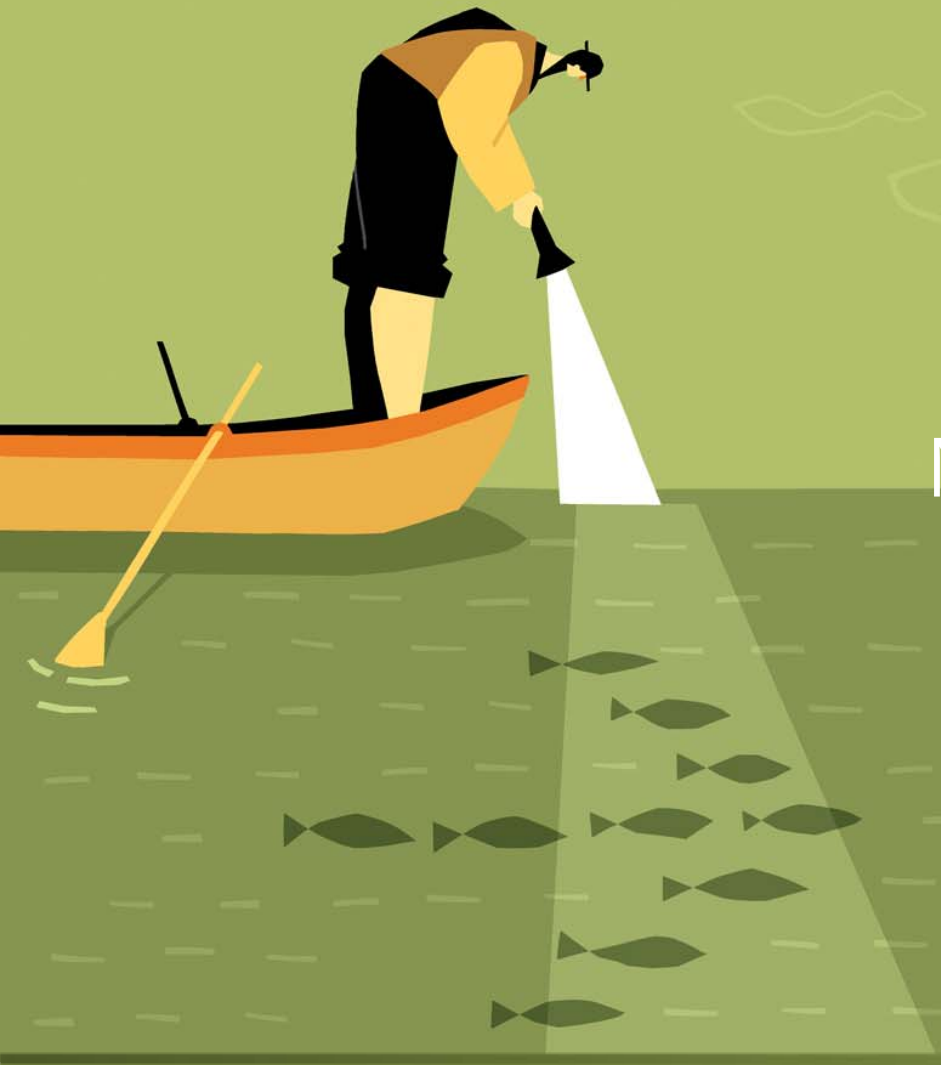

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# National Disclosure Summit
# March 27, 2012

## R&D Compliance Mini Summit

DISPUTES & INVESTIGATIONS • ECONOMICS • FINANCIAL ADVISORY • MANAGEMENT CONSULTING

# Introductions

- J. Mark Farrar – Navigant
- Nikki Reeves – King & Spalding LLP
- Louise Cashman – Boston Scientific Corporation
- Julie Wind – Eli Lilly and Company
- Mary Ann Northrup – Navigant
- Kim Zahan - GlaxoSmithKline

KING & SPALDING

*The National Disclosure Summit*
*Mini Summit IV: R&D Compliance*
*March 26, 2012*

# Public Disclosure of Clinical Investigator Financial Interests

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# FDA Regulations: Public Disclosure of Clinical Investigators' Financial Interests

– Any applicant who submits covered clinical studies as part of a marketing application for a human drug, biological product, or device must disclose to FDA, for each clinical investigator, either:

  - A certification that the clinical investigator (1) does not have a financial arrangement with the applicant where the study outcome could affect compensation, (2) has no proprietary interest in the tested product, (3) does not have an equity interest in the sponsor that is a publicly traded company that exceeds $50,000 during the study and for 1 year after completion, (4) does not have an equity interest in the sponsor whose value cannot be determined by reference to public prices and (5) has not received significant payments of other sorts

    OR

  - A statement disclosing the specified financial arrangement and any steps taken to minimize the potential for bias

(21 C.F.R. § 54)

# FDA Guidance: Public Disclosure of Clinical Investigators' Financial Interests

- Pursuant to FDA's March 2001 Guidance for Industry "Financial Disclosure by Clinical Investigators," FDA may publicly disclose clinical investigators' financial interests if "circumstances relating to the public interest clearly outweigh the clinical investigator's identified privacy interest"
  - Example: If a financial arrangement so affected the reliability of a study, it should be disclosed during evaluation of the study by an advisory panel
  - Public disclosure would be warranted "only rarely"
  - Evaluated on a case-by-case basis

- In light of growing public interest in the financial relationships between industry and physicians, FDA is considering expanding its current policy on public disclosure of clinical investigators' financial interests

# January 2009 OIG Report on FDA Oversight of Clinical Investigators' Financial Information

- Report from HHS Office of the Inspector General ("OIG"), "*The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information*" reviewed clinical investigators' disclosed financial interests for marketing applications approved during fiscal year 2007 to assess FDA's oversight of clinical investigators' financial information
- Findings
  - Only one percent of clinical investigators disclosed at least one financial interest (206 of 29,691 clinical investigators listed on disclosure forms)
  - Forty-two percent of FDA-approved marketing applications were missing financial information
  - FDA did not document a review of any financial information for 31 percent of marketing applications
  - In 20 percent of marketing applications, FDA reviewers did not take action and sponsors did not indicate that they minimized potential bias during the clinical trials

# January 2009 OIG Report on FDA Oversight of Clinical Investigators' Financial Information

- Recommendations:
  - FDA should ensure that sponsors submit complete financial information for all clinical investigators
  - FDA should ensure that reviewers consistently review financial information and take action in response to disclosed financial interests
  - FDA should require that sponsors submit financial information for clinical investigators as part of the pretrial application process

- In March 2011, OIG published the "*Compendium of Unimplemented Recommendations*" which provided a status update on the January 2009 OIG Report clinical investigator financial disclosure recommendations made to FDA. The report noted that FDA agreed with the recommendations except for the requirement that sponsors submit financial information for investigators in the pretrial application process.

# May 2011 FDA Draft Revised Guidance on Financial Disclosures by Clinical Investigators

- In its May 2011 Draft Revised Guidance for Industry "*Financial Disclosure by Clinical Investigators*," FDA sought comments on public disclosure of financial information, including whether the information should be a summary discussion, a listing of that de-identifies clinical investigators, or a listing that includes the names of each investigator
  - Comment period ended in July 2011
- FDA received several comments from stakeholders, including PhRMA, AdvaMed, and BIO
  - Most comments asked that FDA publicly disclose only aggregated or summary-level financial information about clinical investigators
  - Many comments referenced the proposed Sunshine rule's disclosure requirements for research payments and suggested that multiple disclosures could be confusing to the public

# Proposed Sunshine Rule Requirements on Disclosure of Research Payments

# Proposed Sunshine Rule Requirements on Disclosure of Research Payments

**Special Rules for Research Payments (§ 403.904(e))**

- The proposed Sunshine rule requires applicable manufacturers to disclose payments or other transfers of value made in connection with research
- CMS proposes to limit the research category to bona fide research activities, which are subject to (1) a written agreement or contract between the applicable manufacturer and the organization conducting the research and (2) a research protocol
- Payments or other transfers of value made in connection with research are subject to delayed publication on the publicly available website

# Proposed Sunshine Rule Requirements on Disclosure of Research Payments

**Special Rules for Research Payments (§ 403.904(e))**

– Applicable manufacturers must designate each research payment or transfer of value as direct research or indirect research

- Direct Research: Payments or other transfers of value provided to a covered recipient directly by an applicable manufacturer or through a contract research organization ("CRO") (or similar entity)
- Indirect Research: Payments or other transfers of value provided by an applicable manufacturer (including through a CRO or similar entity) to a clinic, hospital, or other institution conducting the research, which in turn pays a physician (or physicians) serving as the principal investigator(s)

# Proposed Sunshine Rule Requirements on Disclosure of Research Payments

**Special Rules for Research Payments (§ 403.904(e))**

- Direct research payments or other transfers of value should be reported under the names of the covered recipient and should indicate the amount the covered recipient received from the applicable manufacturer or CRO (or similar entity)
- Indirect research payments or other transfers of value should be reported under the names of the physician principal investigator(s) and should indicate, for each such physician, the total amount the applicable manufacturer or CRO (or similar entity) paid to the clinic, hospital, or other institution conducting the research (rather than the specific amount that may have been received by the covered recipient)

# Proposed Sunshine Rule Requirements on Disclosure of Research Payments

**Delayed Publication of Certain Payments (§ 403.910)**

– Payments or transfers of value may be delayed from publication on the website if they are furnished:

1. Pursuant to a product research or development agreement for research on or development of a new product, or a new application of an existing product; or
    - The research or development agreement must include a written agreement and research protocol between the applicable manufacturer and covered recipient
2. In connection with a "clinical investigation" regarding a new product
    - Clinical investigation is defined as any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used

# Proposed Sunshine Rule Requirements on Disclosure of Research Payments

**Delayed Publication of Certain Payments (§ 403.910)**

– Payments eligible for delayed publication must be reported to CMS on the first reporting date following the year in which they occur, but CMS will not publicly post the payment until the first annual publication date after the earlier of the following:

- The date of FDA approval, licensure or clearance of the covered drug, device, biological, or medical supply
- Four calendar years after the date the payment or other transfer of value was made

National Disclosure Summit

# R&D Compliance – Boston Scientific

March 27, 2012

Boston Scientific

# Boston Scientific Corporation

Background:

- Global medical device company
- HCP Aggregate Spend Solution first released in July 2009
- Subsequent releases in 2010 and 2011
  - 2011 - Sunshine enhancements
- 2009 CIA requires public posting of certain Company expenditures with HCPs

# R&D Expenditures with HCPs

Boston Scientific

Challenges capturing R&D expenditures fall in to 3 main categories:

| Systems | Processes | Data |
|---|---|---|
| • CTMS system in place – not integrated with Aggregate Spend Solution<br>• Payment interface with SAP<br>• SAP feeds reporting system<br>• Connecting transactional information and clinical trial data<br>• Capturing additional data elements to comply with Sunshine | • Processes and procedures implemented for clinical transactions<br>• Identifying transactions going around the process<br>• Remediation to ensure completeness of data | • Vendor vs. HCP Master Data – connecting Vendor, Trial and HCP<br>• Clinical reference data for Sunshine<br>  • Trial start date<br>  • Product approval<br>  • Tracking for up to 4 years<br>• Principal Investigators<br>• OUS trials with US HCPs |

# R&D Expenditures with HCPs – Other Considerations

- Impact of acquisitions:
  - Existing trials – gathering required data
  - Spend processed outside of our financial systems
  - Leveraging CTMS to create trial information
  - Using “upload” process to capture payment information

- CROs:
  - Requiring CROs to provide information
  - Contracting separately with the HCPs
  - CRO is themselves an HCP
    - Reallocate spend to other HCPs

- HCP Inquiries:
  - Principal Investigators – listed for CIA requirements as related entities, but not payees

# National Disclosure Summit
# R&D Lessons Learned
March 27, 2012

Julie Wind
Director, Physician Payment Reporting

Lilly
Answers That Matter.

# Lessons Learned

**Communication with Physicians**

- Principal investigators don't necessarily perceive that they have financial relationships with study sponsors (relationship is with institution, not individual)

- Leverage existing relationships with physicians

- Don't assume that there will be an obvious relationship owner at your company for every investigator

# Lessons Learned

**Business Processes**

- Adapting existing business processes to capture physician payment data may not be straight forward
- Understand processes and relationships with external entities:
  - Current state
  - Evolution
  - Future plans
- Don't expect business processes to remain static; new business models may not neatly fit into defined categories
- Be prepared to consult

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## IRO Perspective on R&D Payment Reporting

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# CIA Arrangements/Transactions Reviews

- General
  - How do you know you got it all?
    - Arrangements and payments from multiple departments
    - Vendors
    - IRB
  - Institution vs. HCP
  - Pre-clinical research investigators

# CIA Arrangements/Transactions Reviews

- Supporting documentation
  - Legitimate business need for study
  - Justification for selection of site/HCP
  - FMV for payments
    - Creation of template study budget
    - Justification and approval for payments above the template
  - Relying on CRF data/reports and other payment triggers

# PPACA Considerations

- Companies currently under CIAs
  - "OIG may agree to modify or terminate provisions as appropriate"
  - Not all CIAs have this language
- Other transfers of value
  - Medical writing assistance for a publication (vendor or sponsor)
    - Is the publication itself a transfer of value to the HCP?

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**National Disclosure Summit**
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# R&D Considerations and Risks

**Kim Zahan**
**Director R&D HCP compliance**
**GlaxoSmithKline**

Prepared by Kim Zahan
March 2012

## Consider the potential "perceived" conflicts of interest

- Ensuring that the Financial Disclosure forms (FIDS) provided by HCPs to the Company, for filing with the FDA, are accurate (with the Sunshine Act disclosures, it will be easy for anyone to check)

- Hiring an HCP for clinical trial activities when the HCP is already involved, and received payments, in speaking engagements with the commercial branch of the Company. Firewall commercial (viewed as commercial in nature) and Research as much as possible.

- Involving an HCP as a PI in multiple studies for significant amounts of money

- Investigator Sponsored Studies (ISS) / Collaborative Research Trials (CRT)

- Equipment used in trials: consider leases or sale to sites

## Conduct due diligence and background checks on HCPs

➢ The recent Propublica publications have shown that Pharma Companies don't do enough due diligence on the background of the HCPs they pay for research activities.

- Require resume from HCP and verify accuracy of representations (degrees, publications, work,…)

- Do an actual background check on the HCPs

- Language in contracts:
  - ❖ Include contractual language when engaging an HCP to mandate the provision of certain information as well as termination clauses if information is inaccurate
  - ❖ Include contractual language requiring HCPs to immediately disclose any federal, state or board action against them and their license

- Develop Company policies and SOPs around these points
  - o Must have a plan about what to do with a site and its patients enrolled in a clinical trial if you find issues with the PI

- Implement an annual cap on certain types of payments (consultancy, speaking,...)