

SESSION 8

REVIEW OF U.S. GOVERNMENT ACTIVITIES AND INTERESTS

Fred G. Heineken

Tissue engineering has been supported by Federal Government research support since before it was called tissue engineering. In 1987, at a panel meeting at the National Science Foundation (NSF), the name "tissue engineering" was first used to identify what was considered at that time to be an emerging technology. Since 1987, NSF supported the early conferences (UCLA and Keystone Symposia) on tissue engineering and provided the first research grants for projects in "tissue engineering". This technology has grown enormously since 1987, and the Federal Government now has a Multi-Agency Tissue Engineering Science (MATES) Working Group (WG) to coordinate Federal Government activities in tissue engineering. The agencies comprising the MATES WG are: Defense Advanced Research Projects Agency (DARPA), Department of Energy (DOE), Food and Drug Administration (FDA), National Aeronautics and Space Administration (NASA), National Institutes of Health (NIH), National Institute of Standards and Technology (NIST), and the NSF. The MATES WG now has a web site located at: "<http://TissueEngineering.gov>". Kiki Hellman of the FDA provided an overview of the MATES WG activities. This included a review of interagency activities that lead up to the formation of the MATES WG, and a review of the goals of the WG, which are:

1. To facilitate communication across departments/agencies by regular information exchanges and a common web site.
2. To enhance cooperation through co-sponsorship of scientific meetings and workshops, and facilitation of the development of standards.
3. To monitor technology by undertaking cooperative assessments of the status of the field.

A summary of research support for tissue engineering by each of the participating agencies was presented as well as a review of the activities of the American Society for Testing Materials (ASTM) to provide standards for Tissue Engineered Medical Products (TEMPs). The World Technology Evaluation Center (WTEC) study of tissue engineering was also reviewed and presented as an example of one of the MATES WG activities.

**WTEC Workshop
Review of Tissue Engineering in United
States**

Lister Hill

U.S. National Institutes of Health

Bethesda, Maryland

June 5-6, 2000

**“MATES and U.S. Government Tissue Engineering Initiative:
An Overview”**

**Kiki B. Hellman, Ph.D., Senior Scientist
Coordinator for Biotechnology
Center for Devices and Radiological Health
U.S. Food and Drug Administration**

FOCUS

- **Advances in Tissue Engineering**
- **Tissue Engineering and U.S. Government**
- **MATES - U.S. Government Partnership**
- **WTEC Study - International Benchmarking of Tissue Engineering Enterprise**

“Promise” of Tissue Engineering

- **Application of the principles of life sciences and engineering to develop biological substitutes for the repair and regeneration of tissue or organ function.**

Range of TEMPs

- **Human Tissues or Organs**
- **Animal Tissues or Organs**
- **Processed, Selected or Expanded Human/ Mammalian Cells With or Without Biomaterials**
- **Synthetic Biomimetic Materials**

TEMPs - Examples

- **Structural/Mechanical Substitutes**
 - **Artificial Skin Constructs**
 - **Expanded Cells for Cartilage Regeneration**
 - **Engineered Ligament and Tendon**
 - **Bone Graft Substitutes/Bone Repair Systems**
 - **Products for Nerve Regeneration**
 - **Engineered Cornea and Lens**
 - **Products for Periodontal Tissue Repair**

TEMPs - Examples

- **Metabolic Substitutes**
- **Engineered Products for Cardiovascular Repair/Regeneration**
- **Blood Substitutes**
- **Encapsulated Cells for Restoration of Tissue/Organ Function**
 - **Implants**
 - **Ex Vivo Metabolic Support Systems**

Tissue Engineering in U.S. Government

DOC, NIST

- ATP support of U.S. business for high risk, enabling technologies
 - 1991-1999 - \$63M; 1999-10/14 biotech. awards

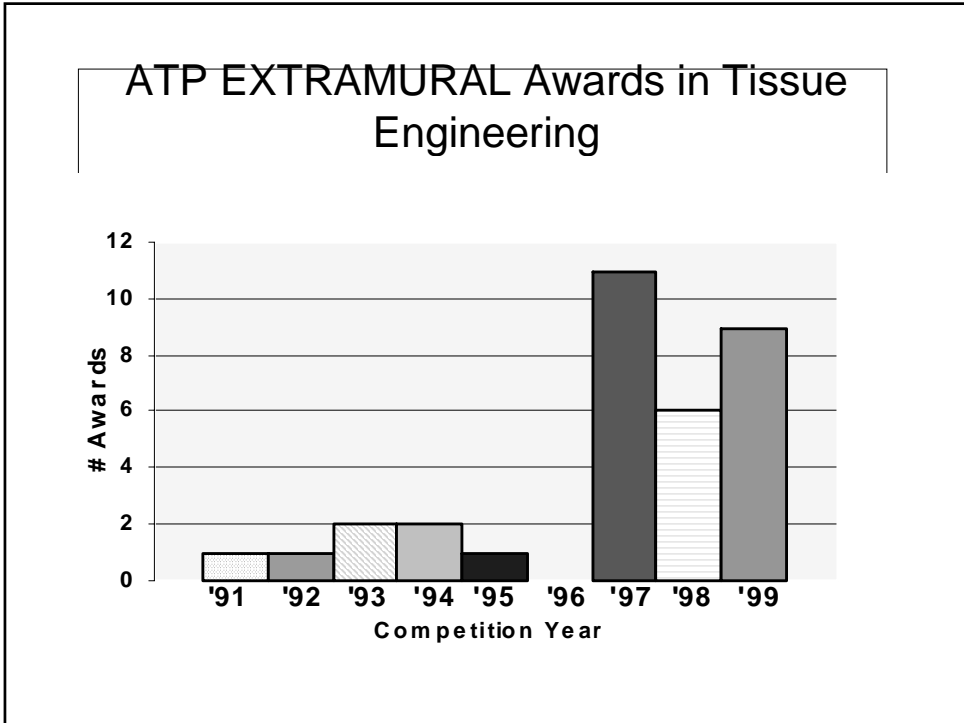
- Standards, reference materials

DOD, DARPA

- Biological weapons detection and response
- Increased Life Science funding
- DARPA Focus 2000: [Bio:Info:Physical] Intersection (6/28-6/30) - future support

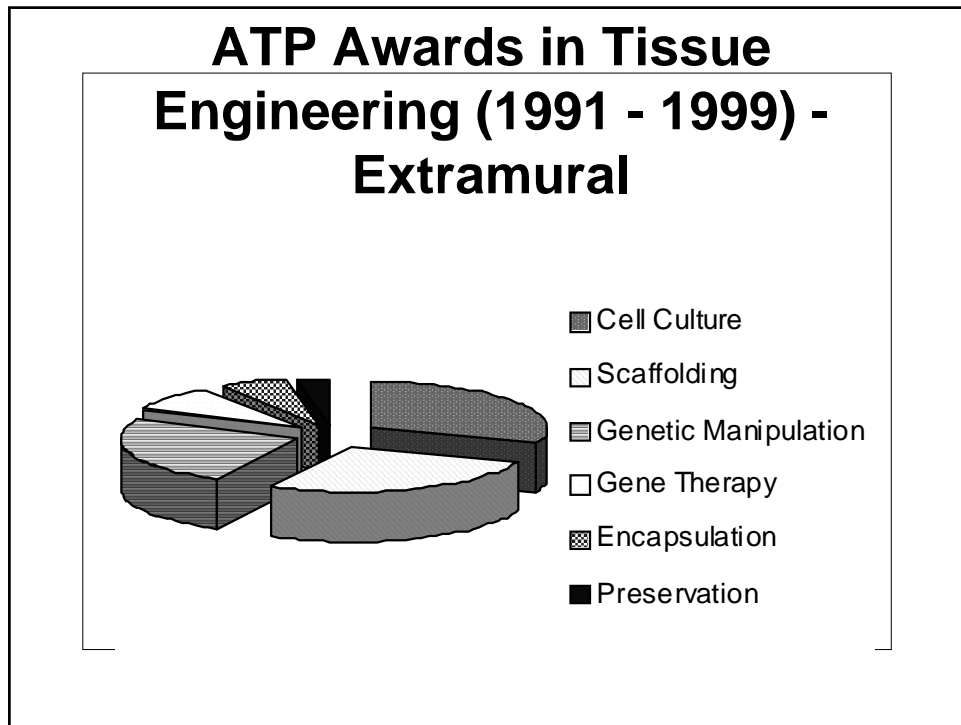
ATP EXTRAMURAL Awards in Tissue Engineering

Year	Competition Awards	ATP \$
• 1991	1	\$1.2M
• 1992	1	\$2.0M
• 1993	2	\$6.2M
• 1994	2	\$4.0M
• 1995	1	\$2.0M
• 1996	0	\$0
• 1997	11	\$20.6M
• 1998	6	\$11.8M
• 1999	9	\$17.8M
• Totals	33	\$65.7M



ATP Awards in Tissue Engineering (1991 - 1999) - Extramural

Category	# Awards	ATP \$
• Cell Culture	10	\$17.70M
• Scaffolding	9	\$18.00M
• Genetic Manip.	8	\$16.00M
• Gene Therapy	3	\$5.80M
• Encapsulation	2	\$6.30M
• Preservation	1	\$1.90M
• TOTALS	33	\$65.7M



- ### Tissue Engineering in U.S. Government
- DOE
- Innovative technologies at DOE Nat'l Labs
 - Pilot Program in Biomedical Engineering
 - TE projects -- increased funding
- DHHS/FDA
- Gatekeeper for product commercialization
 - Technology monitoring
 - Intramural test method development, bioeffects studies, and evaluation research programs
 - Science-based product review/approval process
 - Guidance, Standards (voluntary, consensus)

Tissue Engineering in U.S. Government

DHHS/NIH

- Improve public health through research
- BMISCC-FY98 - \$18M, projected 10% increase
- BECON
 - June 25-26 Symposium on Nanoscience and Nanotechnology
 - March 25-26, 2001, Symposium on Tissue- and Organogenesis

NASA

- Biological system's response to space
- TE-flagship research effort in NASA bioreactor development
 - 1992-present: \$2M-\$7M/year; NRAs every 2 years

Tissue Engineering in U.S. Government

NSF

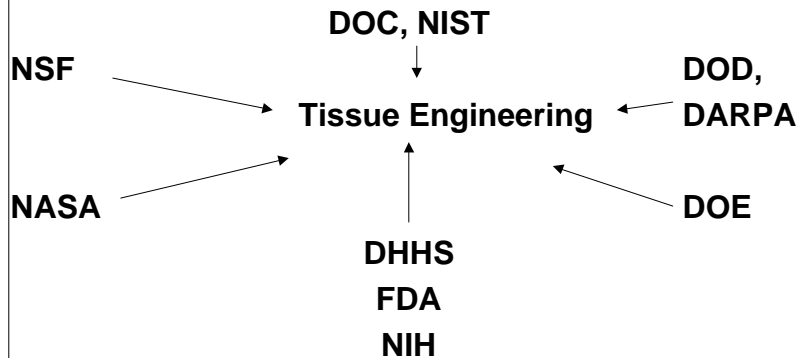
- Science at the cutting edge; integration into new applications
- Supports 3 Engineering Research Centers (ERCs)
 - MIT; University of Washington; Georgia Tech - \$2M/year/center

Tissue Engineering: Joint Efforts

- **Biotech Applications in Biomaterials -- A Workshop (Birmingham, Alabama - 4/93)**
- **Workshop on TE: From Basic Science to Products (NIST - Gaithersburg, Maryland - 11/94)**
- **ASTM, Committee F04, Division IV: TEMPs -- Organization Meeting (NIST - Gaithersburg, Maryland - 12/97)**

MATES - U.S. Government Partnership

(Responds to need for coordination among U.S. Federal agencies;
Working Group - 1/00.)



MATES

Goals

- **Facilitate Communication**
 - Track Federal funding
 - Contribute to agencies strategic funding decisions
 - Common web site/bulletin board - “One-stop shopping” -
<http://tissueengineering.gov/>
- **Enhance Cooperation**
 - Cosponsor scientific conferences
 - Facilitate standards development

MATES

Goals

- **Monitor/Assess Technology**
 - Cooperative assessments of tissue engineering science
 - WTEC Study - global assessment

ASTM FO4 Div. IV Standards for TEMPS

Why Standards for Tissue Engineering?

- **Rapidly evolving interdisciplinary field with potential for substantial health care improvement.**
- **Multi-component technology with complex and diverse interactions.**
- **Need consensus based on sound science.**
- **Mechanism for multidisciplinary collaboration.**
- **Currently, little basis for evaluating biomaterials and biomolecules, no basis for evaluating cellular components.**

ASTM FO4 Div. IV Standards for TEMPS

Why ASTM?

- **Non-profit organization founded in 1989.**
- **Manages consensus development of voluntary standards in any area.**
- **Provides neutral umbrella for voluntary participation of all interested parties.**
- **Ensures technical and legal validity of standards.**

ASTM FO4 Div. IV Standards for TEMPS

Who's Who?

- **Chair: Peter Johnson, M.D.**
(Rcj@tissueinformaticx.com)
- **Vice chair: Grace Picciolo, Ph.D.**
(Picciolograce@nail-me.com)
- **Secretary: Kiki Hellman, Ph.D.**
(Kxh@cdrh.fda.gov)
- **Manager: Teresa Cendrowska**
(tcendro@astm.org)

ASTM FO4 Div. IV Standards for TEMPS

SUBCOMMITTEES

- Terminology
- Normal Biologic Function
- Structural Characterization
- Biomaterials
- Biomolecules
- Cells
- Delivery Systems
- Assessment
- Clinical Trials
- Microbiological Safety/Adventitious Agents

Technology Assessment: Predictive Value for U.S. Government*

- **Emerging Technologies**
- **Technology Applications and Product Development**
- **Progress Determinants**
 - Intellectual capital
 - Infrastructure
 - Reg. environment - research; product review/approval
 - Legal, ethical culture/climate
 - National/international collaboration

* “Preparedness”, i.e., strategic planning, resources, national/international efforts

Technology Assessment: Predictive Value

- **Global Potential**
 - Centers of excellence; manufacturing sites; clinical studies
- **Harmonized Regulatory Approaches for a Global Marketplace**
 - Models - ICH, GHTF, International Standards

WTEC Study: International Benchmarking of Tissue Engineering

- **Predictive Value**
 - Tool for comparing nations' status in scientific fields - NAS COSEPUP (3/20/2000 C&EN)
 - Questions
 - Position of U.S. relative to other countries?
 - Based on current trends worldwide, what will U.S. position be in near/long term future?
 - What are key factors influencing relative U.S. performance?
- **Ratifies/Extends MATES Goals**
 - Monitor/assess technology across national boundaries

For Questions and Further Information:

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