Navigating the Rules of Engagement
In-House Counsel Perspective

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January 21, 2015

HYPOTHETICAL CASE STUDY

- Biopharma Company is studying an investigational compound to determine whether it has the potential to treat March Madness Virus
- March Madness Virus is a contagious disease that creates chronic problems that tend to flare every March
- Company has not had an approved product in this disease so it lacks experience with patients. The Company is planning a Phase 3 study.
- There are several already- existing PAGs that provide advocacy and support for patients with the March Madness Virus.
- As part of the Company's research into understanding patients with the disease and planning the clinical trial, the Company reaches out to these PAGs to determine what resources these groups have that will provide input to improve the upcoming trial design and positively affect trial recruitment.
- One PAG – Krzyzewski March Madness has tangible resources – patient registries/databases as well as a network for real time patient communication
- Another PAG – Calipari March Madness has professionals who have valuable experience in patient recruiting for trials and are interested in ensuring that patients are aware of relevant and high quality clinical trials.

Defining the Relationship - Assessing Interactions

First step in legal analysis – not all interactions are created equal
Must determine what bucket applies
Each bucket will have own contractual rules and parameters to mitigate risk

Service Provider Bucket

- Contractual basis as a service provider
- Important that this relationship is discussed at length so that there is no confusion
- In a service relationship – industry is retaining the PAG to do certain work with a tangible end product and the PAG is compensated FMV

Charitable Giving Bucket

- A donation to a 501(c) (3) organization (tax exempt, non profit)
- Corporate Sponsorship support for general or specific education project(s)
- To mitigate risk, require independence and unrestricted nature of donation

Non-Compensated Collaborations Bucket

Patient Advocacy Group Engagement

- Legal Risk Analysis of Patient Advocacy Group (PAG) interaction with industry
  - Privacy
  - Kickbacks
  - Promotion
  - Appearance of Conflict
  - Recognition of When Informed Consent begins

Examples of Interaction

- Advisory Boards/Consultancies
  - Industry can invite patients or PAG representatives to advisory boards to provide feedback and guidance on bona fide business need
  - Compensation at FMV or volunteer
- Examples of bona fide business need:
  - Protocol development that is patient-centered
  - Advise on strategy for trial program development, benefit/ risk discussion
  - Recruitment strategy development

Examples of Interaction

- Appropriate access to patient registries/databases (de-identified or patient consented) for purposes of recruitment - purchase data
- Use of patient communication networks to conduct patient surveys about needs, attitudes and experiences
  - Privacy issues
  - Aggregate data – more like market research tool
- Charitable Giving/Sponsorships – can be used to support PAG's own initiatives - must be independent
- Everything must be independent from commercial involvement

Recruitment Campaign Example

- Disease is not well understood by general population
- Advertisement campaign targeted patient population with limited knowledge of disease
- Expected confusion between subsets of the disease needed to be explained
- Needed to balance educational components vs. regulatory guidelines vs. compelling content

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Special Considerations for Industry

- PAG's focus is often on disease education and treatment
- The PAG can view trial recruitment as part of its overall mission, which is educating patients about disease and treatment
- Disease education rules are different from those that govern trial recruitment and awareness
- FDA Promotion Guidelines – bottom line for industry – risk increases when you try to mix together different types of communication.
- Industry Goal: Bright line between disease education and patient recruiting to mitigate risk

Patient Recruitment Considerations

- Patient recruiting for a trial(s) is the first step in the informed consent process
- Regulated by the human subject informed consent regulations and subject to prohibition on pre-approval promotion
- Challenge with working with PAG on recruitment communications – not to make promises yet still inform in an interesting manner
- Ensuring that an appropriate grade reading level was used

Metrics

- Patient recruiting
- Recommend innovative non-financial metrics to mitigate risk
- Avoid appearance of patient undue coercion or conflict if industry trying to meet any required PAG metrics
- Financial metrics should not involve anything about the commercial side of the business and should not have any reference to ultimate sales of the compound being studied.