Research on Medical Devices in Academe: A Tortuous Journey
The problem: *Diabetes*

- Type 1 requires blood sampling, insulin injection
- Type 2 is related to obesity, inactivity, lifestyle
  - initially treatable with pills, weight control and exercise
  - requires blood sampling, may require insulin later
  - exacerbates many other medical conditions
  - growing at *epidemic rates*, especially among youth
- All treatments are related to blood glucose control
- US monetary costs: > $100 Billion/year
- Tremendous wastage of human resources
- New therapies are clearly needed
Possible Therapeutic Approaches

• Whole Pancreas and Islet Transplants
  – Limited organ and islet availability
  – Requires a lifetime of anti-rejection medications

• Gene Therapy
  – Multiple gene replacements or modification; Distant

• Stem Cells
  – Many technical hurdles; Must avoid rejection; Distant

• Prevention
  – Lifestyle changes, weight control, exercise
  – The best option, but not a solution for all patients

• Glucose Sensor
  – Hypoglycemia warning; Use with/without other therapies; Key to the artificial pancreas; Near-term
Prototype Implantable Enzyme-Electrode Blood Glucose Sensor with battery-operated telemetry system

Long-Term Implant Results

Sensor implanted in superior vena cava
Telemetry unit in subcutaneous tissue

**Dogs:** Prototype has been accurate (<10 mg/dl) for several months without recalibration.

**Humans:** Sensors of this type have been reported to function > 500 days in clinical trials.
Medtronic/MiniMed Long-Term Sensor

A central venous blood glucose sensor based on UCSD technology is presently in clinical trials. Potential lifetime of several-years; intended mainly for adults.
The Advent of GlySens, Inc.

- Founded in 1998 for development of long-term, tissue glucose sensor based on new UCSD sensor technology
- Tissue sensors are particularly advantageous for children
- Mass transfer in tissues is complex, and requires research; studies done at UCSD, funded by NIH
- Implantable telemetry, membranes, materials development, and extensive testing done by GlySens
- GlySens has received substantial funding by peer-reviewed grants – validates solid scientific foundation of the device
- Approaching human clinical trials
- Academic-industrial collaboration can be highly beneficial for complex projects
Sensor Array for Tissue Glucose

- Based on immobilized glucose oxidase with oxygen detection
- Sensor designed by systematic modeling
- Documented enzyme and oxygen sensor stability
- Thick film fabrication
- Biocompatible materials
- Wired connections for research

Analytical Chemistry 76 (2004), 1773-7
Tissue Sensors Implanted in Rodent Window Chambers

American Journal of Physiology 284 (2003), H2288-94
R and D are Fundamentally Different

- **RESEARCH**
  - Funded by grants from public largess
  - Usually a slow process, outcome not easy to predict
  - Benefits from open communication
  - Open-ended, leads to more research
  - **Universities** ideally suited for research, not development

- **DEVELOPMENT**
  - Funded mainly by borrowed money
  - Requires a clear market need, plan to recoup investment
  - Requires a straightforward path, predictable outcome
  - Highly selective communication environment
  - **Industry** ideally suited for development, but sometimes also does research
From Invention to Innovation

New idea → proposal → grant → research → spin-off → patent → …

then what?

The “valley of death” – patent not ready for license but there is a need for development funds, additional talents, market contacts, etc.
Obstacles Exist within Academe

- Faculty usually have limited understanding of the process.
- Tech transfer activities are time-consuming, there are almost no incentives, and they conflict with other demands.
- Faculty management of companies is usually not a good idea. Finding appropriate management talent is difficult.
- Conflict of Interest policies are not settled or effectively implemented.
- Differing opinions exist about the role of tech transfer in the academic mission.
Professor E.F. Gizmo and some of his many inventions
Strengths of UCSD

- UCSD has a long history of excellence in research, which is essential for sustained invention
- Culture of interdisciplinary research and interaction
- von Liebig Center is a unique resource
- TTIPS
- Rady School will provide management talent
- UCSD Extension
- CONNECT
- Vigorous, high density industrial neighborhood
A Few Suggestions …

• To increase credibility, the Academic Senate (composed of faculty representatives) is in a better position to appreciate and oversee Conflict of Interest issues.

• TTIPS needs a bigger budget and more effective collaboration with inventors.

• von Liebig Center should be expanded.

• The tech transfer process should be further streamlined wherever possible.

• Cultivation of the local investment capital industry is necessary for biotechnology.

• The teaching of innovation to students should be an integral part of the academic mission.

• Excellence in research is the foundation of tech transfer.
Thank you!