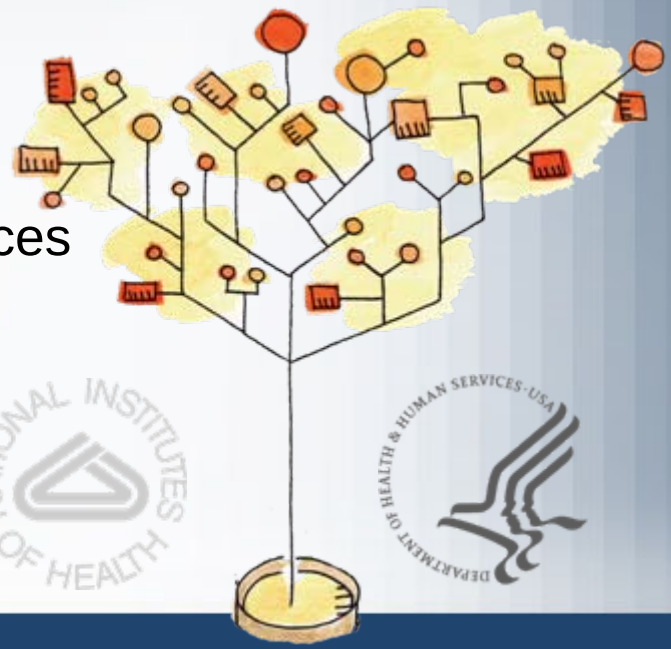
NIH TECHNOLOGY TRANSFER

Mark L. Rohrbaugh, Ph.D., J.D.
Director
Office of Technology Transfer
National Institutes of Health
U.S. Department of Health & Human Services



COPR
April 21, 2006

Technology Transfer

What Does This Mean?

Movement of information, materials, and technologies from the research laboratories to the commercial enterprise

To support further research and develop new products to improve public health

OTT Goals

Benefit the public health

Utilize IPR appropriately as incentive for commercial development of technologies

Attract new R&D resources

Obtain return on public investment

Stimulate economic development

Technology Transfer at NIH

- Office of Technology Transfer

  Invention Review, Patenting, Licensing, Monitoring, Administration, Policy
- Offices in Institutes and Centers

  Technology Development Coordinators

  Invention reporting, Collaborative Agreements, CTAs, MTAs
- License Royalties flow back to ICs where the inventions were made, inventors are paid a share

Employee Invention Report (EIR)

PATENT (Intellectual Property)

Marketing

Negotiate and Execute License

Product Development

Clinical Trials &Regulatory Approval

Product Launch

Success Stories: Kepivance™

- Oral Mucositis is a common side effect of many cancer therapies. Eating, drinking, swallowing, and talking are almost impossible.
- Known factor (Keratinocyte Growth Factor) with unpredictable new use
- First of its kind therapeutic
- Improved quality of life for cancer patients

KGF discovered 1989

Patents Filed

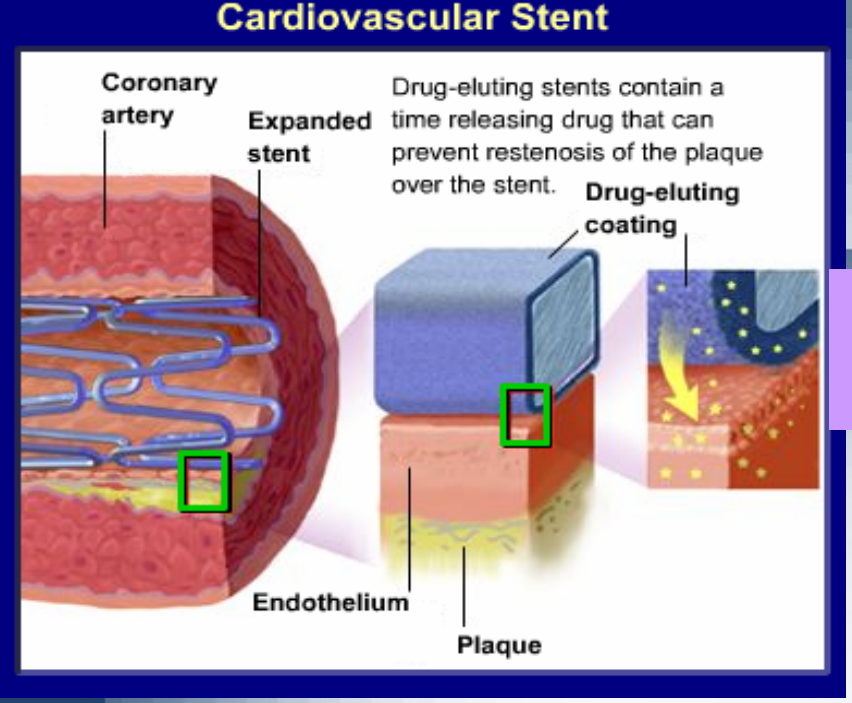
License to Amgen 1992

Amendments to License Agreement 1995, 1996, 2000

FDA Approval 2004

TAXUS® Express2™

- Paclitaxel-coated cardiovascular stent
- “Taxol embedded in a polymer on the stent itself modifies the healing process, so that scar tissue does not build.” Boston Scientific
- Combination of two existing products
- Reduced restenosis rates to 3-6%
- Fewer return visits to catheterization lab
- Fewer returns to operating room
- More than 350,000 patients per year



Combination discovery Taxol® and stents 1993

Patents filed 1996-2002

License 1996 Angiotech

Angiotech and NIH CRADA 1996

Sublicenses 1998-99 Boston Scientific

Patents issued 1997,2002

FDA approval 2004

70% market in 1 month!

NIH Licensed Products

AcuTect™ AIDS Test Kit Alfaxan® injectable anaesthetic for cats/dogs Apodasi™ (ddI) Beaucage Reagent BIOMAX Multi-Blot Kit BRCA1 Diagnostic Certiva™ CHAPS Generic ddI delayed-release capsules Fludara® Fecolator Havrix® ImmunoWELL® Kepivance™ KLEPTOSE® (betacyclodextrin) Matrigel® Invasion Chamber Mirakelle™ NeoTect™ NeuTrexin® Ocuvite®PreserVision™ *Para*Sight F™ Parvovirus B19 enzyme immunoassay PathVysion™ HER-2 DNA Probe Kit PixCell™ Soluble Interleukin-2 Receptor SPORANOX® oral solution Squirrel Free™ capsaicin-treated birdseed Synagis™ Taxol® TAXUS™ coronary stent system Thyrogen™ TWINRIX® TransProbe-1® Velcade™ Videx® Vitravene™ ZENAPAX® ZEVALIN™

Portfolio

- **2500 patents pending and issued**
- **More than 1500 active licenses**
- **Cooperative Research and Development Agreements (CRADAs)**
  - **1612 CRADAs executed FY88-05**
  - **350 Companies**
  - **240 CRADAs still active**
- **About 200 products (including research tools) on the market, 23 FDA approved**
- **FY05 $98M royalties flowing back to support research and TT programs where invention was made**

ACTIVE LICENSEES

Technology Transfer Around the Globe

- International Technology Transfer

  Technologies licensed for commercialization to public and private institutions in Brazil, China, Egypt, India, Indonesia, Korea, and Mexico
- Hosting web site for Neglected Diseases Technologies including NIH, UMD, UCA, Georgetown, Cornell Medical School
- Host technology training for minority serving US schools and Developing Countries

NIH Office of Technology Transfer

www.ott.nih.gov

Success Stories

www.ott.nih.gov/about_nih/success_stories.html

Science. Ideas. Breakthroughs.