

Morgan Lewis

***FAST BREAK:***  
**COMPLIANCE TOPICS FOR HEALTHCARE  
PROFESSIONALS INTERACTING WITH  
PHARMA/DEVICE MANUFACTURERS**

November 30, 2021



# TODAY'S PRESENTERS & HOST



**Terrence Burek**  
Senior Counsel – Neurology &  
Immunology | EMD Serono, Inc.



**Scott Memmott**  
Partner | Morgan Lewis



**Jake Harper**  
Associate | Morgan Lewis

# Compliance Risks for HCP Interactions with Pharma/Device Manufacturers

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## Federal Anti-Kickback Statute

- Criminal offense – 10 years/\$100,000/mandatory exclusion
- Applies to “remuneration” = any transfer of value
- Implicated if only “one purpose” is to induce or reward the referral of federal healthcare program business
- Applies to both offeror/payer and solicitor/recipient of kickbacks
- Safe Harbors for personal services/management contracts and other routine business practices
- Equivalent state statutes in most states – many are “all payor” statutes that include commercial payors and sometimes self-pay

2

## Federal Civil False Claims Act

- The federal government’s strongest and most frequently deployed healthcare fraud enforcement tool
- Whistleblower “qui tam” statute
- Applies to false/fraudulent claims presented (or caused to be presented) for reimbursement to federal healthcare programs
- Treble damages and per-claim penalties (whistleblower gets share)
- A violation of the federal Anti-kickback Statute is a *per se* violation of the False Claims Act
- Equivalent state statutes

# Compliance Risks for HCP Interactions with Pharma/Device Manufacturers

3

## Off-label Promotion

- Becoming an “agent” of industry off-label promotion
- Responding to off-label promotion

4

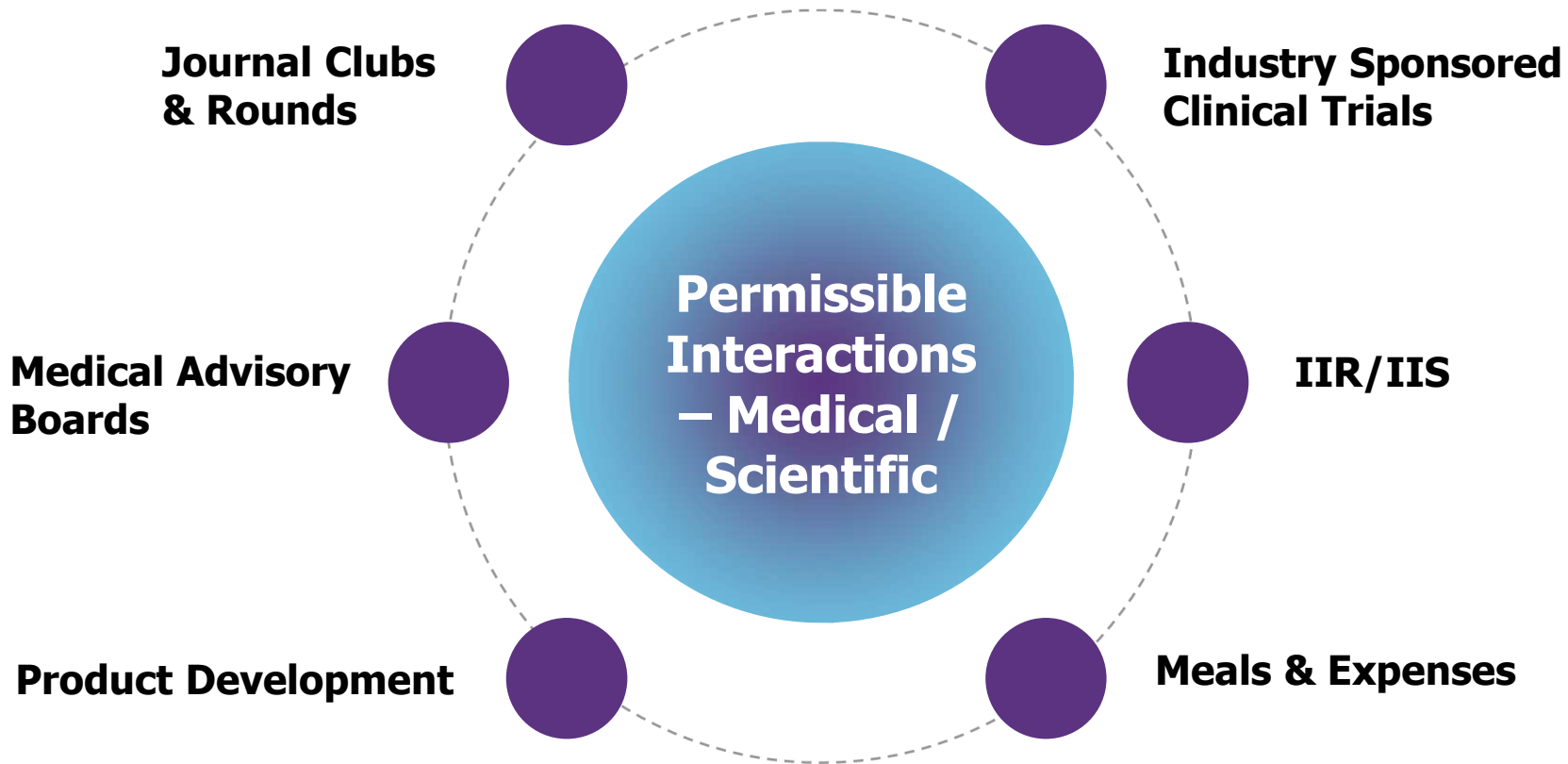
## Federal Physician Payments Sunshine Act

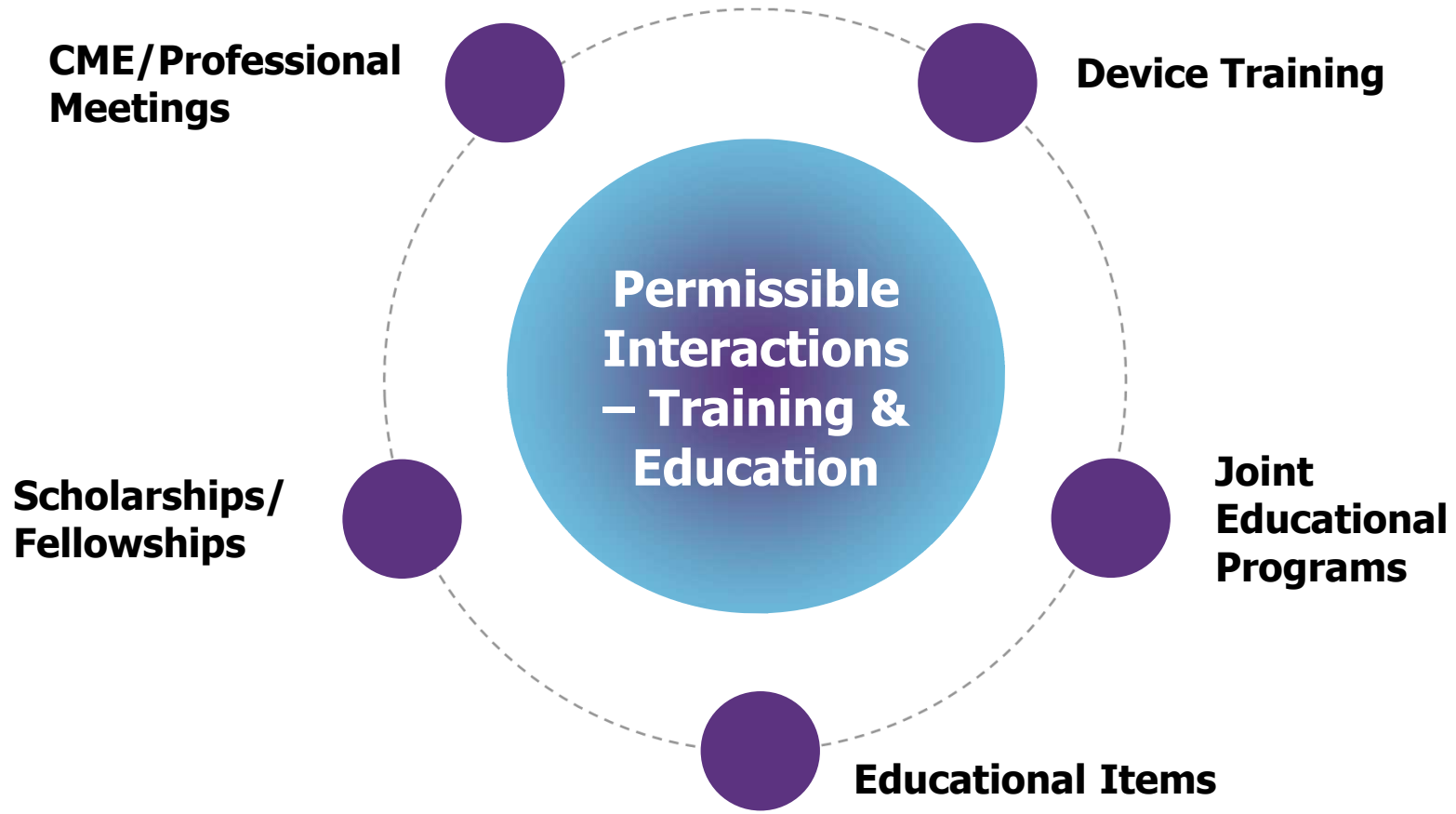
- Applicable manufacturers must report annually to CMS certain payments and other transfers of value to “covered recipients”
- Covered recipients are teaching hospitals and certain US-licensed HCPs (“physicians” per the SSA, PAs, NPs, clinical nurse specialists, CRNAs, certified nurse-midwives)
- Not a proscriptive statute
- Payments/transfers of value are posted annually on Open Payments website
- Opportunity for covered recipients to review and dispute prior to being made available to the public

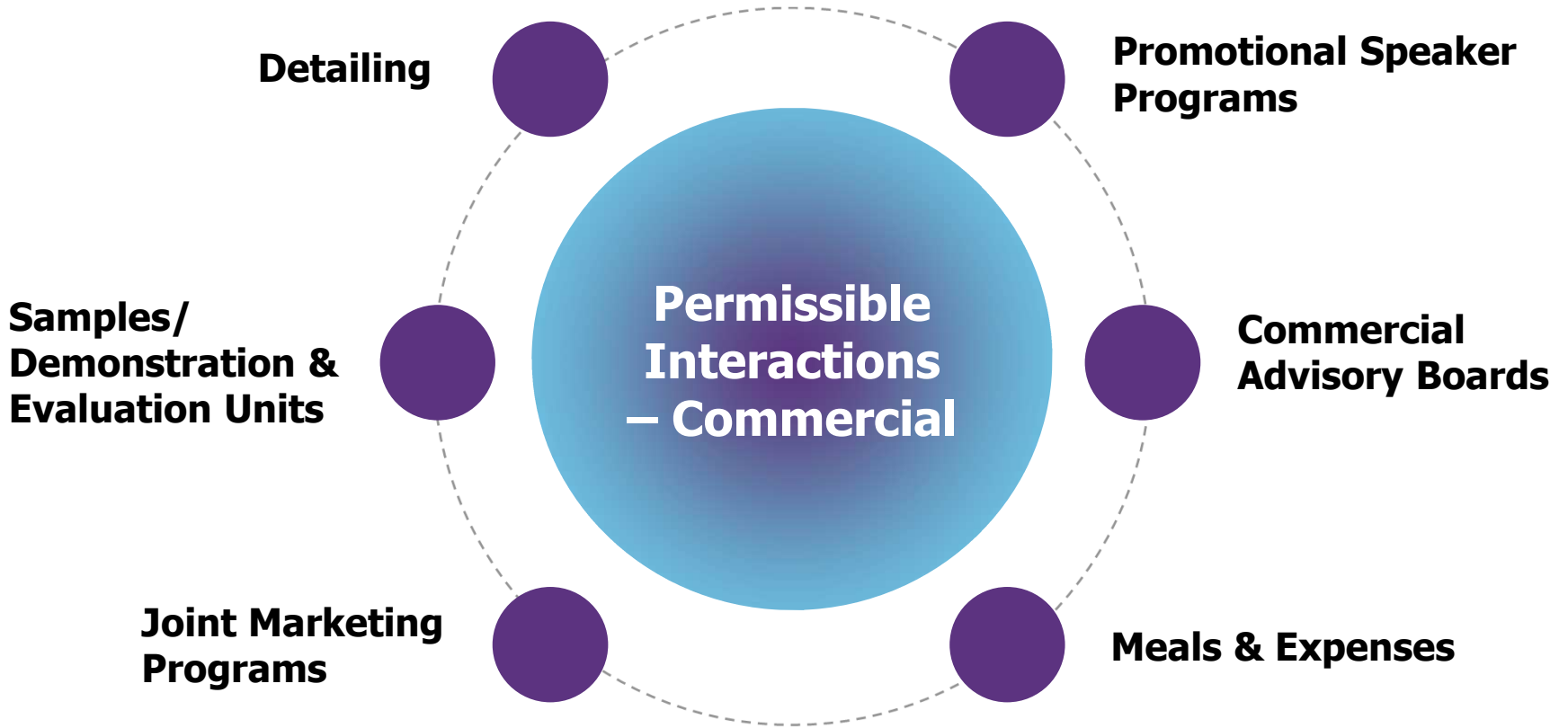
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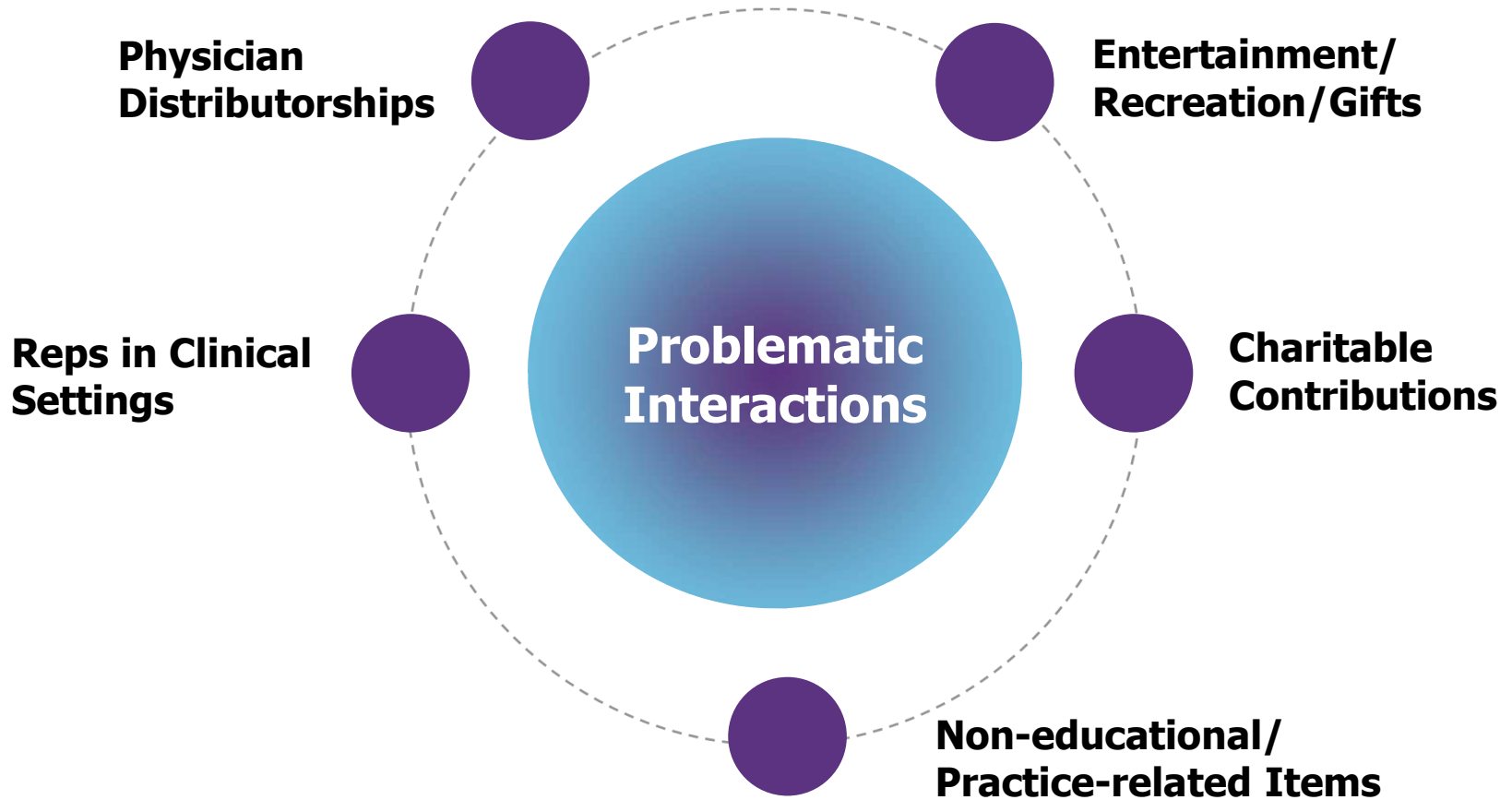
## State Transparency Laws, Gift Ban and Compliance Laws

- Reporting requirements – CT, DC, MA, MN, NV, VT
- Gift bans – MA, ME, MN, **NJ**, VT











# Current Enforcement Environment

## HHS-OIG Special Fraud Alert: Speaker Programs

November 12, 2020

- PhRMA Code – “educate and inform . . . [HCPs] about the benefits, risks, and appropriate uses” of products
- HHS-OIG is “skeptical” about educational value and has “significant concerns”
- “Parties” – drug/device companies, HCP speakers, HCP attendees – may be subject to increased scrutiny, and HCPs “could be liable under the anti-kickback statute for any prohibited remuneration”
- DOJ and HHS-OIG have “pursued civil and criminal cases against companies and individual HCPs involving speaker programs”
- Consultant/speaker arrangements could be improper inducement to prescribe based on loyalty or to get more money not the best interests of the patient
- Includes “disease state” education programs
- Availability of information through other means (online resources, package insert, third-party educational conferences, medical journals) suggests one purpose of remuneration to HCPs is to induce/reward referrals
- Recent study – only 25% would engage in virtual program, even with new data/information

# Current Enforcement Environment

## HHS-OIG Special Fraud Alert: Speaker Programs

November 12, 2020

- Suspect characteristics (indicative of intent of the parties):
  - Selecting high-prescribing HCPs to be speakers
  - Lucrative speaker deals/compensation greater than FMV
  - Remuneration linked to sales targets/volume or value of referrals
  - Expensive meals/**alcohol**
  - Venue not conducive to educational presentation
  - Little or no substantive information
  - No recent substantive change in relevant medical/scientific information
  - Attendees previously attended the same program
  - Attendees include friends/family/significant others, clinicians from own practice, and others without legitimate clinical or business need
- Extend to speaker training programs? In-person detailing?
- Future state – return to F2F?
- Compliant compensation models for virtual/hybrid programs

# Current Enforcement Environment

## Updates to PhRMA Code on Interactions with Health Care Professionals

August 6, 2021

Effective:  
January 1, 2022

- Updates and clarifies principles applicable to speaker programs
- Reiterates purpose of speaker programs is to present substantive educational information to address a bona fide education need among attendees taking into account recent substantive changes in relevant information
- High-end restaurants are inappropriate
- Alcohol should not be provided or paid for
- Repeat attendance generally is not appropriate
- Speaker participation as attendee at substantially the same program generally is not appropriate
- Attendance by friends, significant others, family members and other guests (in addition to spouses) is not appropriate unless independent, bona fide educational need

# Current Enforcement Environment

**Novartis Pharmaceuticals**  
July 1, 2020

- **Speaker Program Attendees**
- **“Lunch and Learns”**
- **Roundtables**

**Merit Medical Systems, Inc.**  
October 14, 2020

- **Advertising Assistance**
- **Practice Development**
- **Practice Support**
- **Educational Grants**

**Medtronic USA Inc.**  
October 29, 2020

**Dr. Asfora**  
May 3, 2021

- **Speaker Program Social Events**
- **Medical Distributorships**

# Best Practices

## Contracting Best Practices

- Have one!
- Responsibilities/deliverables are accurately and completely described
- Compensation methodology is spelled out in the agreement and doesn't vary with volume or value of referrals
- Manufacturer has process to determine FMV
- Compensation is commercially reasonable/"gut check" FMV
- Careful communications

## Risk Mitigation Best Practices

- Comply as much as possible with PhRMA or AdvaMed Code
- Address risk factors outlined in OIG Special Fraud Alert
- Review speaker program activities and address gaps in existing controls
- Complete tasks for which being paid
- Submit required deliverables
- Maintain accurate and complete records (time sheets/expenses)
- Reconcile to budgets and return unused funds

# Join us next month!

Please join us for next month's webinar:

## **Fast Break: A Year in Review 2021**

Featuring

Jake Harper

➤ Thursday, December 16, 2021 3:00 PM (EST)

Morgan Lewis

**QUESTIONS?**



# Thanks and Be Well!



**Terrence Burek**

Senior Counsel –  
Neurology & Immunology |  
EMD Serono, Inc.

Terrence Burek currently serves as Senior Counsel, Neurology & Immunology at EMD Serono, Inc. In this role, he counsels internal commercial, medical, and global colleagues. He previously served as in-house counsel at Oncopeptides, Inc. and was a member of King & Spalding's FDA & Life Sciences practice group where he represented pharmaceutical and medical device manufacturers, as well as healthcare providers and suppliers. Terrence's expertise centers on healthcare fraud and abuse and compliance with federal and state laws (including the Anti-Kickback Statute), advertising and promotional considerations under FDA regulations, and federal, state, and global transparency issues.



# Thanks and Be Well!



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Scott represents life sciences and healthcare organizations in government and internal corporate investigations; civil, criminal, and administrative enforcement actions by government agencies; and complex civil and criminal litigation. Scott handles a range of fraud, abuse, and compliance matters involving the False Claims Act, the Anti-Kickback Statute, the Stark Law, off-label promotion, government reimbursement, and quality of care for global pharmaceutical and medical device manufacturers; healthcare providers, suppliers, and payors; biotechnology companies; contract research organizations; diagnostic testing facilities; and laboratory equipment manufacturers.

# Thanks and Be Well!



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Jake advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.