Corporations: A Lever for Research and Development

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Disclosure: My Relationship with Medical Device Companies

- Geometrics@*
- Gammex-RMI*
- Adac
- GE Medical
- TomoTherapy@*
- Accuray$
- CPAC@*$
- Novelos*$
- Biolonix*$
- Shine Medical Technologies*$
- HealthMyne@*$
- Accelerated Devices@*$

* Indicates Former or Current Board Membership
@ Indicates Founder
$ Indicates Current Relationship

The Mine and the Mill

Good ideas tend to come from academia and get implemented and refined in a company.

The University is the Mine

The Company is the Mill

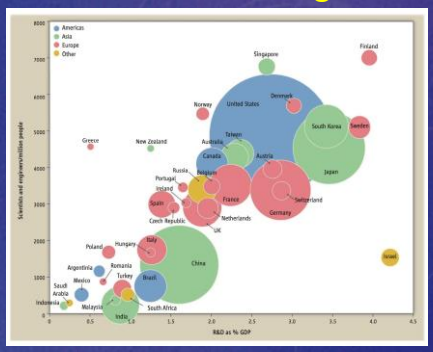
A mill won't last long if the mine is not productive.

Resistance to University-Industrial Partnerships

- In 1996, Lee found that only 44% of faculty agreed with policy of offering technology assistance to companies.
- And only 26% of faculty thought it was OK for the university to take equity in university startup companies.
- Faculty with the least linkage to industry had the least favorable view of university-industrial partnerships.

Lee, Y (1996) Technology transfer and the research university. A search for the boundaries of university-industry collaboration. *Research Policy* 25:843-63

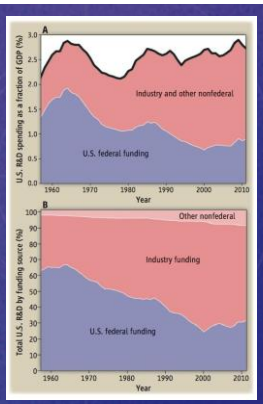
R&D Ranking



Press WH, Science 342:817-822 (Nov. 15, 2013)

Sources of Funding for R&D

- Total US R&D spending has constant at about 2.5% of GDP.
- US federal proportion of R&D spending fell from 1965 to 2000.
- 80%+ of R&D in our field is corporate.



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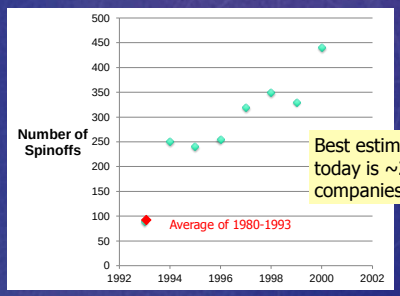
Number of University Spinoffs/year in the US



Best estimate today is ~2000 companies/year

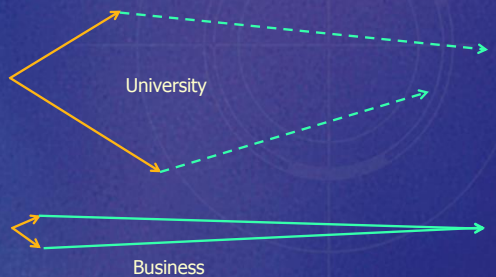
From Association of University Technology Managers

Divergent and Convergent Thinking: Focus is a Dimension, Not a Point

Divergent Thinking
- Thinking Outside the Box
- Exploring Possibilities
- Brainstorming
- 1% Inspiration
- "Undisciplined", "Unfocussed"

Convergent Thinking
- Step by Step Execution
- Getting the Job Done
- Project Management
- 99% Perspiration
- "Incremental", "Boring"

Project Management Differences



I would not consult for a company that would hire me as a consultant.

Do's and D'Oh's

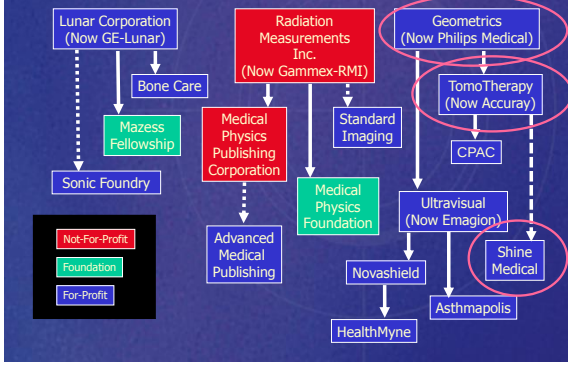
Do = Wahoo

D'oh = Damn

Why in the World Would You Want To Do This?

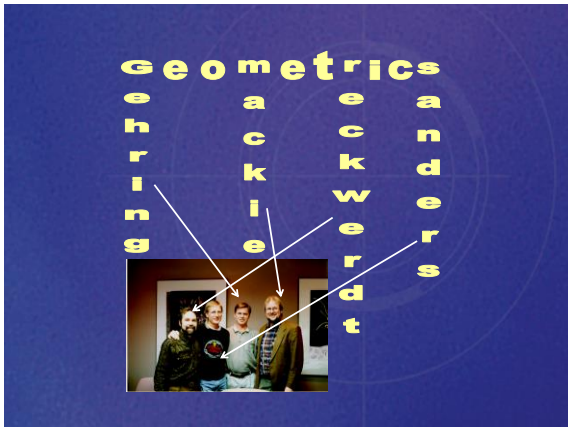
- What is your motivation?
- How will you get the financing needed?
- Who owns the intellectual property?
- Do you have the time?
- Will you enjoy doing it?
- Do you have business experience?
- Isn't there an easier way to accomplish your research ends?

Medical Physics Dept. Spin-Offs



History of Geometrics

- 1988 – First Development to Enable Stereotactic Radiosurgery (UW First in Midwest).
- 1991 – Tried to Give Away Software to Six Radiotherapy Clinics – FDA Stopped Us.
- 1992 – Founding of Geometrics Corporation.
- 1996 – FDA Clearance to Market.
- 1996 – Sale of Geometrics to ADAC.
- 1999 – Largest Selling Radiotherapy Treatment Planning Software in the World.
- 2001 – Sale of ADAC to Philips Medical.
- 2014 – Development team still based in Madison.

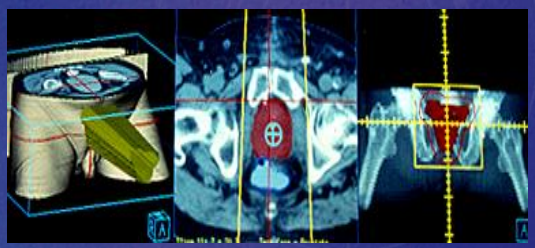


In 1992, Starting a UW Spin-Off Was Like Pulling Teeth

Founding of Geometrics

- UW University Hospital funded development.
- FDA prohibition on clinical use of non-cleared medical software.
- Programmer funding was cut by UW Hospital.
- UW does not take an "work-for-hire" position.
- Equity in proportion to effort on development.
- Mark Gehring and Cameron Sanders went full-time to the company.
- I and Paul Reckwerdt stayed at the UW.
- Pledged $300,000 to UW, what it cost them.
- Gave an indefinite license to UW on derivative software that was named Pinnacle.
- License has saved UW >$1 million in costs.

Pinnacle, 1994



Corporate Partnership

- Corporation gets exclusive access to IP or products in return for working capital.
- They may want an ownership interest in your company.
- They may directly or indirectly exercise great control over your company.
- Partnerships can maximize your exposure to the marketplace.
- Partnerships limit the ultimate value of your company.
- Geometrics was based on a partnership with ADAC.

Successful Product, Unsuccessful Business

- Geometrics was funded on an advance of royalties (like a textbook).
- In 1996, ADAC received FDA 510(k) and could market Pinnacle.
- ADAC controlled the marketing and we perceived a go-slow.
- With what we were going to get back in royalties we would struggle to put the improvements we wanted to put into the product.
- We sold to ADAC for ~1% of eventual sales.

History of Tomotherapy

> Two Decades

- 1988 – First ideas at the University of Wisconsin.
- 1992 – First patents filed
- 1993 – First paper of tomotherapy published.
- 1994 – GE funds UW research project.
- 1996 – Sale of Geometrics to ADAC.
- 1997 – GE gets out of radiotherapy.
- 1997 – TomoTherapy founded.
- 1999 – Received first investment.
- 2002 – Received FDA 510(k) to market.
- 2002 – First patient treated at UW.
- 2004 – TomoTherapy profitable.
- 2007 – TomoTherapy goes public
- 2011 – TomoTherapy sold to Accuray

Founding of TomoTherapy

- TomoTherapy was formed when GE got out of radiotherapy.
- We gave more than 1/3 of stock to the staff in my UW research group who joined the company.
- WARF tomotherapy patents were licensed.
- WARF was the first investor in company.
- WARF helped find VC investors.
- Low interest loan from the State of Wisconsin.
- SBIR grant from Federal government.
- First money raised was used to finish the version of the UW prototype with GE components.
- $250,000 gift to Wisconsin Foundation.
- First sales to Canadian radiotherapy clinics.

Approximate Startup Budget for TomoTherapy Inc. (1998-1999)

Legal	10,000
Salary	40,000
Consulting	20,000
Accounting	5,000
Computers	3,000
Office Supplies	2,000
Travel	10,000
Rent	0
Miscellaneous	10,000
Total	$100,000

We were off by $50,000.

Risk-Reward Matrix for New University Technology

	Low Risk	High Risk
High Reward	Best Position, But Easy to License to A Big Company	Most Spin-Offs
Low Reward		

Where Existing Companies Perceived TomoTherapy

	Low Risk	High Risk
High Reward	Best Position	TomoTherapy
Low Reward	OK, But Don't Look for VC's to Invest	Modern Role of Big Government

Where TomoTherapy Founders Perceived Their Technology

	Low Risk	High Risk
High Reward		TomoTherapy
Low Reward	OK, But Don't Look for VC's to Invest	Modern Role of Big Government

VC Financing

- Necessary evil - VC may be the only viable source when funding requirements are large.
- VC come in flocks and they will help you find other investors.
- The will be able to contribute to future rounds of financing or provide bridge loans.
- They can help you tune your business plan.
- They will be able to help with key business decisions – like a merger/acquisition or a marketing decision.
- They will be able to be a bridge with investment bankers.
- Usually their interests are aligned with your's.
- TomoTherapy was VC financed ($32 M until profitable).

Issues of Conflict of Interest

- My relationship between with the University is carefully managed by the UW Conflict of Interest committee.
- What is good for my company is not necessarily good for the UW and visa versa.
- Disclosure of the financial situation is the first requirement.
  - Disclosure to the UW
  - Disclosure in oral and written communications

Financial Disclosure

"I am a co-founder of TomoTherapy Inc. (Madison, WI) which is participating in the commercial development of helical tomotherapy."

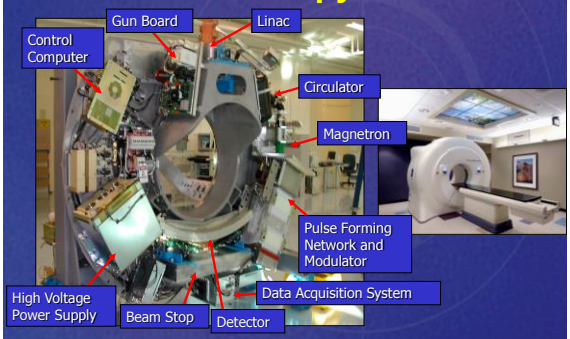
Do's

- Disclosure
- Disclosure
- Disclosure
- Get everything in writing.
- I have a letter from the WI Attorney General giving official approval of my activity.
- The Smell Test – Does it somehow stink (Entre – Manure)?
- The Newspaper Test – Imagine what a negative newspaper article would do.

Absolute D'Oh's

- Be responsible for a clinical trial involving your company's products.
- Be responsible for either end of a contract (written or verbal).
- Force your institution's co-workers or students to be involved with the company.
- Limit the rights of your institution's co-workers or students, e.g., restrict publications.

TomoTherapy - 2007



Conflict of Commitment

- When and what hats do you wear?
- You need a formal agreement with your employer on your time commitment to the company – Don't assume "a day a week".
- You must not do business at your employer's place of business without compensation.
- When in doubt, your first obligation is to your employer.
- With financing of TomoTherapy I first went from a 100% appointment to a 75% appointment at the UW and finally to a 50% appointment upon IPO.

Is There a Coincidence of Interest?

- What is good for the company may also be good for your employer.
- Is the intellectual property owned by your employer and licensed to your company?
- Does a royalty or other benefit return to your employer?
- Is there a grant or a contract linking the employer and company?
- You are not the arbitrator of what is good for your employer, only your employer is.

Conflict/Coincidence of Interest Matrix

	Good for Your Company	Not Good for Your Company
Good for Your Employer		
Not Good for Your Employer		

Shine Medical: A Public – Private Partnership

- In 2009 Canadian NRU Reactor shut down for 15 months.
- In 2010 DOE offers cooperative agreements worth $25 M for ideas to create a sustainable US supply of medical isotopes.
- In 2011 Morgridge Institute and Phoenix Nuclear Labs partner and obtain funding and Shine Medical is formed.
- Involves UW, multiple government labs, and private entities.
- In 2013 Environmental and Construction permits were filed with the NRC.
- In 2013 Morgridge role on the project ended.

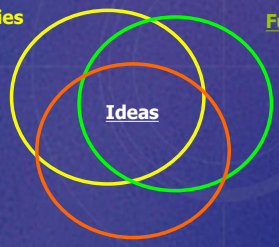
Sub-Critical Intense Neutron Emitter (SHINE)

Inherently Safer Than a Reactor

Angel Investors

- Behave like venture capitalists in most ways.
- Often have motivation to help their community.
- Have less capacity than venture capitalists.
- Best for early stage investments.
- Shine Medical received > $11 M from angel investors.
- Shine needs to find >$100 M in equity and debt financing over the next three years.

Ingredients for a Successful University



Excellent Faculty, Staff and Students

Ingredients for a Successful Business

Excellent Management and Staff

How the Field Can Help

- Promote entrepreneurship in your university.
- Teach trainees the basics needed for business:
  - Cultural differences between academia and business,
  - Understanding finance and marketing,
  - Defining user requirements,
  - Product development and regulatory affairs,
  - Scheduling – using tools like Gantt charts,
  - Useful for the working in the clinic as well.
- AAPM and other organizations in our field should partner more effectively with companies.

Conclusions

- Corporations fund 80%+ of medical physics R&D.
- Working with companies or starting a business is an efficient way to have ideas actualized.
- You should be aware of the cultural differences between universities and companies.
- You should understand your motivation before starting a company.
- There are several ways to fund the startup of a company.
- Potential conflict of interests can be managed.
- Private-public partnerships are more likely if academics have business knowledge.

Questions?