

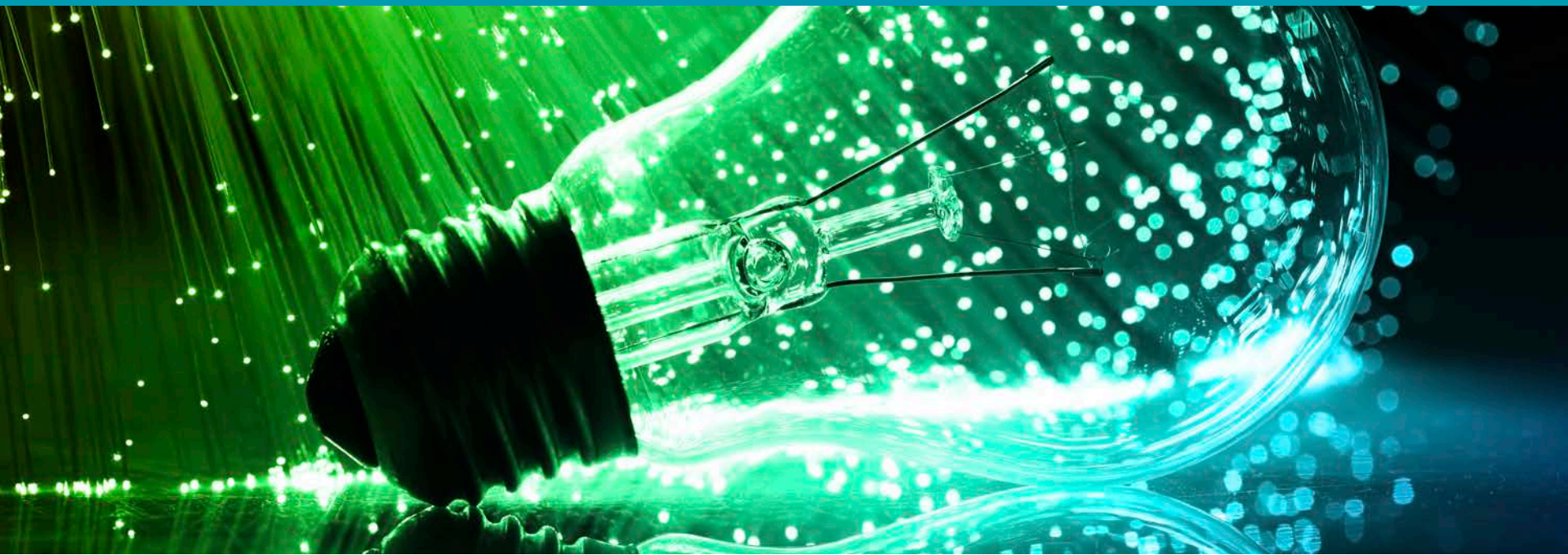
Conflicts of Interest – Real and Apparent Issues

Ron Bartek

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Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative.

INTRODUCTION

- COIs exist within each and among all 3 stakeholders
- Will focus on those experienced by PGs and their industry partners, as those COIs have been identified as potential barriers to engaging patients early and often throughout the drug-development process.
- You will see or already know that COI in this arena is extremely complex and that this brief presentation will scratch the surface.

COI Is All Important

- Trust - Nothing more important to PG than the trust of the patients and patient families. Everything the PG is able to accomplish & all assets it is able to provide its partners depend on that trust:
 - Fundraising, grantmaking, patient registry, natural history database, bio-repository, cell models, recruitment, etc.
- So, PGs take any potential for real or apparent COI very seriously – could erode that all important trust.

Can't Avoid COI – Manage It

- If you have no conflict – you have no interest!
- PGs seeking deeper relationships with academic investigators & industry partners – essential to doing their jobs.
- Almost always involve financial engagements that are perfectly legal and ethical.
- So, not a matter of avoiding COI – but of managing it.
- Based on the disclosure and transparency necessary to build and maintain trust.

Definition

- A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.
- Pervasive in every aspect of society. Incentives that motivate effort & performance but can sometimes conflict with professional responsibilities in ways not always clear to the public or one's own mind.

Rules of Engagement & Guidelines

- Internal COI of a PG (individuals such as officers, staff, directors).
- External (organizational) COI of a PG (with industry partners, FDA, etc.).
- For PG, internal & external COI in eye of the beholder – patient families and donors.
- Internal COI – Informal monitors such as BBB & Charity Navigator publish guidelines and ratings.
- External COI – some government regs/guidelines (Treasury, FDA).

Rules of Engagement & Guidelines

BBB Center for Science in the Public Interest:

- No transaction(s) in which any board or staff members have material conflicting interests with the charity resulting from any relationship or business affiliation.
- Factors that will be considered include arm's length procedures established by the charity; the size of the transaction relative to like expenses of the charity; whether the interested party participated in the board vote on the transaction; if competitive bids were sought and whether the transaction is one-time, recurring or ongoing.

Charity Navigator:

- Accountability – explaining actions to stakeholders
- Transparency – making available critical data about org
- Consider form 990 and website; does the PG follow good governance & ethical best practices? Does the PG make it easy for donors to find critical info about the org?

Rules of Engagement & Guidelines

- When capital flow is from industry to PG
 - No legal restrictions; concerns re disclosure & level of funding; possibility of influence on policies, positions, commo w/ patients.
 - Eye of the stakeholder (esp. patient community & donors) test always applies, requiring transparency, disclosure and maintenance of trust.
- When capital flow is from PG to industry - PGs engaging in wide variety of arrangements striving to support efforts of industry partners to develop treatments for their diseases:
 - Matchmaking
 - Providing translational tools -- e.g., assays, cell and animal models, bio-samples, tissues and organs, biomarker data.
 - Providing clinical infrastructure (natural history databases, registries, clinical networks)
 - Research Grants
 - Investments

Rules of Engagement & Guidelines

FDA Policies re COI w/ PG & Industry Partner

- From my experience, FDA not concerned about PG's potential COI when PG accompanies sponsor to FDA mtg (pre-IND, milestone, etc.); PG is w/ sponsor on sponsor's side of table.
- SGE/Patient Rep: Key person (officer, staff, director) of PG significantly engaged w/sponsor considered in conflict

Dept. of Treasury Guidelines

- Foundations may buy stock or make loans to commercial venture if venture's activities promote foundation's charitable objectives = Program Related Investments (PRI).
- PRI is investment that has primary purpose of accomplishing one or more charitable purposes, no significant purpose of producing income or appreciation of property, and no purpose to accomplish prohibited political purposes.
- Alternative form of financing charitable programs, allows for (and anticipates) repayment enabling reinvestment of capital in charitable programs.
- Existence of high potential rate of return on investment does not, by itself, prevent the investment from qualifying as PRI.

Rules of Engagement & Guidelines

- CFF's recent transaction drew attention to this arena:
 - CFF invested early in company developing CF drug. "Evergreen" contract provision provided for royalties to CFF. Recently received from 3rd party total of \$3.7B for royalties.
 - CFF Pres/CEO letter to editor: "our sole commitment is to people with cystic fibrosis; our only 'return' is in the tomorrows we add to their lives. Any funds generated from our research investments are plowed directly back into new research to find a cure and improve the health and quality of life of people with the disease."
- Sustainability issues - pricing & reimbursement:
 - CFF Pres/CEO also stated, "We are concerned about the high price of cystic fibrosis drugs, which we know place a burden on patients and families and are unsustainable for the health care system over all. We're committed to finding the balance between fostering new treatments and ensuring that cost is not a barrier to people with cystic fibrosis."
 - But, PGs seem to me to have little impact on pricing (beyond emphasizing cost savings the PG provided. Some impact on reimbursement.
 - gravely serious societal issue - goes well beyond role of PGs and COI.

What CAN & SHOULD Be Done

- “Pfizer Inc. has concluded that **patient-focused drug development must be an iterative approach that starts early and lasts throughout the R&D process ... the long-term goal is that we’ ll be able to develop medicines that are much more relevant and meaningful as far as **outcomes to patients.****” (Roslyn Schneider, Pfizer senior director, medical strategy & patient advocacy)
- You can navigate these waters effectively – being done every day to great effect.
- PGs are managing their COI, saving industry partners time and money, improving prospects of success by providing patients’ voice, experience, insights, assets & partnership throughout R&D process.

Thank you.



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