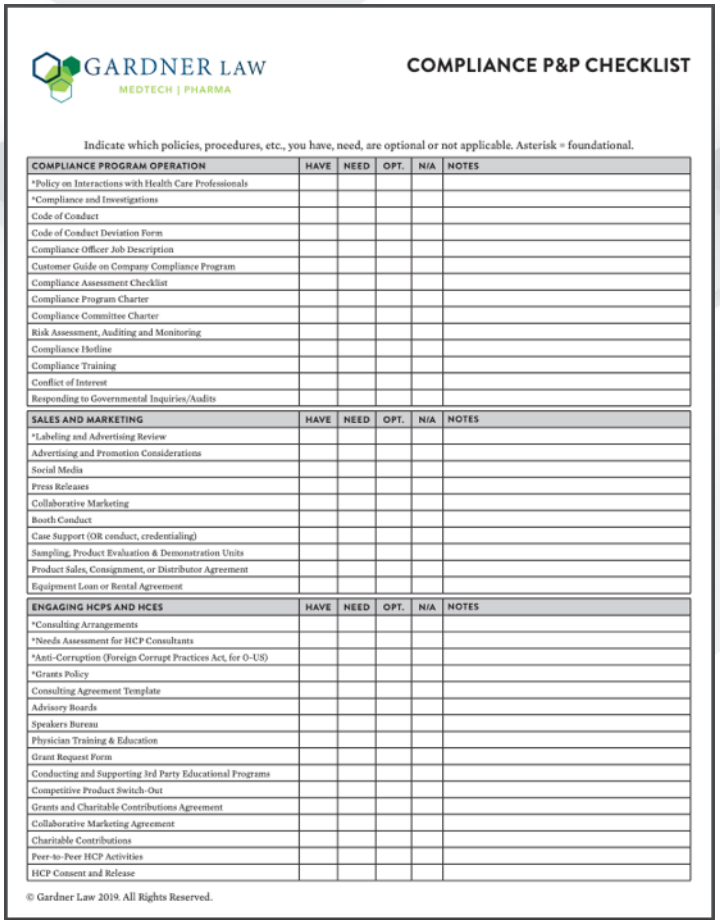
Looking for a place to start?

- Audit your compliance policies and procedures
- Free assessment tool:
  - https://gardner.law/wp-content/uploads/2019/10/Compliance_CheckList.pdf



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COMPLIANCE P&P CHECKLIST

Indicate which policies, procedures, etc., you have, need, are optional or not applicable. Asterisk = foundational.

COMPLIANCE PROGRAM OPERATION	HAVE	NEED	OPT.	N/A	NOTES
*Policy on Interactions with Health Care Professionals					
*Compliance and Investigations					
Code of Conduct					
Code of Conduct Deviation Form					
Compliance Officer Job Description					
Customer Guide on Company Compliance Program					
Compliance Assessment Checklist					
Compliance Program Charter					
Compliance Committee Charter					
Risk Assessment, Auditing and Monitoring					
Compliance Hotline					
Compliance Training					
Conflict of Interest					
Responding to Governmental Inquiries/Audits					

SALES AND MARKETING	HAVE	NEED	OPT.	N/A	NOTES
*Labeling and Advertising Review					
Advertising and Promotion Considerations					
Social Media					
Press Releases					
Collaborative Marketing					
Booth Conduct					
Case Support (OR conduct, credentialing)					
Sampling, Product Evaluation & Demonstration Units					
Product Sales, Consignment, or Distributor Agreement					
Equipment Loan or Rental Agreement					

ENGAGING HCPS AND HCES	HAVE	NEED	OPT.	N/A	NOTES
*Consulting Arrangements					
*Needs Assessment for HCP Consultants					
*Anti-Corruption (Foreign Corrupt Practices Act, for O-US)					
*Grants Policy					
Consulting Agreement Template					
Advisory Boards					
Speakers Bureau					
Physician Training & Education					
Grant Request Form					
Conducting and Supporting 3rd Party Educational Programs					
Competitive Product Switch-Out					
Grants and Charitable Contributions Agreement					
Collaborative Marketing Agreement					
Charitable Contributions					
Peer-to-Peer HCP Activities					
HCP Consent and Release					

See our July Regulatory Alert for more info: https://gardner.law/2019/09/sept-2019/

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Questions?

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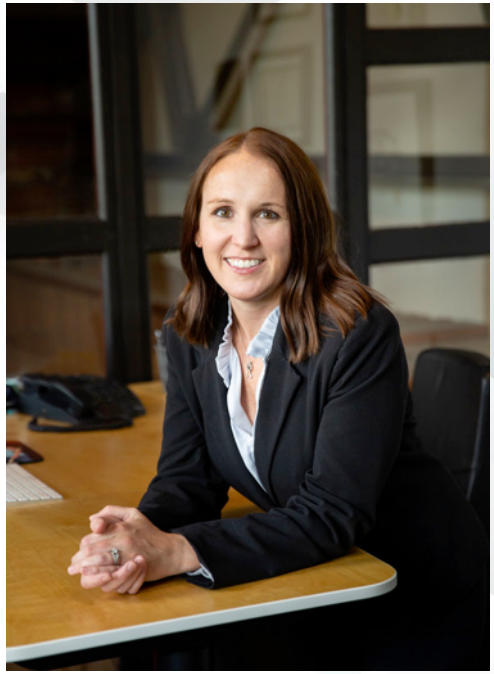

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Panel Discussion – Noon to 1 PM CST

Oliver Süme, Partner
Technology, Outsourcing and Privacy

Dr. Cord Willhöft, LL.M. (KCL), Partner
Life Sciences

Jim Murray, M.S.c.
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