

The logo for Hogan Lovells, consisting of the words "Hogan" and "Lovells" stacked vertically in a black serif font, set against a solid lime green square background.

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Mini Summit 28: Practice Development Programs- Free or Discounted Marketing Services

Pharmaceutical and Medical Device Compliance Congress

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False Claims Act (FCA)

31 U.S.C. § 3729 et seq.

- Cannot knowingly submit or **cause the submission** of a false claim for payment to the federal government
 - No intent required; can be prosecuted for deliberate ignorance or reckless disregard of the truth
 - Private **qui tam relators/whistleblowers** may file suits and receive a portion of the recovery; government may intervene
- Penalties:
 - Up to \$22,363 *per claim* (now adjusted annually for inflation)
 - Treble damages
 - Exclusion from Medicare and Medicaid

How FCA Cases Typically Proceed

- Relator files complaint under seal
- DOJ is required to investigate the allegations
 - Sometimes this involves issuing a subpoena or CID to the defendant
- DOJ decides to intervene or not
- Case is unsealed
- Litigation
 - Motion to dismiss
- With some exceptions, the vast majority of cases that DOJ does not bring forward fail. As such, the DOJ investigation aspect of FCA matters is key

Background – Anti-Kickback Statute (“AKS”)

42 U.S.C. § 1320a-7b

- Prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to **induce the referral, purchase or use** of items or services reimbursable by a federal health care program
 - Applies to both the payers and the recipients
 - “Remuneration” is essentially **anything of value**
 - Also prohibits inducements to “arrange for” or “recommend” covered items or services
- Penalties:
 - Criminal: 10 years in prison; \$50,000 fine
 - Civil: \$100,000 penalty per violation
- A violation of the AKS also is a violation of the **False Claims Act**

Key Legal Principles

- The AKS is incredibly broad
 - Even traditional marketing activities and price reductions are within scope
- Applies to everyone
 - Not just health care professionals (“HCPs”) and providers
 - Especially including drug and device manufacturers
- Violated if “**one purpose**” is to induce federal program business
- *Quid pro quo* not required
 - Intent to influence judgment is enough
- **Increased costs to federal programs** is highly relevant, but not necessary to establish a violation
 - Government also cares about corrupting medical decision making and unfair competition

Safe Harbors

- Regulations that protect certain financial arrangements from AKS prosecution
 - Transactions satisfying all elements of a safe harbor will not be prosecuted
 - Transactions not satisfying all elements are not *per se* illegal, but are subject to government scrutiny and **facts-and-circumstances analysis**
- Safe harbors exist for—
 - Discounts
 - Warranties
 - GPO admin fees
 - Personal service contracts at fair market value

Co-Marketing and the Covidien Case

- In March 2019, Covidien paid over \$17 million to settle allegations it provided illegal remuneration in the form of **practice and market development support** to physicians
- To induce the purchase of Covidien’s vein ablation products, the company is alleged to have provided support that included –
 - Customized marketing plans for specific vein practices
 - Scheduling and conducting “lunch and learn” meetings and dinners with other physicians to drive referrals to specific vein practices
 - Planning, promoting and conducting vein screening events to cultivate new patients for those practices

“Today’s settlement serves as an important reminder to those in the health care community that unlawful kickbacks come in many forms and are not limited to monetary payments to providers.”

*Jody Hunt
Assistant Attorney General, DOJ*

Covidien is Just the Latest Example

Cardiovascular Systems, Inc. (June 2016)

- CSI paid \$8 million to resolve allegations that CSI paid illegal kickbacks to induce use of the company's medical devices
 - Allegations raise concerns regarding **marketing support and other practice development**
- CSI allegedly:
 - Developed and distributed marketing materials to promote physicians utilizing CSI's devices to referring physicians
 - Coordinated meetings between utilizing physicians and referring physicians
 - Developed and implemented business expansion plans for utilizing physicians
- CIA requires detailed safeguards for co-marketing activities, including:
 - Documented needs assessment
 - Analysis of role and contribution for each provider/institution
 - Evaluation of fair market value for co-marketing services
 - Written agreement for co-marketing services that includes the scope of work, fees, and work product

Other Practice/Customer Support Enforcement Cases

- **Medtronic (2016)** – court denies motion to dismiss *qui tam* alleging Medtronic violated the AKS by assisting physician practices with the fitting of insulin pumps
- **Respironics (2016)** – \$35 million FCA settlement by sleep apnea equipment manufacturer for providing no cost telephone call center services to DME suppliers
- **Allergan (2017)** – motion to dismiss denied in case alleging Allergan provided cataract surgeons with a “no-cost suite of products and office supplies consisting of large shipments of Allergan drugs, supplies of cataract surgery patient care kits, physician-branded practice-related medical instructions for physicians to provide to patients, and pre-printed physician prescription pads.”
- **Olympus (2016)** – \$646 million criminal and civil settlement included allegations that the company provided various kickbacks to physicians, including “permanent loans” of expensive equipment at no charge (along with consulting payments, foreign travel, lavish meals and research and education grants)
- **Shire (2017)** – \$350 million FCA settlement of kickback allegations that included free equipment and supplies, excess or sham payments for speaking, sham payments for case studies, and expensive travel and entertainment

New AdvaMed Code Standards

Jointly Conducted Education and Marketing Programs

- The Code suggests the following principles –
 - There must be a bona fide, legitimate need for the company to engage in the activity **for its own benefit**
 - Participating HCPs should be required to comply with company guidelines on off label promotion and appropriate health economics information
 - Programs should be balanced and promote **both** the company’s technologies and the HCP
 - Company and HCP “should serve as **bona fide partners** in the program and should make **equitable contributions** towards the activity and its costs”
 - e.g., developing content, invitations, space rental, AV needs and other event costs
 - The arrangement should be documented in a written agreement

HYPOTHETICALS

Hypotheticals – Referral Lunch

Scenario:

Dr. A recently moved to the area and opened his first office-based lab. Dr. A came from a clinical setting that almost exclusively used Skittles products, so he is well versed in the clinical uses of the technology. He is very experienced in complex cases involving the use of intravascular ultrasound (IVUS). He would like to get to know doctors in the local area. Dr. A approaches his local Skittles sales representative, Sally Sales, and asks if we, Skittles, can sponsor a lunch event at a local moderately priced restaurant. At the event, he would like to pass out marketing materials and would love for the sales rep to make some personal introductions! Sally Sales responds, “we can put on a local event together, but we cannot pay for the whole thing.” Dr. A agrees to split the cost and provides Sally with a list of potential attendees.

Analysis: ???

Hypotheticals – Practice Building

Scenario:

During a routine sales visit, Dr. A mentions that his practice is really booming and he is interested in starting a second lab, but he is not sure what location has the most demand. Sally Sales, a Skittles rep, volunteers that she has access to a database that could help to target underserved populations in the area that she could share with him over dinner later in the week. That Friday, Sally and Dr. A have dinner at a local moderately priced restaurant and Sally shows Dr. A the database as well as other materials on the Skittles website, such as the Doctor Finder, that might help as well. Dr. A takes photos of database information and Sally assures Dr. A that rather than taking photos, she would email Dr. A the information. The next morning, Sally downloads the entire database list of local specialists and emails the list to Dr. A. Dr. A responds thanking Sally for the list and asks if she could set up a meeting with a few of the doctors and personally reach out to them, as that goes a long way. Sally says she plans to see them at a conference later that month and will try to do so.

Analysis: ???

Hypotheticals – Practice Building

Scenario:

A marketing director who recently joined Skittles from a competitor proposes to provide practice-building support materials for physicians new to the specialty. She said at her previous company, a highly-successful HCP put together a slide deck and white paper on techniques for practice development, including working closely with a manufacturer's marketing department to provide patient education and build a referral network. The HCP, who is a consultant for Skittles, would be willing to make presentations to physicians at academy meetings.

Analysis: ???

Hypotheticals – Marketing Services

Scenario:

The sales department proposes a new Account Manager position that will be responsible for managing existing customer relationships. The Account Manager is essentially a customer success manager, and will help provide existing customers with individualized strategic input to help ensure maximum utilization & ROI of Skittles' technology. This will include performing a market analysis for customers and include suggestions to increase referring physician volume, drive patient awareness, and drive patient demand. The Account Manager's compensation will be based in part on the existing customers' purchase of new systems and upgrades.

Analysis: ???

Hypotheticals – Consulting Services

Scenario:

An implantable product business unit proposes to offer consulting services designed to improve efficiency (and maximize revenue) by conducting a detailed analysis of customer ORs, and potentially pre and post-op services. The end product would be a report that reflects a SWOT analysis and potentially a one-on-one meeting with the consultant. If the business unit cannot provide this as a value-add, they would like to propose a bundle or discount arrangement to customers willing to commit to a certain dollar volume of implantable products.

Analysis: ???

Hypotheticals – Consulting Services

Scenario:

CMS requires each state to survey ASCs every three years. ASC managers struggle to keep up with ever-changing regulations. Could Skittles help customers prepare for surveys by providing free consulting services (mock surveys; updating policies and procedures)? How about discounted consulting services?

Analysis: ???

Hypotheticals – Advertising

Scenario:

Physicians would like Skittles to help them reach more patients by engaging in joint advertising campaigns. Marketing has proposed several ideas, including TV and radio ads, billboards, and newspaper ads. The business would like to cover the cost of the ads on the theory that the prominent display of the manufacturer's name justifies the expense and helps ensure brand awareness among end-users.

Analysis: ???



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