

Technology Transfer Seminar

October 21, 2005

Nathan S. Kline Institute

Orangeburg, NY

October 21, 2005





Program

- I. Role of RFMH in Technology Transfer
- II. OMH/OMRDD Patent Policy
- III. NIH Requirements for Inventions & Intellectual Property
- IV. Pitfalls of MTAs
- V. Panel Discussion “Opportunities & Challenges of Licensing Research Tools”

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I. Role of RFMH in Technology Transfer

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Role of RFMH in Technology Transfer

- What is technology transfer?
- Why do we transfer technology?
- What is our role?
- Who are we?
- What exactly is it that we do?
- How can you contact us?
- Examples of success?

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What is technology transfer?

Movement of information, materials and technologies from research laboratories to commercial enterprises for the purpose of further development and commercialization.

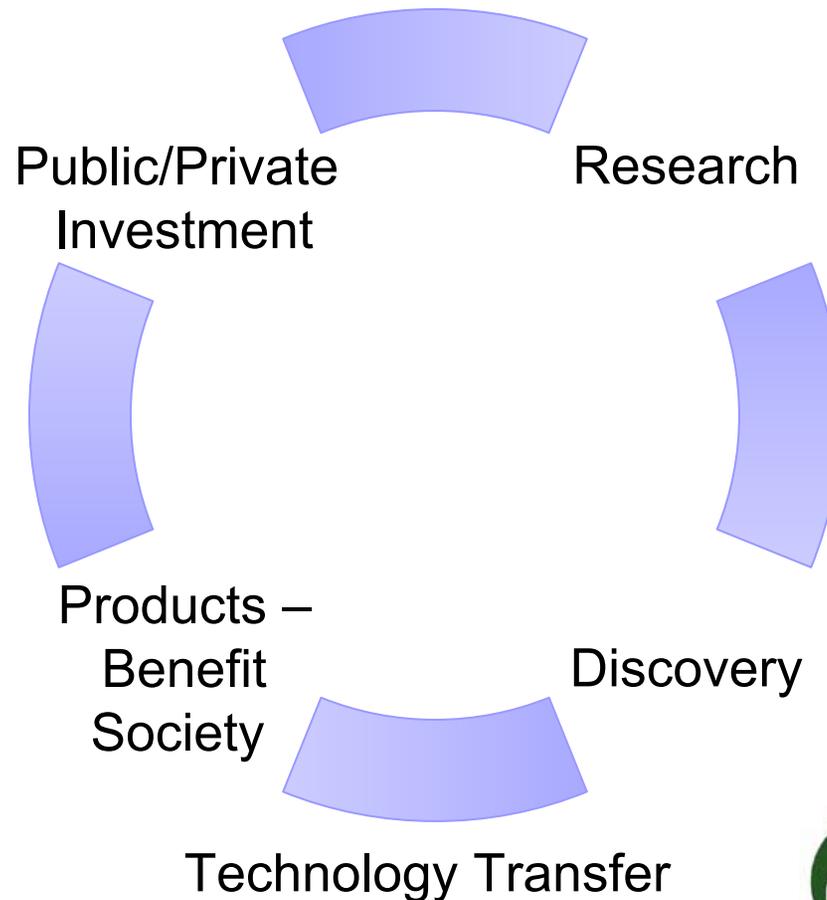
- Patented inventions
- Research tools and reagents
- Computer software
- Diagnostics
- Vaccines
- Therapeutic compounds

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Why do we transfer technology?

Completing the Circle



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What is our role?

- Private, not-for-profit corporation organized in 1952, for the purpose of assisting and enhancing the research and training objectives of the New York State Department of Mental Hygiene and its component agencies.
- Administer +100 million dollars in annual sponsored research grants and contracts.
- Title to invention conceived or first reduced to practice in performance of sponsored research.

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What is our role?

- Protect interests of the inventor(s), the Foundation, NYS, the sponsor & the public
- **PARTNER!**
- Resource/service
- Facilitator between worlds of science, law & business

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Who are we?



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What do we do?

- Identify new technologies
- Protect inventions – patents, copyrights & trademarks
- Form commercialization strategies
 - market and license to existing companies
 - create new start-up companies
- Negotiate agreements
- Administration & compliance

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How can you contact us?

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Technology Transfer Associate

Research Foundation for Mental Hygiene, Inc.

150 Broadway, Suite 301

Menands, NY 12204

Phone: (518) 408 2186

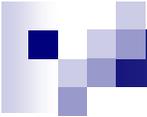
dpotvin@omh.state.ny.us

<http://corporate.rfmh.org>



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Examples of success?

1. Commercial products
 - Taurine – component of infant formulas
 - Travil – medical food for treatment of tardive dyskinesia
 - Copyright protected clinical & educational materials
 - Research tools – monoclonal antibodies
2. Industry sponsored research funding



II. OMH/OMRDD Patent Policy

Robin Goldman, Esq.
Assistant Counsel, OMH

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III. NIH Requirements for Inventions & Intellectual Property

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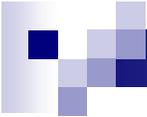


NIH Requirements for Inventions & Intellectual Property

- What is a subject invention?
- What is the Bayh-Dole Act?
- What are the NIH requirements for inventions?
- What about research tools & model organisms?
- Where can you go for help?

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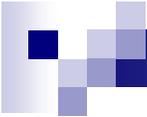


What is a subject invention?

Any invention or discovery conceived or first reduced to practice in the performance of work under a funding agreement (grant or contract) with the U.S. federal government.

- Patented & unpatented inventions
- Compositions of matter, machines, methods, manufacture & processes
- Software, business practices & algorithms
- Research tools
- Model organisms





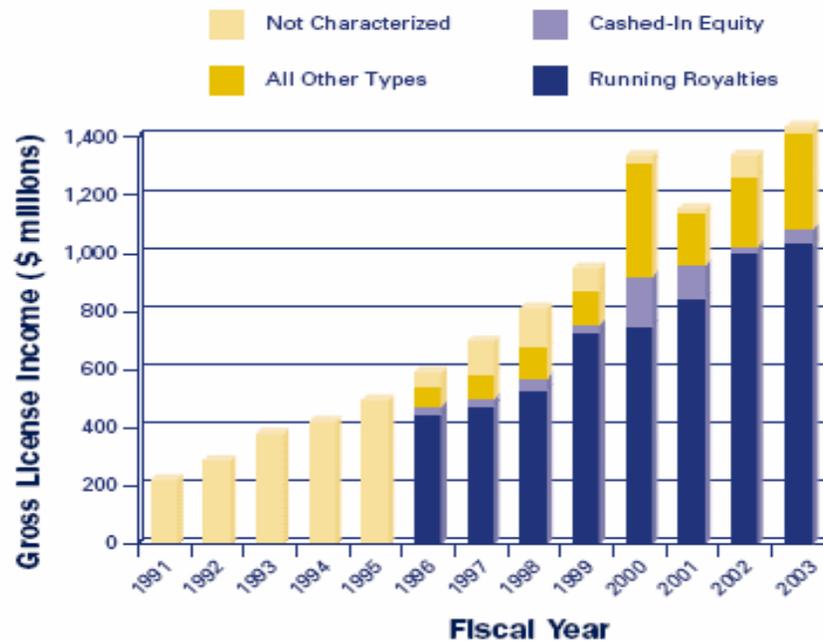
What is the Bayh-Dole Act?

- Bayh-Dole Act (Patent and Trademark Act Amendments of 1980) created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs.
- The Act is “perhaps the most inspired piece of legislation to be enacted in America over the past half-century,” according to The Economist.



Bayh-Dole Act

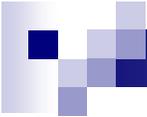
Figure US-27: Gross Income Received by Income Type, All Respondents, 2003



AUTM Licensing Survey™: FY 2003

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What are the NIH requirements for inventions?

1. Invention disclosure
 - Failure to disclose invention to NIH can result in loss of rights.
2. Annual reports & final report
3. Diligently protect & commercialize invention
4. Grant license to U.S. Government





What about research tools & model organisms?

NIH Guidelines & Principles:

- Ensure academic freedom and publication
- Ensure implementation of Bayh-Dole Act
 - Licensing allowed (nonexclusive preferred)
- Minimize administrative impediments to research
- Ensure dissemination of research resources
 - MTAs

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Where can you go for help?

- Yours truly
- Colleen Corcoran, RFMH
- Institute grant office
- Program manager
- <http://corporate.rfmh.org>
- <http://iEdison.gov>

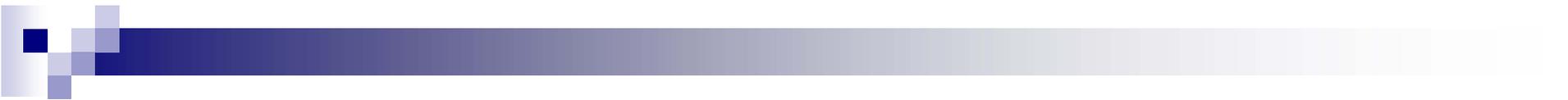
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IV. Pitfalls of MTAs

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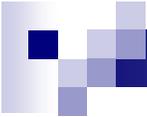


Outline

- What is an MTA?
- What is the # 1 pitfall?
- What are the pitfalls of incoming agreements?
- What are the pitfalls of outgoing agreements?
- Where can I find the forms?
- Where can I go for help?

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What is an MTA?

Material Transfer Agreement – MTA:

Agreement or contract that governs the transfer of tangible research materials between organizations.

1. Academic ↔ Academic
2. Academic → Industry
3. Industry → Academic



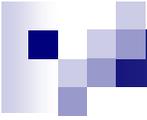


Why do we transfer materials?

- Foster scientific collaboration
- Comply with NIH guidelines, federal statutes and publication requirements
- Facilitate licensing
- Encourage industry sponsored research

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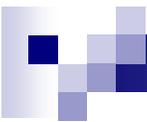


What is the # 1 pitfall?

Not having one!

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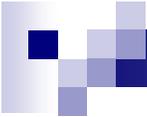




What are the pitfalls of incoming agreements?

- Freedom to publish
- Ownership
 - Data
 - Inventions, Intellectual Property
- Conflicts with sponsored research
- Reach through royalties and compelled licenses





What are the pitfalls of outgoing agreements?

- Noncommercial use
- Distribution to third parties
- Liability & Warranties
- Modifications and derivatives

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Where can I find the forms?

RFMH website <http://corporate.rfmh.org>



PIAI

WebFtask

NYSPI



- Main Page
- Corporate Information
- Grants Administration
- Human Resources and Payroll
- Accounts Payable/Purchasing
- Research Compliance
- RFMH Business Systems
- Technology Transfer
 - Available Technologies
 - Forms
 - Resources
 - Links

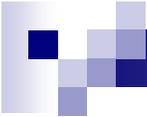
Forms

Name of Form	Online Fillable Forms	Online Printable Forms	Other (*.doc, etc)
Biological Material Disclosure		Download	
Invention Disclosure		Download	
Material Transfer Agreement	Download	Download	
Confidentiality Agreement	Download	Download	

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Where can I go for help?

Dan Potvin

518 408- 2186

dpotvin@omh.state.ny.us

- NKI – Tom O’Hara
- NYPI – Frank Mucha
- IBR – Dr. Ted Brown

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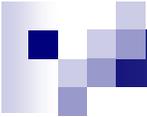


V. “Opportunities & Challenges of Licensing Research Tools”

Panel Discussion

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Panel

Dan Potvin – Moderator

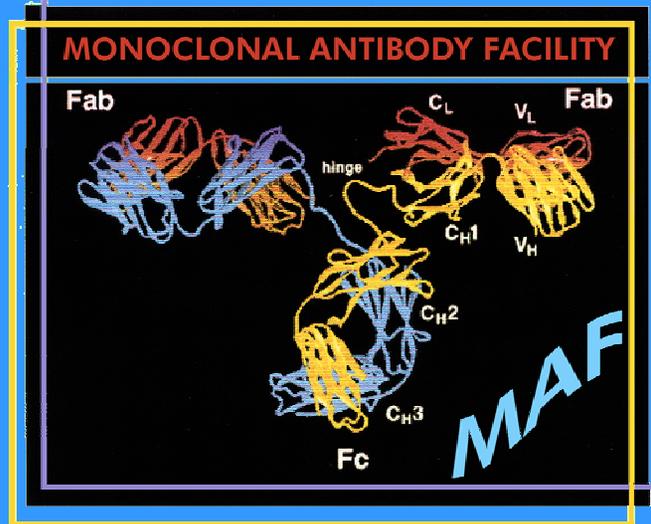
**Dr. Richard Kascsak - Director Monoclonal
Antibody Facility & Research Scientist,
Institute for Basic Research**

Mr. Joe Bertelsen - Neuroscience Product
Manager, Signet Laboratories

Dr. Ricardo Mesa-Tejada - Senior Vice President,
Thieme Consulting

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Richard J. Kascsak, Ph.D.

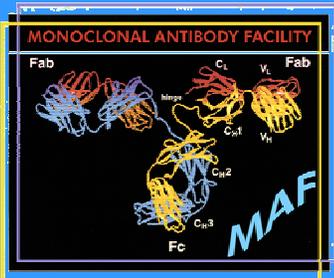
Regina Kascsak, B.S

Daryl Spinner, Ph.D..

Cheng-Mo (James) Chen, M.S.

Heni Hong, B.S.

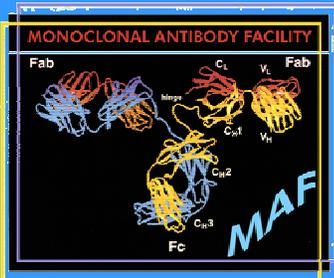
Victor Sapienza, M.S.



Monoclonal Antibody Facility (MAF)

Importance of Biotech/Pharmaceutical Industry
Partnership to New York State

Companies Collaborating/Partnering with MAF:
Bayer, Pfizer, Wyeth, Q-RNA Inc., Pall Corp.,
Senetek / Signet Laboratories



CURRENTLY AVAILABLE ANTIBODIES

Down's Syndrome/Alzheimer's Disease

i.e., beta amyloid, tau, ERAB, synuclein, apoprotein E

Fragile-X Syndrome

i.e., FMRP

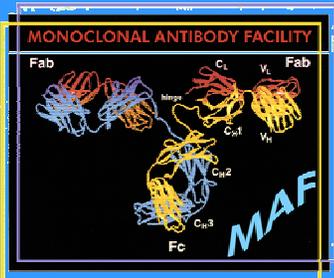
Batten's Disease

i.e., NCL2, NCL3

Infectious Agents

i.e., CMV

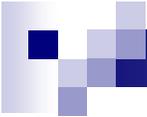
Autism



MAF GOALS

Assist Scientists and Physicians in the study and treatment of Developmental Disabilities

Expand and Improve Repertoire of Monoclonal Antibodies available through IBR MAF/Signet Laboratories



Panel

Dan Potvin – Moderator

Dr. Richard Kascsak - Director Monoclonal
Antibody Facility & Research Scientist, Institute
for Basic Research

**Mr. Joe Bertelsen - Neuroscience Product
Manager, Signet Laboratories**

Dr. Ricardo Mesa-Tejada - Senior Vice President,
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Signet Laboratories, Inc.

Business Overview

Signet Laboratories: Background

Signet Background

- Founded 1989, spinout of J&J Cambridge Research Labs
- Initial specialization in ***cancer markers*** and ***infectious disease***
- Major expansion of product line in 2000 to include antibodies for ***neurodegenerative disease***
- FDA-registered, GMP manufacturer of over 800 products worldwide

Core Competency

- Recognized leader in ***immunopathology***
- Experts in ***tissue-based assays*** and binding phenomena
- Development and manufacturing of ***antibodies and assays***
- Sales and distribution of antibodies and assay kits

Signet Laboratories' Customer Base / Distribution Channels

	Immunohistochemistry	Research/ Neurodegenerative
Customer Base	<i>Hospitals/Clinics</i>	<i>Biotech/Pharma Research Institutes</i>
Distribution Domestic	<i>Direct/OEM/VAR</i>	<i>Direct/OEM/VAR</i>
Distribution International*	<i>Distributor</i>	<i>Distributor/Direct</i>

Top Five Products for Each Sector of Signet's Business

ImmunoHistoChemistry

- **Breast Cancer Marker, Clone D6, Monoclonal, Gross Cystic Disease Protein**
- **Cancer Marker, Clone D2-40, Lymphatic Invasion**
- **Breast Cancer Marker, Clone B72.3, Monoclonal, Membrane Protein**
- **Ewing's Sarcoma Marker, Clone CD99, Monoclonal**
- **Multi Drug Resistance Marker, Clone C219, Monoclonal**

Research/Neurodegenerative

- **Monoclonal Ab – 6E10**
- **Monoclonal Ab – 4G8**
- **Monoclonal Ab – 3F4**
- **Polyclonal Ab – ABeta 1-40**
- **Polyclonal Ab – ABeta 1-42**

Production and Development Capabilities

FDA registered cGMP facility

Full antibody production and purification capabilities

Research use and diagnostic assay development

- ELISA based readouts
- IHC

Signet's Role in Licensing of Technologies

- Aggressively identify target markets for new technologies
- Identify technologies to address market needs
- Negotiate license with institution's tech transfer office
- Produce consistent, high quality products through our FDA approved laboratory
- Promote the products worldwide to all pertinent market segments
- Generate revenue for all parties involved

Value of Licensing Technologies Through Signet

- **REDUCE TIME** researcher spends on promoting and distributing inventions
- Realize commercial value for technologies not considered blockbusters
- Utilize our core competencies to optimize efficacy and commercial value of technologies
- Feed back market information to inform researchers of new target areas
- **GENERATE REVENUE**



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Monoclonal Antibodies on the Market

<i>Type</i>	<i>Product</i>	<i>Marketer</i>	<i>Approved</i>
Murine	Orthoclone OKT3 Allograft rejection	Johnson & Johnson	June 1986
Chimeric	ReoPro PTCA adjunct	Lilly	December 1994
Chimeric	Rituxan Non-Hodgkin's lymphoma	Genentech	November 1997
Chimeric	Simulect Organ rejection prophylaxis	Novartis	May 1998
Chimeric	Remicade Rheumatoid arthritis, Crohn's disease	Johnson & Johnson	August 1998
CDR-grafted	Zenapax Organ rejection prophylaxis	Roche	December 1997
CDR-grafted	Synagis Respiratory syncytial virus (RSV)	Medimmune	June 1998
CDR-grafted	Herceptin Metastatic breast cancer	Genentech	September 1998
CDR-grafted	Mylotarg Acute myeloid leukemia	Wyeth	May 2000
CDR-grafted	Campath Chronic lymphocytic leukemia	Millennium	July 2001



Monoclonal Antibodies on the Market

<i>Type</i>	<i>Product</i>	<i>Marketer</i>	<i>Approved</i>
Murine Radiolabeled	Zevalin Non-Hodgkin's Lymphoma (relapsed or refractory low-grade, follicular, or transformed B cell)	IDEC Pharmaceuticals and Schering AG	March 2002
Phage Display	Humira Rheumatoid arthritis	Abbott Laboratories	December 2002
CDR-grafted	Xolair Moderate to severe persistent asthma	Genentech and Novartis	June 2003
Murine Radiolabeled	Bexxar CD20 positive, follicular, Non-Hodgkin's Lymphoma (NHL)	Corixa and GlaxoSmithKline	June 2003
CDR-grafted	Raptiva Chronic moderate-to-severe psoriasis	Genentech and Xoma	October 2003
Chimeric	Erbitux Colorectal cancer	Imclone and Bristol-Myers Squibb	February 2004
CDR-grafted	Avastin Colorectal cancer	Genentech	February 2004
CDR-grafted	Tysabri Multiple sclerosis	Biogen-Idec and Elan	November 2004