University – Industry Collaborations
The Good, The Bad, and the Ugly

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What this talk is about

- Takes a broad view of collaborations in the pharmaceutical and biotechnology research areas.

- **THESIS** – Collaborations can be of greatest benefit when both parties are contributing in ways that are consistent with their basic missions and with the inherent nature of their organizations.

- University and industry goals and issues.

- Collaborative research issues.

- Benefits of university-industry collaborations.

- Impediments and liabilities of university-industry collaborations.

- Expanding university opportunities.

- Final thoughts.
What is my background?

- **ACADEMIC EXPERIENCE**
  - Professor of Chemistry and Biochemistry
    Departments of Chemistry and Biochemistry
    University of Kansas, 1970-1985
  - Professor of Pharmaceutical Sciences
    College of Pharmacy and BIO5 Institute
    University of Arizona, 2003-2007

- **INDUSTRIAL EXPERIENCE**
  - Director of Computer-Aided Drug Discovery
    Discovery Research
  - Research Fellow
    Discovery Research
    Pharmacia & Upjohn and Pharmacia, 1998-2003
Selected References

- “Can Science be a Business”

- “Drug Discovery in Jeopardy?”

- “Working Together, Creating Knowledge”
  Business-Higher Education Forum
  The University-Industry Research Collaborative Initiative (2001)
  *Co-chair*: N. Hasselmo, President, Association of American Universities
  *Co-chair*: H. McKinnell, Chairman of the Board and CEO, Pfizer Inc.

- “Guiding Principles for University-Industry Endeavors”

- “Pharmaceutical Strategy and Innovation: An Academic’s Perspective”

- “Finding Improved Medicines: The Role of Academic-Industrial Collaborations”

- “Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections”
What caught my interest?

- 2005 Spring ACS Meeting – CINF & COMP Division Symposium
  "Safe Exchange of Chemical Information: Can Relevant Chemical Information be Exchanged Without Disclosing Chemical Structures?" C. Lipinski & T. Oprea, Organizers

  Numerous papers discussing the “safe” exchange of chemical information.

- “Sharing Chemical Information without Sharing Chemical Structure”.
Is this an important issue?

- Yes, but ....

- Is the approach appropriate or desirable for optimal university-industry collaboration?

- Sharing chemical information but not structure can lead to what may best be called "black-box" science, which precludes important insights that can only be gained when structural information is available.

  - "The purpose of computing is insight, not numbers". Richard Hamming, inventor of the Hamming error-correcting codes.

- Optimal collaborations should involve transfer of knowledge and not just information and data.
A Bit of History

- Morrill Act, 1862. Established Land Grant College system in US.
- Minutes of the Pennsylvania State College Research Council meeting, February 6, 1928. Two questions were considered:
  - “To what extent should the College enter into agreements with commercial concerns and under what conditions?”
  - “What should be the institutional policy in reference to patents and patent rights?”
University Mission

- Educating students.
- Supporting and developing appropriate curricula.
- Discovering and disseminating new knowledge through basic and applied research.
University Issues

- Providing adequate infrastructure to facilitate teaching and research.
- Uncertain and declining funding for both basic and applied research. Declining freedom to pursue novel ideas.
- Departmental reductions of faculty and students due to declining jobs in some research areas.
- The role of proprietary research in universities. What about contract research?
- Patents – The good, the bad, and the ugly.
- To what extent should/can universities become involved in drug discovery and development programs?
- Difficulty in developing integrated, cross-disciplinary team approaches to research, an important feature of the industrial research process.
- Can universities behave as businesses? Should they?
Company Mission

- Make a profit.
- Increase shareholder value.
- Produce goods and/or services
- Discover new and/or improved medicines and therapies.
Company Issues

- Large uncertainty and high risk of pharmaceutical research.
- Significant investment required to support advanced technologies:
  - For example, high-throughput, high-content, and high-density screening, corporate compound collections, combinatorial chemistry, gene chips, etc.
- Research productivity:
  - Managing a (distributed) highly-complex research enterprise.
  - Controlling costs – What are the true costs?
  - Outsourcing – Where, when, and how much: Costs, benefits, and morale factors?
- Balancing productivity with innovation.
  - Devolution towards “assembly-line” science.
Univ.-Indus. Research Collaborations

- University-industry collaborations can be helpful, but they should not be an end in themselves.

- Broad institutional grants and/or smaller, more focused grants ("casting a wide net vs. spear fishing").

- Allow in-depth exploration of research areas and methodologies that cannot be undertaken by a company alone.

- Provide knowledge as opposed to outsourcing to CROs that provides mostly information and data.

- Provide synergies that lead to better science, especially at interfaces between disciplines.

- Can lead to improved products.
Some Benefits of Collaboration

Universities
- Financial support.
- Broaden the experience of students.
- Expose students and faculty to significant, interesting, and relevant “real world” problems.
- Enhance regional economic growth.
- Increase employment opportunities for students. Provide Sabbaticals opportunities for faculty.

Industry
- Access to expertise and knowledge not typically available in industrial laboratories.
- Aid in the renewal and expansion of a company’s science and technology base.
- Gain access to students as potential employees. Gain access to faculty consultants.
- Leverage internal research capabilities.

**Possible Impediments**

### University
- Practical difficulties with negotiating and managing a collaboration.
- Proper assessment for indirect costs.
- Deleterious effects on faculty and students. Loss of academic freedom.
- Impact on the mission, reputation, and financing of a university.
- Background rights.
- Difficulties faced by good but not top-tier universities.

### Industry
- Practical difficulties with negotiating and managing a collaboration.
- Appreciation for university indirect costs.
- Respecting the value of research collaborations.
- Incorporating university research into product development.
- Management barriers.
- Research tools: exclusive vs. non-exclusive licensing agreements.

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Possible Liabilities of Collaboration

- Significant opportunities for conflicts of interest:
  - Financial.
  - Intellectual.
  - Commitment.
  - Institutional.
- Confidentiality – Loss or compromise of intellectual property.
- Timeliness of progress on a project due to student labor. Lack of research experience of students.
- Patent issues: Flexibility, reach-through royalties,...
- Publication: 60-90 day limit, effects on patents, grants, and company goals,...

Guiding Principles

- **Guiding Principle #1** – A successful university-industry collaboration should support the mission of each partner. Any effort in conflict with the mission of either partner will likely fail.

- **Guiding Principle #2** – When possible institutional practices and national resources should focus on fostering appropriate long-term relationships between universities and industry.

- **Guiding Principle #3** – Universities and industry should focus on the benefits to each party that will result from collaborations by streamlining negotiations to ensure timely conduct of research and the development of the research findings.

Expanding University Opportunities

- Applying network theory, which is currently fashionable in chemical and systems biology, to study the inter-relationships in pharmaceutical research organizations.

- Applying other tools of modern sociology, operations research, and business to pharmaceutical research organizations.

- Developing methods for improving communication among widely separated research groups.

- Investigating the design of local and distributed research environments that enhance productivity.

- Investigating the social and business impacts of outsourcing.

- Developing productivity measures that more accurately measure research productivity.
Final Thoughts

- Companies and universities are not natural partners as their missions and cultures differ. Neither are democracies.

- Companies are hierarchical with clear chains of command.

- Universities are more loosely organized with significant authority vested in departments and schools – more like feudal states with multiple power centers.

- Company goals (the prime responsibility of upper management) are to make a profit and increase shareholder value by serving customers.

- Traditional university goals are to develop and disseminate new knowledge and educate the next generation of students.

- These differences must be understood and accommodated if university-industry collaborations are to be robust and successful.

The Technology Cycle

Does this describe University-Industry Collaborations as well as Technology?

For Three Men
The Civil War
Wasn't Hell.
It Was Practice!

CLINT EASTWOOD

"THE GOOD,
THE BAD 
& 
THE UGLY"

LEE VAN CLEEF
ELI WALLACH

ALDO GIUFFRE 
MARIO BREGA

SERGIO LEONE

TECHNISCOPE TECHNICOLOR

United Artists
Nature of Pharmaceutical Research

- Large degree of uncertainty and risk.
- Large number of diverse disciplines, some in immature stages of development:
  - What is currently known is a small fraction of what can potentially be learned about a given field.
  - Rapid advances in science and technology have, ironically, increased technical risks—mistakes are made because we are pushing the envelope of what is known.
  - Research experience of scientists is a crucial component of successful research.
- High degree of interdependence among disciplines.
- Long-term learning is essential to a successful research organization.
- Unlike in many highly technical industries (e.g., computers, airplanes,...) a drug candidate must be extensively tested in humans before it can be deemed "safe".

The Changing Research Landscape

- Dramatic advances in computers and instrumentation and the emergence of mega-science:
  - “High-throughput” biology; massive, diverse data sets; large compound collections, etc.

- Experimental and computational advances in “omics” sciences, systems biology, cell biology, biophysics, CADD, experimental medicine, bio- and cheminformatics, etc.

- The rediscovery of polypharmacology, the emergence of systems medicine – multi-drugs/multi-targets.

- Pharmacogenomics and the coming era of personalized medicine.
The Backcloth of Scientific Research

- Reduced funding.
- Declining number of available industrial and academic jobs.
- Diminishing numbers of domestic students.
- Hiatus in Ph.D. production – importance of maintaining continuity.
- Are there too many Ph.D.’s?
Pharmaceutical Industry Challenges

Decreasing Success, Increasing Cost

Source: PHARMA, CMR international