

**KING & SPALDING LLP**

**Kickbacks, False Claims and Fraud/Abuse Issues for  
Pharmaceutical and Biotech Companies**

**A Primer for Lawyers and  
Compliance Officers**

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# Summary of Presentation

- The Federal Anti-Kickback Statute
- The Civil False Claims Act
- Risk Areas for Biotechnology and Pharmaceutical Manufacturers
- Questions

# Anti-Kickback Statute

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

## Anti-Kickback Statute (cont'd)

- Knowingly and willfully
  - Several cases hold that intent is improper if one purpose -- not the sole (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)

# Anti-Kickback Statute (cont'd)

- Offer or receive
  - Both parties to a prohibited transaction are liable and at risk
- 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

# Anti-Kickback Statute – Safe Harbors

- There are important statutory exceptions and regulatory safe harbors to the Anti-Kickback Statute's prohibitions
- The statutory exceptions and regulatory safe harbors are similar (though not identical)
- There are important limits to the protections provided by the Safe Harbors:
  - Safe harbors are very narrowly drawn and often not feasible given commercial realities
  - Must meet all criteria to be guaranteed protection

# Anti-Kickback Statute – Safe Harbors (cont'd)

- 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)

# Anti-Kickback Statute – Safe Harbors (cont'd)

- Regulatory Safe Harbors, 42 C.F.R. § 1001.952
  - Discounts (including rebates) to "buyers" that receive payment from Federal healthcare 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 healthcare programs (e.g., PBMs, wholesalers)



# Anti-Kickback Statute – Safe Harbors (cont'd)

- Personal services arrangements
  - Payment from company to agent to perform services (e.g., consulting, speaker programs, advisory boards)
  - Must be in writing, have term not less than one year, specify all services by the individual/entity to the company, and specify the exact schedule/interval for the provision of services
  - Very difficult in practice to meet all of the requirements
  
- Space or equipment rental

# Anti-Kickback Statute – Penalties

- Imprisonment for up to 5 years, \$250,000 fine, or both
- Exclusion from participation in government programs
  - An excluded manufacturer's products not eligible for Medicare and Medicaid reimbursement, or other Federal healthcare program payments
  - OIG may allow a company to enter a Corporate Integrity Agreement instead of seeking exclusion
- Civil monetary penalties

# Civil False Claims Act

- The FCA 31 U.S.C. §§ 3729-33 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 claim plus treble damages sustained by the Government

# Civil 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

# Civil False Claims Act (cont'd)

- Implied Certification (cont'd)
  - Suits have been filed under FCA based on wide variety of alleged regulatory violations
    - GMP violations
    - Patient/antitrust violations
  - DOJ has embraced the theory in some of these cases (while not necessarily intervening based on facts in particular case)
- 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,

# Whistleblower ("Qui Tam") Provisions of FCA

- 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

# Whistleblower ("Qui Tam") Provisions of FCA (cont'd)

- 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
- Vast majority of major health care fraud cases in past 10 years involved qui tam complaint
- DOJ and HHS OIG officials have said there are many qui tam complaints against pharmaceutical manufacturers in the pipeline

# 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"



## Risk Areas (cont'd)

- 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 pharmaceutical context, HHS OIG has said that discounts "deserve careful scrutiny" because of potential to implicate Best Price requirements
  - Discounts should be structured 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.
  - Any remuneration to a purchaser that is "expressly or impliedly related to a sale" should be carefully reviewed.
  - Remuneration offered only to selected set of purchasers increases risk if selection relate

## 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.

# Risk Areas (cont'd)

- Educational and Research Funding (cont'd)
  - It is not altogether clear why manufacturer control over content 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 new 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

## 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

## 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

## 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



## 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

# 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'").

# Compliance Resources

- 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.)

# Biography

- John Bentivoglio is a partner in the King & Spalding LLP's Washington, D.C., office and serves as Co-Chair of the FDA/Healthcare Group.
- From 1997-2000, he served as Associate Deputy Attorney General and Special Counsel for Healthcare Fraud at the U.S. Department of Justice. Earlier in his career, Mr. Bentivoglio served as a professional staff member on the U.S. Senate Committee on the Judiciary, where he handled criminal law and white-collar.
- In private practice, Mr. Bentivoglio represents a wide range of pharmaceutical and medical device companies on regulatory issues, including fraud and abuse issues under Federal health care programs; Federal and state pricing and reimbursement issues; state pharmaceutical regulatory laws; and Federal, state and international data privacy and security laws and regulations.
- He also has represented clients on internal investigations and compliance audits and defended companies in government investigations. He has assisted numerous companies in developing and implementing compliance programs pursuant to the HHS OIG guidelines, industry codes of conduct, and U.S. Sentencing Commission standards.

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