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Kickbacks, False Claims, and Risk Areas:

**A Primer for Pharmaceutical and
Biotechnology Companies**

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Summary of Presentation

- The Federal Anti-Kickback Statute
 - The statute and safe harbors
 - How to analyze a transaction under the statute
 - Penalties for violations

- The Civil False Claims Act
 - False claims
 - The relator (“whistleblower” provisions)
 - Kickback violations as predicates for FCA liability
 - Penalties for violations

- Risk Areas for Pharmaceutical Manufacturers

The Anti-Kickback Statute -- 42 U.S.C. § 1320a-7b(b)

- The Anti-Kickback Statute makes it a criminal offense to:
 - knowingly and willfully
 - offer, pay, solicit or receive
 - any remuneration (in cash or in kind)
 - to induce (or in exchange for)
 - the purchasing, ordering, or recommending of any good or service reimbursable by any Federal health care program

The Anti-Kickback Statute (cont'd)

- Knowingly and willfully
 - Several cases hold that intent is improper if one purpose -- not the sole or (or even primary purpose) -- is to “induce” the purchase or recommendation of a company’s goods or services
 - U.S. v. Greber, 760 F.2d 68 (3d Cir. 1985); U.S. v. LaHue, 261 F.3d 993 (10th Cir. 2001)
 - Payment of fair market value does not, by itself, immunize a transaction!
 - Need not be proof of a contractual “agreement” to order, purchase or recommend medical items or services
 - Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995)
- Offer or receive
 - Both parties to a prohibited transaction are at equal legal risk

The Anti-Kickback Statute (cont'd)

- Remuneration (virtually any thing of value)
 - Cash, cash equivalents
 - Other items of value (examples: meals, golf fees, entertainment, travel, lodging)
 - Services that have an independent value (e.g., practice management consulting, “value-added services”)
- To induce the purchase, prescribing or recommending of a product
- Whole or partial payment by any Federal health care program
 - Medicare, Medicaid, CHAMPUS (Civilian Health and Medical Program of the Uniformed Services), and many other federal or federally-funded health care programs

Anti-Kickback Statute -- Penalties

- Imprisonment for up to 5 years, \$250,000 fine, or both
- Exclusion from participation in government programs
 - Manufacturer's products not eligible for Medicare and Medicaid reimbursement, or other Federal health care program payments
 - OIG may allow a company to enter a Corporate Integrity Agreement instead of seeking exclusion
- Civil monetary penalties
- Qui Tam suits brought by whistleblowers under the False Claims Act

- ① Is there an Anti-Kickback issue in the first place?
 - Are you providing something of value to a person in a position to purchase, prescribe or recommend your company's product?
 - Does the arrangement involve Federal reimbursement (in whole or in part) for the product?
 - Risk areas identified in HHS OIG Guidance (partial list):
 - Gifts and business courtesies (including meals, entertainment)
 - Discounts
 - Educational and research activities
 - PBM arrangements
 - AWP
 - Consulting and other fee-for-service arrangements
 - Sales Agents

② If there is a potential kickback issue, can the arrangement be structured within a statutory or regulatory safe harbor?

- 21 regulatory safe harbors (some safe harbors parallel statutory exceptions contained in the Anti-Kickback Statute)
 - Safe harbors are very narrow
 - Must meet all criteria to be guaranteed protection
 - In making enforcement decisions, the Government usually will consider the degree to which practices outside the “four corners” of a safe harbor satisfy safe harbor criteria

- Statutory Exceptions, 42 U.S.C. § 1320a-7b(b)(3)
 - Certain discounts or other price reductions, if properly disclosed and appropriately reflected in costs claimed by the provider under a Federal healthcare program
 - Payments to bona fide employees
 - Administrative fees paid to group purchasing organizations (GPOs)

- Regulatory Safe Harbors, 42 C.F.R. § 1001.952
 - Certain discounts (including rebates) to “buyers” that receive payment from Federal health care programs.
 - Discounts must be disclosed by manufacturer and reported by purchaser
 - Applies only to true discounts or rebates -- does not include upfront payments, prebates
 - Application to “bundled” discounts is not entirely clear
 - Note that many entities that receive discounts / rebates are not “buyers” and/or do not receive payments from Federal health care programs (e.g., PBMs, wholesalers)
 - Personal services contracts -- Payment from company to agent to perform services (e.g., consulting, speaker programs, advisory boards)
 - Space or equipment rental

③ Does the transaction comply with the PhRMA Code on Interactions with Healthcare Professionals?

- PhRMA adopted (July 2002) a voluntary code regarding manufacturer interactions with individual healthcare professionals (e.g., physicians).
- PhRMA Code contains provisions on gifts and business courtesies (including meals and entertainment), consulting relationships, educational conferences, speaker programs.
- HHS OIG Guidance for Pharmaceutical Manufacturers:
 - Describes the PhRMA Code as “useful and practical advice for reviewing and structuring relationships” with physicians and others in a position to prescribe or influence the purchase of a company’s products.
 - While not a legal safe harbor, Guidance states that compliance “will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.”

The PhRMA Code -- Gifts, Meals & Entertainment

- Gifts:
 - Generally prohibited
 - Exceptions: (1) gifts of \$100 or less that benefit patients, (2) gifts of nominal value (e.g., pens, note pads)
- Meals
 - Only modest meals accompanying informational presentation
- Entertainment and Recreational Events
 - Generally prohibited
 - Exception: Entertainment at meetings with bona fide consultants
- Spouses
 - Never appropriate to pay for lodging, travel, meals, or entertainment

The PhRMA Code -- Consultants

- Prohibits “token” consulting arrangements
- Identifies six factors that support the existence of a bona fide arrangement:
 - Written contract
 - Legitimate need for services, identified in advance
 - Selection criteria related to purpose of services
 - Number of consultants should not exceed that necessary to achieve identified purpose
 - Retention of documentation, and demonstration of appropriate use of services provided
 - Venue of any consultant meetings are conducive to services provided; social or entertainment must be “clearly subordinate”
- Companies cannot pay for consultant spouses to attend meetings.

The PhRMA Code -- Educational Conferences

- Financial sponsorship of CME and other educational conferences is permitted.
 - Support should be provided directly to conference sponsor, not directly to healthcare professionals.
 - Sponsor should control selection of content, faculty, educational materials and venue.
 - Conference faculty -- but not attendees or faculty spouses -- may be paid/reimbursed for time, travel, and lodging.
 - Generally, support for meals or receptions may be provided to sponsor; provided, they are modest, conducive to discussion between faculty and attendees, and “clearly subordinate” to educational activities.
- Exception: Companies may pay for travel/lodging for healthcare professionals in training to attend educational conferences; training institution must select individuals to receive assistance

The PhRMA Code -- Speaker Training

- Reasonable payments to participants in training programs for company-sponsored speaker bureaus are permitted.
- Criteria for speaker training programs:
 - Speakers should receive “extensive training” on company’s products and on FDA requirements for communications on such products.
 - Training will result in the participants providing a valuable service to the company.
 - Participants meet all of the same criteria applicable to consultants.
 - Number of speaker trainees cannot significant exceed number of speakers the company actually uses.

④ If the transaction can not be fit within a Safe Harbor and does not comply with PhRMA Code, consider the following factors (discussed in recent HHS OIG guidance):

- Does arrangement skew clinical decision-making?
- If info is provided, is it complete, accurate, non-misleading?
- Have potential to increase costs to Fed HCPs?
- Have potential to be “disguised discount” -- circumventing BP?
- Result in inappropriate over- or under-utilization?
- Raise patient safety, quality of care concerns?

⑤ Review sources of official guidance (particularly from the HHS OIG)

- Published advisory opinions (caution: they provide legal protection only for the party requesting the opinion)
- Text and preamble to initial and amended regulatory safe harbors
- Published special fraud alerts
- HHS OIG Guidance for Pharmaceutical Manufacturers
- HHS OIG Guidances for other industry sectors (small physicians, DME, hospitals, etc.)
- www.oig.hhs.gov

False Claims Act, 31 U.S.C. §§ 3729 et seq.

- The FCA imposes civil liability against a person or entity who:
 - knowingly (which can be shown by reckless disregard for the truth)
 - presents a false claim for payment, or
uses a false record or statement to get a claim paid or approved, or
causes a third party to do either of the above

- Violators are liable for \$5,000-\$11,000 per false claims plus treble damages sustained by the Government

False Claims Act (cont'd)

- Lower evidentiary standards vs. anti-kickback statute:
 - Knowledge is defined to include: actual knowledge, reckless disregard, deliberate ignorance
 - Must prove only by preponderance of the evidence
- Under “implied certification” theory, violations of regulatory requirements may be adequate predicate for FCA violation
 - Example: A US District Court recently allowed qui tam plaintiff to proceed on theory that GMP violations could form the basis of an FCA suit in the context of a Defense Department contract for the production of anthrax vaccine. (BioPort)
- Prosecutors (and some courts) have embraced use of FCA for kickback violations
 - Theory: Government would not reimburse for goods/services that are the subject of the kickback, companies therefore “cause” false claim to be submitted.

Whistleblower (“Qui Tam”) Provisions of False Claims Act

- Private citizens (“relators”) may bring an action under the FCA by filing a “qui tam” complaint, which is filed under seal and served on Attorney General
- Government required to investigate and make decision on whether to “intervene”; if so, government takes over investigation
- If government does not intervene, private qui tam relator may pursue the action on his/her own (though gov’t may still participate in the case)
- Successful qui tam relators can receive up to 25% of eventual recovery in cases where gov’t intervene; 30% where relator pursues case on his/her own
- Every major health care fraud case in past 10 years involved qui tam complaint

Risk Areas for Pharmaceutical and Biotechnology Companies

- Kickbacks, Other Illegal Remuneration (partial list)
 - Discounts
 - Educational and research activities
 - PBM arrangements
 - AWP
 - Consulting and other fee-for-service arrangements
 - Sales Agents
 - Miscellaneous

- HHS OIG Guidance (April 2003) describes factors for assessing activities “at greatest risk of prosecution”
 - Does arrangement skew clinical decision-making?
 - If info is provided, is it complete, accurate, non-misleading?
 - Have potential to increase costs to Fed HCPs?
 - Have potential to be “disguised discount” -- circumventing BP?
 - Result in inappropriate over- or under-utilization?
 - Raise patient safety, quality of care concerns?

Risk Areas (cont'd)

- Kickbacks -- Discounts
 - In pharma context, discounts “deserve careful scrutiny” because of potential to implicate Best Price requirements
 - Discounts should be structure to fit within discount safe harbor when possible. Generally only protects discounts at time of sale or fixed at time of sale (rebates). Does not protect “prebates” or other forms of “upfront” payments.
 - Final guidance drops language suggesting bundled discounts never qualify for safe harbor protection, but doesn't explain how
 - Any remuneration to a purchaser that is “expressly or impliedly related to a sale” should be carefully reviewed. Examples: prebates, upfront payments, free or reduced-price services, payments to cover purchaser's cost of converting from competitor's product.
 - Remuneration offered only to selected set of purchasers increases risk if selection relate directly/indirectly to volume of business

Risk Areas (cont'd)

- Kickbacks -- Educational and Research Funding
 - To reduce their risks, manufacturers should divorce educational and research grants and contracts from their sales and marketing functions.
 - Educational and research funding should not be linked in any way to the funding recipient's purchases or capacity to generate business for the manufacturer.
 - Manufacturers should have no control over the content of funded educational activities.
 - It is not altogether clear why this is an anti-kickback issue, but in any event the OIG has embraced FDA's CME guidance and "codes of conduct promulgated by the CME industry."
 - Makes the proposed changes to the ACCME standards more critical, since the ACCME standards are apparently viewed by the OIG as pertinent to anti-kickback compliance.
 - Post-marketing research and research not reviewed by a manufacturer's science component deserve heightened scrutiny.

Risk Areas (cont'd)

- Kickbacks -- Relationships with PBMs
 - In several cases, the OIG's pronouncements on formularies and PBM payment arrangements involve practices under the control of the PBM - - not the manufacturer.
 - Formularies are unlikely to raise significant anti-kickback issues as long as "the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs."
 - Manufacturers should "review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety and efficacy." Any remuneration from a manufacturer to a person capable of influencing formulary decisions is "suspect" and warrants careful scrutiny.

Risk Areas (cont'd)

- Kickbacks -- Relationships with PBMs (cont'd)
 - Manufacturer rebates to PBMs (and other payments to PBMs based on sales to the PBM's clients) can be protected under the GPO safe harbor, essentially by requiring the PBM to make the same disclosures about vendor payments to its clients that a GPO makes to its members. This is likely to fuel the growing trend toward transparency in the PBM industry.
 - Manufacturers should still avoid ("carefully scrutinize") "lump sum" payments to PBMs for formulary inclusion or placement. Payments to fund PBM formulary support activities - - "especially communications with physicians and patients" - - also have a semi-suspect status.

Risk Areas (cont'd)

- Kickbacks -- Average Wholesales Price (AWP)
 - AWP discussed in context of kickback statute -- not integrity of data -- but seems an implicit focus of the integrity of data section.
 - The guidance states that “it is illegal for a manufacturer knowingly to establish or maintain a particular AWP if one purpose is to manipulate the ‘spread’ to induce customers to purchase its product,” and manufacturers should thus “review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process.”
 - The guidance states that pharmaceutical manufacturers generally report either AWP “or pricing information used by commercial price reporting services to determine AWP,” but does not specifically mention WAC or specify whether its recommendation regarding AWP reporting applies to WAC.

Risk Areas (cont'd)

- Kickbacks -- Consulting Arrangements
 - At least generally, fair market value payments to “small numbers” of physicians for bona fide consulting and advisory services are unlikely to raise significant concerns.
 - Manufacturers should structure these arrangements to fit within the personal services safe harbor whenever possible
 - Certain types of service arrangements with physicians create heightened concerns, *i.e.*:
 - Services connected to a manufacturer’s marketing activities, “such as speaking, certain research, or preceptor or ‘shadowing’ services” and “ghost-written articles”; and
 - “Consulting” arrangements where the physician attends meetings or conferences “primarily in a passive capacity.”

Risk Areas (cont'd)

- Kickbacks -- Sales Agents
 - Payments to sales agents should be “carefully reviewed” if they do not fit within a safe harbor (*i.e.*, the employee safe harbor or, for contracted sales agents, the personal services safe harbor).
 - Even if compensation payments to sales agents do fit within a safe harbor, they “can still be evidence of a manufacturer’s improper intent when evaluating the manufacturer’s relationships with [potential referral sources]” - - for example, providing sales agents with “extraordinary incentive bonuses and expense accounts” might support an inference that the manufacturer “intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration.”

Risk Areas (cont'd)

- Kickbacks -- Miscellaneous
 - Paying physicians for their time spent listening to marketing presentations is “highly susceptible to fraud and abuse, and should be discouraged.”
 - The same is true for variations on pay-for-detail arrangements (paying “consulting” fees for a physician to complete “minimal paperwork,” or paying physicians for the time spent “accessing websites to view or listen to marketing information or perform ‘research’”).

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