Second Annual Summit on
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Clinical Trial Disclosure Requirements: The Legal Framework

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Good news / Bad news

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The Good News:

- Many existing and proposed state disclosure laws contain an exemption from reporting obligations for expenditures relating to clinical trials or research

The Bad News:

- The definitions of clinical trial and research vary among those laws
- The trend is to require reporting
- The pending federal Sunshine bills do not contain a clinical trial or research exemption

How do your colleagues who deal with clinical trials understand the term?

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- Under FDA regulations, 21 CFR 312.3(b), a "clinical investigation" is "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects." An "experiment" is "any use of a drug except for the use of a marketed drug in the course of medical practice."
- For medical devices, under 21 CFR 812.3(h), an "investigation" means "a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device."

What buzz words and factors help distinguish a clinical trial from “use in the course of medical practice” ?

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- Interventional versus observational
- Phase 4/post-market trials – ordered by FDA; agreed to as condition of approval; unilaterally undertaken by sponsor or investigator
- IND vs. IND-exempt and IDE vs. IDE-exempt
- Expanded access (treatment) IND or IDE
- IRB review
- Drug labeling (for investigational-use only)
- Existence and type of controls
- Patient registry
- Case reports

Massachusetts

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- "Genuine research" and "clinical trials" are excluded from the definition of reportable "sales and marketing" activities
- "Genuine research project": a "project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry."

Massachusetts (cont.)

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- "Clinical trial": "a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of a particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board ("IRB") after reviewing and evaluating it in accordance with [federal] human subject protection standards . . . ."
  - Trial to evaluate patient compliance or consumer preference?
  - IND-exempt trials of marketed drugs?
  - Strictly observational trials?
- *But:* Clinical trials posted on www.clinicaltrials.gov are deemed to be exempt from disclosure

Massachusetts – Phase 4 trials

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- FAQ #V.5 (Guidance III, Sept. 6, 2009): states that "post-market trials" must be reported
- But "post-market trials" is undefined in the FAQ
- It is reasonable to interpret the term in the context of other guidance from Massachusetts that "any research project designed or sponsored by marketing division of company or has marketing, product promotion or advertising as its purpose" is included in the definition of reportable sales and marketing
- Thus, Phase 4 trials that meet the MA definitions of "genuine research project" or "clinical trial" should qualify as exempt from reporting, as long as they are not sponsored by marketing
- And, should be exempt if registered on www.clinicaltrials.gov and meets the definition of "genuine research project" or "clinical trial"

Maine

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- Exception for “reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy or treatment”
- “Bona fide clinical trial” is “any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and health outcome.”
  - Observational trials?
  - Single arm?
  - Historical controls?
  - Expanded access / treatment INDs?

West Virginia

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- Payments of reasonable compensation and expenses in connection with a bona fide clinical trial do not have to be reported
- A “bona fide clinical trial” is a clinical trial approved by an IRB, which is in compliance with the statutory and regulatory requirements set by the FDA, and conducted in connection with a research study where the principle purpose is scientific research.
  - Covers IND-exempt
  - Expanded access / treatment IND?

Other States

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- Vermont – similar definitions as Massachusetts
  - "Bona Fide Clinical Trials," "Clinical Trials," and "research projects" have similar definitions as MA's "Clinical Trial," and "Genuine Research," and are excluded from gift ban
  - But are not exempted from reporting: related expenses must be reported within 2 calendar years after the payment was made, or at the time FDA approves or clears the product if sooner
- DC
  - Exception from reporting requirement for "reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy or treatment"
  - But bona fide clinical trial is not defined

Other States

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- California
  - Payments to health care professionals for legitimate professional services, at fair market value, do not need to be considered in calculating the annual spending limit set forth in the company's Comprehensive Compliance
  - No specific definition of clinical trial or research
- Minnesota
  - Compensation for substantial professional or consulting services of a practitioner in connection with a genuine research project
    - not considered a gift under the gift ban
    - But must be reported

Federal Sunshine Bills

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- Do not pre-empt state disclosure laws, except to the extent the disclosure requirements are identical
- Do not exempt clinical trial expenditures from the reporting requirements; merely allow a delay in reporting
  - In House Bill:
    - For payments made under a product development agreement, reporting is required in the reporting period after 2 years have elapsed since the payment was made, or in the period right after approval or clearance, if sooner.
    - For payments made in connection with a clinical investigation, reporting is required in the period after 2 years have elapsed since payment, or after the product is registered on www.clinicaltrials.gov
  - In Senate Bill:
    - For payments made under a product research or development agreement, or in connection with a clinical trial, reporting is required 4 years after the payment, or when approved or cleared, if sooner

Federal Sunshine Bills (cont.)

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House and Senate Bill definitions of “Clinical investigation” are the same:

- 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
- “experiment” is not defined

Grants supporting Investigator-Sponsored Investigations (ISIs)

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- Grants generally fall into the same category as other types of payments to investigators related to clinical trials
- Thus, the key issue is whether the ISI itself qualifies as a clinical trial or as research under the relevant law – a statute-by-statute determination

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