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Perspectives on Financial Relationships and Conflict of Interest in Basic and Early-Stage Translational Research:



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Two underlying factors contributing to challenges for physicians/scientists

- Current lack of clarity and consistency in policies may cause confusion and noncompliance
- Sufficient uniform awareness of these issues on the part of investigators may be lacking, incomplete education

- What is the core mission of the University?
 - Discovery of and dissemination of knowledge
 - to educate

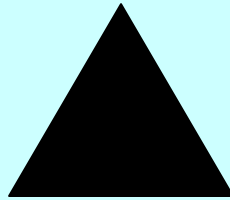
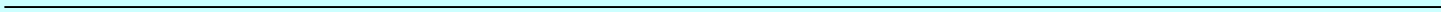
- Faculty and public understand that universities get money from outside sources to support its mission.
- However , this should not be at the expense of its core mission to openly discover and disseminate knowledge
- It should be in a manner that does not appear to have the potential for bias by undue influence.

- Look at tech transfer as an extension of the University's role in service to the community. In many cases university service might even be for free; i.e. service on study sections, other national not for profits, even services to help at a science museum, others.

- In this – tech transfer should function to facilitate the University's and faculty member's mission, i.e., discovery and dissemination of knowledge.
- To the degree we deviate from this I think we will have a problem.

RISK

REWARD



What is the most straightforward way to do this?

- Driving money into faculty members lab via research agreements or sponsoring clinical trials.
- Another alternative is from a proven technology in the marketplace.

Technology Transfer

SERVICES vs INCOME vs
ECONOMIC IMPACT

Service Model

Definition: Emphasis is placed on providing service to the faculty, and not on the generation of income. The Technology Transfer Office is not dependent on the income that it generate from royalties, license fees, and equity deals.

Benefits: Each project gets the same attention - Significant income earning opportunities may be lost because an emphasis is not placed on income. Higher budget subsidies will be needed.

- Measures of faculty “customer” satisfaction are likely to be high.

Income Model

Definition: Income (or business) model, emphasis is placed on the generation of income.

- Licensing professional acts as an entrepreneur who identifies the inventors and inventions with the greatest potential to generate income.

Benefits:

- Works well with experienced staff who have a good understanding of the markets and industries that the technologies go into.
- Benefits of income will accrue to the research program, the college, the department, and the inventor .

Income Model, cont.

Drawbacks:

- Focus of this model on maximizing income, emphasis will be placed on inventions that are likely to be the big hits rather than on equal treatment.
- Pressure is to get the deal completed so that the licensing professional can get back to the big deal.
- Could create a negative attitude among those other faculty.
- An inherent feature of this model is a “rigorous” triage of inventions; much doesn’t get patented.
- As licensing professional focus on the more significant inventions, it is likely that fewer licenses will be completed; slow, ponderous process.

Economic Development

Definition: Economic development model, emphasis is placed on the establishment of companies around university technology, and income that is generated through the equity in those companies that the university takes.

Benefits:

- Significant potential for big hits through equity deals.
- Publicity can be good or bad.
- Benefits of the technology transfer program through the number of people employed in the university start ups.

Options for “Technology Transfer”

- Contract Research – “peanuts”, but sustains mission
- Licensing Deal – bags of peanuts (maybe?)
 - Upfront payments
 - Milestone payments
 - Royalties
 - Equity
- Company start up – same options as in #2 above
 - Opportunity to own the peanut farm
 - Huge challenges - management, money, etc.

What if government changes their policies?

- Since the Fed has funded and school gets their “cost” of doing the research direct and indirect, what if NIH said they want any or 50% equity or royalty turned back to them?
- What if NIH/Fed said we funded this, will give you a royalty, but NIH will recoup 90% of the “upside” from any commercialized technology?
- This could be used as a separate fund for translational/clinical trial research.

How to enhance clinical research

- The research community should lobby to get some of the revenue a school currently gets turned back to support more clinical research
- Change how income from commercialization is allocated

Many University Impediments have Nothing to do with COI

- Trying to balance the competing pressures for money.
- Each “deal” is a new deal; nothing is ever the same, protracted and costly negotiation; many walk away.
- Unreasonable expectations – most university technology is very, very early stage and unproven though often with lots of promise; this does not generally have huge value.

Impediments absent COI

- Indirect cost percentage
- Ownership of the technology
- Terms to license any discovery, i.e.
 - Only an option
 - Unreasonable terms
 - Difficult negotiations
- Inter-university negotiations if study has a number of investigators from different sites.
- IRB
- Many other reasons

However . . .

- It is very difficult, if not impossible, if there are major financial consulting or other relationships to assure the absence of bias in clinical research or clinical care decisions.
- How high a bar is the “Rebuttable Presumption?” principle (or AL) in AAMC policy?
- The public believes the system is broken, there is undue influence of the corporate sector on physician and physician scientists.

- Absence of more uniform ways of institutions dealing with financial relationships with industry opens the door or “begs” for governmental regulatory intervention.
- For those who believe in preserving the status quo, change will be difficult i.e. “it wouldn’t seem so bad if it hadn’t been so good.”

Government Intervention Would Likely Be:

- Bureaucratic, “heavy” handed, too broad
- Miss the mark
- Costly
- Audits
- “Results” for non compliance
- Have an adverse effect on biomedical research R&D
- Effect on clinical Care? Better , less expensive, fact based.