

Dissemination of Clinical Trial Information: It's a Fine Line Between Scientific Exchange of Information and Product Promotion

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Scientific Exchange vs. Promotion

My Thoughts

- Education vs. spin
- Context and perception
 - ✓ solicited vs. unsolicited request
 - ✓ marketing vs. medical affairs
 - ✓ greatest hits vs. entire reprint
- Relevance is the level of FDA regulation and oversight

Non-Promotional Information

Some Examples

- Disease awareness communications
- Continuing Medical Education (CME)-type activities
- Specific responses to unsolicited requests for information

Pre-Approval Discussions (But Not Promotional) May Occur In A Variety Of Settings

- Journal reprints
- Trade shows
- Educational conferences/medical meeting exhibits
- Press releases/securities-related documents
- Internet

Pre-Approval Discussions (But Not Promotional) May Occur In A Variety Of Settings

(cont'd)

- Response to an unsolicited request (oral or written)
- Market research (advisory boards)
- Faculty and investigator training
- Investigator recruitment
- www.clinicaltrials.gov

Pre-Approval Discussions (But Not Promotional) May Occur In A Variety Of Settings

(cont'd)

- It is important to communicate information about products in clinical trials in order to:
 - ✓ have a full exchange of scientific information
 - ✓ develop products that reflect healthcare provider needs
 - ✓ recruit clinical investigators and subjects

Pre-Approval Discussions (But Not Promotional) May Occur In A Variety Of Settings

(cont'd)

- ✓ comply with Securities and Exchange Commission (SEC) requirements to publicly announce clinical trial results that are material or that will significantly affect company stock
- ✓ comply with FDA's requirements regarding clinical trial posting

FDA Regulation

- A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new product is safe or effective for the purposes for which it is under investigation or otherwise promote the product
- This regulatory provision is not intended to restrict the full exchange of scientific information concerning the product, including dissemination of scientific findings in scientific or lay media
- Beware of conclusory statements, such as “will,” “best,” “safe,” “effective,” and “when approved”

Key Statutory Definitions

The Federal Food, Drug, and Cosmetic Act

- **Label** – “[A] display of written, printed, or graphic matter upon the immediate container of any article”
- **Labeling** – “[All] labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article”
- FDA regulates all product labeling and prescription drug advertising

Labeling

- The reach of the term “labeling” is broad, because it extends beyond mere physical association with the product
- However, the reach is not unrestricted
 - ✓ it must function as labeling
 - i.e., it must supplement or explain a product to help in the product’s use
 - disease state communications, without product reference, and CME activities are typically not considered labeling

Labeling

(cont'd)

- ✓ it must be supplied or disseminated by or on behalf of the manufacturer, packer or distributor
- ✓ materials prepared by persons who have no commercial interest in the product may not be labeling
 - it's a control issue

But It's Not Labeling

- Verbal statements that are not “labeling” can change a product’s intended use and get a company into regulatory trouble
 - ✓ e.g., statements at trade shows, workshops, seminars, or hands-on demonstrations cannot be violative
- The intended use is what the product does
- Based on the objective intent of persons legally responsible for labeling
- Determined by expressions or circumstances surrounding distribution of product

Good Reprint Practices Guidance

- FDA recently finalized a guidance, “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices”
- FDA intends the guidance to provide manufacturers with guidelines regarding the dissemination of peer-reviewed scientific journal articles regarding unapproved uses of drugs or medical devices

Good Reprint Practices Guidance

(cont'd)

- Some focus points include independence, peer-reviewed and truthful information, full disclosure of potential relationships with the authors and regulatory status of mentioned product, education (versus promotion), and scientifically sound data
- Relevance to our discussion is dissemination of information about possible investigational uses of an approved product

Good Reprint Practices Guidance

(cont'd)

- The guidance does not apply to the following publications, which are not considered scientifically sound:
 - ✓ letters to the editors
 - ✓ abstracts of a publication
 - ✓ reports of Phase 1 clinical trials
 - ✓ reference publications that contain little or no substantive discussion of the relevant investigation
- We prepared a Bulletin that we can send you, which describes in more detail the guidance

Recommendations

- Establish procedures before distribution and a team to review all materials, regardless of the intended audience or the form of the material
 - ✓ e.g., an internal review checklist that requires signoff by appropriate personnel
 - ✓ make clear in training and in Standard Operating Procedures the roles of individuals, the laws, government guidances, and company policies

Recommendations

(cont'd)

- Consider using Medical Affairs / Medical Science Liaisons to convey clinical trial information as scientific and educational exchange of information, and not as product promotion
- Be careful – MSAs cannot promote unlawfully
 - ✓ e.g., MSAs cannot promote off-label uses or suggest an investigational drug is safe and effective
- FDA is more concerned about the content of the company's presentation of information than the title of the person providing the content

Recommendations

(cont'd)

- No handmade materials should be prepared and distributed
- Can report study or scientific findings – scientific exchange of good and bad information – but don't editorialize, promote, exaggerate, or commercialize if the product isn't approved
- Do not draw conclusions of safety or efficacy (including quotes from investigators or company executives) if unapproved product

Recommendations

(cont'd)

- Be careful about symbols, logos, URL addresses, or graphics that can also get a company into trouble with intended use issues
- Disclaimers or qualifying statements are helpful but won't eliminate risk if the whole promotion, when viewed in full and in context, is violative

Recommendations

(cont'd)

- Train employees and third parties you employ about company policies
 - ✓ you don't want renegade personnel getting the company in trouble
 - ✓ audit and monitor internally to make sure everyone is on the same page
 - ✓ document accordingly

Freebie

- We have written or been quoted in articles about off-label information dissemination and ramifications. If you'd like a free copy, please email me at alan.minsk@agg.com.



