WTEC Panel on
Tissue Engineering Research
WTEC Panel on

TISSUE ENGINEERING RESEARCH

FINAL REPORT

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Dear Colleague:

As America enters the 21st century and a new age, strategic investments in science and engineering will be increasingly important determinants in enabling us to meet threats to our national security, improve the health and quality of life for our citizens, and maintain our economic strength and our overall leadership in the civilized world. The next 5 to 10 years will be critical for the maturation of tissue engineering and its pivotal role in clinical medicine. Tissue engineering, a multidisciplinary science that emerged from discovery research in the 1970s, has evolved towards applications for the repair and regeneration of diseased or damaged tissues. The 1990s witnessed the development of products for a variety of different medical conditions, affecting virtually every organ system in the body; some have been approved for clinical use, while many are still under investigation or evaluation. This study by the World Technology Evaluation Center (WTEC) provides a basis for developing future national research and development (R&D) priorities and formulating a strategy for effective Federal Government support in the field of tissue engineering. The purpose of this study was to gather information on tissue engineering research in Japan and Europe compared to that in the United States and to assist the Multi-Agency Tissue Engineering Science (MATES) Working Group of the National Science and Technology Council in determining if the Federal Government is providing the appropriate strategic R&D investments in this emerging field. The findings of the WTEC study will assist MATES member agencies in guiding the Federal tissue engineering research agenda, assuring the continued maturation of the field to its full potential.

The final report from this effort, Tissue Engineering Research - A WTEC Panel Report, highlights new developments in biomaterials, bioinformatics, imaging and related areas of computer science, cell biology research, as well as non-medical applications such as novel methods for detection and remediation of biological and chemical threats. In its comparative review of research programs in the United States, Europe, and Japan, the report provides a broad perspective on research directions in tissue engineering worldwide. While the
United States maintains its lead in the field, major new government-funded research programs in both Europe and Japan are challenging the U.S. lead.

This document will serve as a basis for continued dialogue within our nation’s tissue engineering R&D community and with other important stakeholders, providing guidance for future programs. It highlights the necessity for providing continued and enhanced resources to further the progress in tissue engineering, harness new developments, and maintain our scientific and economic leadership.

Sincerely yours,

Kiki B. Hellman, Ph.D.  Fred G. Heineken, Ph.D.
Co-Chair                  Co-Chair
MATES Working Group      MATES Working Group
ABSTRACT

This report is a comparative review of tissue engineering research and development activities in the United States, Japan, and Western Europe conducted by a panel of leading U.S. experts in the field. It covers biomaterials, cells, biomolecules, non-medical applications, engineering design, informatics, and legal and regulatory issues associated with tissue engineering research and applications. The panel’s conclusions are based on a literature review, a U.S. review workshop held at NIH in June of 2000, and a series of site visits to leading tissue engineering research centers in Japan and Western Europe. A summary of the June 2000 workshop is included as an appendix, as are site reports from each of the panel’s overseas visits. An executive summary is included conveying the panel’s overall conclusions.

ACKNOWLEDGEMENTS

I would like to thank the U.S. Government sponsors of this study: Frederick Heineken, Bruce Hamilton, Lynn Preston, and Elbert Marsh of NSF; Christine Kelley, John Watson, and Dick Swaja of NIH; Alan Rudolph, Kurt Henry, and Joseph Bielitzki of DARPA; Rosemarie Hunziker, Hoda Elgendy, and Angela Hight-Walker of NIST; Stephen Davison of NASA; and Kiki Hellman, Darin Weber, and Joyce Frey-Vasconcells of FDA. We are very much indebted to our panel chair, Larry McIntire of Rice University, and to all the members of the panel for their invaluable contributions of time and intellect to this study. It was indeed an honor to work with such a wonderful group. Special thanks are due to Alan Russell of the University of Pittsburgh, McGowan Institute for Regenerative Medicine, William Wagner of the University of Pittsburgh, and Jennifer West of Rice University for traveling with the panel and contributing site reports to this volume and their insights to the study in general. Finally, we are extremely grateful to all of our hosts and correspondents around the world who took the time to share their work with us, as well as their vision of the future of this exciting field.

Geoffrey M. Holdridge
Vice President for Operations, WTEC, Inc., and Series Editor
INTERNATIONAL TECHNOLOGY RESEARCH INSTITUTE
World Technology (WTEC) Division

WTEC at Loyola College (previously known as the Japanese Technology Evaluation Center, JTEC) provides assessments of foreign research and development in selected technologies under a cooperative agreement with the National Science Foundation (NSF). Loyola’s International Technology Research Institute (ITRI), R.D. Shelton, Director, is the umbrella organization for WTEC. Elbert Marsh, Deputy Assistant Director for Engineering at NSF’s Engineering Directorate, is NSF Program Director for WTEC. Several other U.S. government agencies provide support for the program through NSF.

WTEC’s mission is to inform U.S. scientists, engineers, and policymakers of global trends in science and technology in a manner that is timely, credible, relevant, efficient and useful. WTEC assessments cover basic research, advanced development, and applications. Panels of typically six technical experts conduct WTEC assessments. Panelists are leading authorities in their field, technically active, and knowledgeable about U.S. and foreign research programs. As part of the assessment process, panels visit and carry out extensive discussions with foreign scientists and engineers in their labs.

The ITRI staff at Loyola College help select topics, recruit expert panelists, arrange study visits to foreign laboratories, organize workshop presentations, and finally, edit and disseminate the final reports.

WTEC has now been spun off to a private, nonprofit corporation that will conduct all future WTEC studies, while continuing to assist in dissemination of older WTEC reports. See http://www.wtec.org.

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# Table of Contents

Foreword ........................................................................................................... xiii  
List of Figures .................................................................................................. xvii  
List of Tables ................................................................................................. xix  

Executive Summary ........................................................................................ xxii

1. **Introduction**  
   *Larry V. McIntire*
   
   Background: The Significance of Tissue Engineering ....................... 1 
   History of Tissue Engineering ............................................................... 1 
   Promise of Tissue Engineering .............................................................. 2 
   Other Applications ............................................................................... 3 
   Emerging Industry of Tissue Engineering ........................................... 3 
   Objectives of the WTEC Study .............................................................. 3 
   Scope and Methodology ..................................................................... 4 
   Vision for the Future .......................................................................... 6 
   Acknowledgements ........................................................................... 6 
   References ........................................................................................... 7

2. **Biomaterials**  
   *Linda G. Griffith*
   
   Introduction ......................................................................................... 9 
   U.S. R&D Activities ........................................................................... 12 
   Japanese R&D Activities .................................................................. 16 
   European R&D Activities ................................................................. 17 
   Summary ............................................................................................ 19 
   References .......................................................................................... 21

3. **Cells**  
   *Nancy L. Parenteau*
   
   Introduction ....................................................................................... 23 
   Analysis of Current State of the Art and Factors Influencing Progress ... 23 
   Control of Cell Proliferation and Differentiation ................................ 27 
   U.S. R&D Activities ........................................................................... 28 
   Background ........................................................................................ 28 
   Current Efforts ................................................................................... 29 
   Future Position .................................................................................. 32 
   R&D Activities in Europe .................................................................. 33 
   Japan .................................................................................................... 34 
   Summary ............................................................................................ 35 
   References .......................................................................................... 36
# Table of Contents

## 4. Biomolecules

*Howard P. Greisler*

- Introduction ................................................................................................... 41
- Gene Transfer ................................................................................................ 42
- Angiogenic Factors/Growth Factors .............................................................. 48
- Differentiation Factors .................................................................................. 55
- Bone Morphogenic Proteins ......................................................................... 56
- References ..................................................................................................... 58

## 5. Cell-Based Technologies: Non-Medical Applications

*Milan Mrksich*

- Introduction ................................................................................................... 61
- Overview of R&D Activities ......................................................................... 63
- Summary ....................................................................................................... 66

## 6. Engineering Design Aspects of Tissue Engineering

*David Mooney*

- Introduction ................................................................................................... 71
- Bioreactor Technology .................................................................................. 72
- Preservation of Cells and Engineered Tissues ............................................... 74
- Mass Transport Issues Following Implantation ............................................. 75
- Biomechanics Issues...................................................................................... 77
- Summary ....................................................................................................... 80
- References ..................................................................................................... 81

## 7. Informatics and Tissue Engineering

*Peter C. Johnson*

- Introduction ................................................................................................... 83
- Informatics Components That Will Ultimately Support Tissue Engineering ................................................................................................................................. 86
- U.S. R&D Activities ...................................................................................... 90
- European R&D Activities ............................................................................ 90
- Japanese R&D Activities ............................................................................. 92
- Summary ....................................................................................................... 93
- References ..................................................................................................... 94

## 8. Legal and Regulatory Issues

*David Smith*

- Introduction ................................................................................................... 97
- FDA Regulation ............................................................................................ 98
- Other Considerations Relevant to Engineered Tissues .................................. 109
- Regulation of Pharmaceutical/Medical Human Tissue Products in Europe ................................................................................................................................. 111
# Table of Contents

Regulation of Pharmaceutical/Medical Human Tissue Products in Japan ......................................................................................................113
Conclusion...................................................................................................115
References ...................................................................................................116

## APPENDICES

A. Biographies of Panelists .............................................................................117

B. Site Reports—Europe
   - bwA, Aachen Centre of Competence: Biomaterials ..................122
   - Cell Lining GmbH .................................................................125
   - Berlin Workshop ..................................................................127
   - ERA Consulting (UK), Ltd......................................................132
   - ETH Zurich ..........................................................................135
   - European Agency for the Evaluation of Medicinal Products (EMEA) ......141
   - European Molecular Biology Laboratory (EMBL) .....................144
   - German Cancer Research Center (DKFZ) ...............................146
   - German Heart Institute .......................................................149
   - Humboldt University of Berlin, Charité ....................................151
   - Biomaterial and Tissue Repair Laboratory (INSERM) ................153
   - Imperial College of Science, Technology and Medicine ..........157
   - Imperial College of Science, Technology and Medicine ..........161
   - University of Glasgow .........................................................163
   - IsoTis (Technical Report) .....................................................165
   - IsoTis (Regulatory Report) ..................................................167
   - Kirchhoff Institute of Physics (KIP) .......................................169
   - Manchester University .........................................................171
   - Max Planck Institute for Polymer Research .........................175
   - MeVis ..................................................................................177
   - Smith & Nephew Group Research Centre ................................179
   - University of Freiburg ........................................................182
   - University of Koln ...............................................................185
   - University of Regensburg ....................................................187
   - University of Twente ........................................................189

C. Appendix C. Site Reports—Japan
   - Hokkaido University .............................................................190
   - Japan Tissue Engineering Company, Ltd. ............................193
   - Keio University .....................................................................195
   - Kyoto University .................................................................197
   - Kyushu University ...............................................................205
   - Nippon Telegraph and Telephone Corporation (NTT) Basic Research Laboratories ..............................................................209
   - Nagoya University ...............................................................213
   - National Cancer Center Research Institute ...........................216
   - National Institute for Advanced Interdisciplinary Research (NAIR) ....219
Table of Contents

National Institute of Bioscience and Human Technology .................222
Institute of Physical and Chemical Research (RIKEN) Cell Bank ........225
Tokyo Institute of Technology .................................................................227
Tokyo Women’s Medical University ......................................................229
University of Tokyo .............................................................................232
University of Tsukuba ..........................................................................235

D. Summary of the June 2000 U.S. Review Workshop ......................240

E. The Federal Investment in Tissue Engineering ..............................262
FOREWORD

We have come to know that our ability to survive and grow as a nation to a very large degree depends upon our scientific progress. Moreover, it is not enough simply to keep abreast of the rest of the world in scientific matters. We must maintain our leadership.¹

President Harry Truman spoke those words in 1950, in the aftermath of World War II and in the midst of the Cold War. Indeed, the scientific and engineering leadership of the United States and its allies in the twentieth century played key roles in the successful outcomes of both World War II and the Cold War, sparing the world the twin horrors of fascism and totalitarian communism, and fueling the economic prosperity that followed. Today, as the United States and its allies once again find themselves at war, President Truman’s words ring as true as they did a half century ago. The goal set out in the Truman Administration of maintaining leadership in science has remained the policy of the U.S. Government to this day: Dr. John Marburger, the Director of the Office of Science and Technology (OSTP) in the Executive Office of the President made remarks to that effect during his confirmation hearings in October 2001.² The OSTP Web site states that “the Federal Government plays a critical role in maintaining American leadership in science and technology.”³

The United States needs metrics for measuring its success in meeting this goal of maintaining leadership in science and technology. That is one of the reasons that the National Science Foundation (NSF) and many other agencies of the U.S. Government have supported the World Technology Evaluation Center (WTEC) and its predecessor programs for the past 19 years. While other programs have attempted to measure the international competitiveness of U.S. research by comparing funding amounts, publication statistics, or patent activity, WTEC has been the most significant public domain effort in the U.S. Government to use peer review to evaluate the status of U.S. efforts in comparison to those abroad. Since 1983, WTEC has conducted over 50 such assessments in a wide variety of fields, from advanced computing, to nanoscience and technology, to biotechnology.

The results have been extremely useful to NSF and other agencies in evaluating ongoing research programs, and in setting objectives for the future. WTEC studies also have been important in establishing new lines of communication and identifying opportunities for cooperation between U.S. researchers and their colleagues abroad, thus helping to accelerate the progress of science and technology generally within the international community of

¹ Remarks by the President on May 10, 1950 on the occasion of the signing of the law that created the National Science Foundation. Public Papers of the Presidents 120: p. 338.

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civilized nations. Just as many of the scientific and technological triumphs of the World War II and Cold War eras were accomplished through international cooperation between the United States and its allies, so our continued progress in science and technology depends on unfettered communication and cooperation among friendly nations. Finally, WTEC is an excellent example of cooperation and coordination among the many agencies of the U.S. Government that are involved in funding research and development: almost every WTEC study has been supported by a coalition of agencies with interests related to the particular subject at hand. In some cases, these coalitions formed to support a WTEC study have outlived the studies themselves, evolving into ongoing cooperative efforts among the agencies involved.

The present study, reviewing the status of tissue engineering research and development in the United States, Japan, and Europe, is a case in point. Support for this study came from NSF, agencies of the Department of Health and Human Services (the National Institutes of Health and the Food and Drug Administration), the National Institute of Standards and Technology, the Defense Advanced Research Projects Agency, and the National Aeronautics and Space Administration. It has been a focal point over the past 18 months for the activities of the Multi-Agency Tissue Engineering Science (MATES) interagency working group, under the auspices of the Subcommittee on Biotechnology, Committee on Science of the President’s National Science and Technology Council (NSTC). The results of the WTEC study are being used now by MATES to plan a joint interagency program announcement in tissue engineering. MATES represents the first effort to coordinate tissue engineering research and development activities within the Federal Government. Formally established in January of 2000, it is charged with facilitating communication across departments/agencies by regular information exchanges and a common web site (http://tissueengineering.gov), enhancing cooperation through co-sponsorship of scientific meetings and workshops, facilitating the development of standards, and monitoring technology by undertaking cooperative assessments of the status of the field. As recognized by a recent National Academy of Sciences report, international benchmarking studies can be an important tool for strategic planning by U.S. Government agencies. The MATES group therefore embraced the WTEC study as a key element in carrying out its mission.

It would be difficult to overstate the promise of this exciting new field of tissue engineering. Starting from a few modest NSF grants in the mid-1980s, followed by major funding from NIH and NIST, the field has spawned a burgeoning industry that has enjoyed over $3 billion in funding over the past decade, much of it from private sources. According to the WTEC panel, the United States maintains a lead in tissue engineering, particularly in privately funded applied research; however, governments in both regions have initiated

major new research programs in this area that will challenge the U.S. lead. The panel also found that Japan offers new insights in biomaterials, and Europe is providing strong support for basic cell biology research that is the underpinning for future progress in the field. In the long term, tissue engineering offers the promise of revolutionizing health care, prolonging and improving the quality of life for millions of people around the world, and greatly reducing the cost of treating debilitating diseases such as diabetes, heart disease, and liver failure. In the near term, tissue engineering is already having an important impact in treatment of skin ulcers and burns. Perhaps most notable in the context of our current international crisis, tissue engineering is being used today to develop new ways of detecting biological threats (as documented in Chapter 5 of this report), and may offer promise in the future of helping remediate such threats. Even the very first FDA-approved tissue engineered medical products have had an impact on our ability to respond to the threat of global terrorism: living engineered tissue (Apligraf®) was donated by Organogenesis, Inc. to treat burn victims from the World Trade Center attack.7

As we seek to refine the WTEC activity, improving the methodology and enhancing the impact, the program will continue to operate from the same basic premise that it has from its inception: improved awareness of international developments in science and technology can help inform U.S. research funding decisions, and can significantly enhance the scope and effectiveness of international scientific collaboration. This in turn contributes to the security, health, and economic well being of the United States and the entire world. As President Truman said over 50 years ago, our very survival depends upon continued leadership in science and technology. WTEC plays a key role in determining whether the United States is meeting that challenge.

Elbert Marsh
Deputy Assistant Director for Engineering
National Science Foundation

6 Apligraf is a registered trademark of Novartis Pharmaceuticals.
LIST OF FIGURES

4.1 Schematic of the regulated gene therapy system ........................................45
4.2 Serum hGH concentration in nu/nu mice receiving HT26-1 cells and various doses of rapamycin. .............................................................46
4.3 Time course of serum hGH levels after a single rapamycin administration .................................................................................................47
4.4 Invasion of collagen gels and formation of vessel-like structures by PMA-treated microvascular endothelial cells (a-c). Consecutive serial sections showing the continuity between the endothelial cells forming the surface monolayer and those delimiting a tube-like structure inside the collagen matrix (d-f). Serial sections showing the branching of a vessel-like structure into two smaller tubes that progressively diverge from one another. Bar = 50 µm. ...........................49
4.5 Quantitation of VEGF165 and bFGF-induced in vitro angiogenesis ....50
4.6 Development of blood vessel network in VEGF-transplanted hepatic tissues. ......................................................................................51
4.7 Fibrin Gel/FGF-1/Heparin Treated ePTFE graft canine Thoracoabdominal aortic bypass, 20 weeks .......................................................52
4.8 Fibrin Gel/FGF-1/Heparin Treated ePTFE graft canine Thoracoabdominal aortic bypass, 20 weeks .......................................................52
4.9 Images of DRGs cultured within fibrin gels with and without heparin binding peptide ............................................................................54
4.10 Sagittal reformations of a computed tomography scan from a patient who underwent anterior lumbar interbody arthrodesis with a titanium threaded fusion device filled with rhBMP-2/absorbable collagen sponge instead of autogenous bone graft. .................................57
4.11 Histological scores for articular cartilage repair of the 5 mm diameter defects treated with saline alone or treated with 50 pg/h of FGF-2. .................................................................................................57
5.1 (Left) Example of a microfabricated substrate that combines an array of electrical elements with a pattern of polymer that directs the positions and connections of neural cells. (Right) Image of a population of neuronal cells that are patterned on the substrate. The cells assemble functional synapses and display coordinated electrical activities. ............................................................................64
5.2 Example of a dynamic substrate that can be electrically switched to turn on cell migration ...........................................................................65
6.1 Typical tissue engineering approach demonstrating multiple engineering design issues which must be addressed. ........................................71
6.2 Bioartificial liver support device ................................................................73
6.3 Illustration of rapid depletion of oxygen provided by a capillary as it diffuses into, and is consumed by cells in the surrounding tissue ...... 75
<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.4</td>
<td>The ultimate strength of engineered smooth muscle tissues subjected to mechanical stimulation (cyclic strain), no strain (control tissue), and the scaffolds alone (matrix (no cells)) over time in culture.</td>
</tr>
<tr>
<td>6.5</td>
<td>Novel device for applying specific regimens of mechanical and/or electrical stimulation to engineered tissues in vitro developed in laboratory of R. Dennis (University of Michigan).</td>
</tr>
<tr>
<td>7.1</td>
<td>Bioinformatics deals with discrete sets of information (such as the sequence of the human genome) and with the correlation of data between sets of information (such as between the presence of active genes and the cell, tissue and whole person manifestations of that gene activity).</td>
</tr>
<tr>
<td>8.1</td>
<td>Human tissue therapies.</td>
</tr>
<tr>
<td>8.2</td>
<td>FDA classification criteria.</td>
</tr>
<tr>
<td>8.3</td>
<td>European classifications.</td>
</tr>
<tr>
<td>8.4</td>
<td>Japanese classification of medical products.</td>
</tr>
</tbody>
</table>
LIST OF TABLES

ES.1 Comparisons Among U.S., Japanese, and European Tissue Engineering R&D .................................................. xxiii
3.1 Worldwide Distribution of Competitive Progenitor Cell Research ..........30
3.2 Rapid Development of Intellectual Property on Neural Stem Cells .......31
4.1 Scoring System for the Histological Appearance of Full-Thickness Defects of Articular Cartilage .................................................................58
5.1 Comparisons Among U.S., Japan, and Europe: Cell-Based Technologies & Non-Medical Applications .............................................66
6.1 Current Levels of Knowledge and Research in the Engineering Design Aspects of Tissue Engineering ..................................................80
7.1 Major Bioinformatics Centers .................................................................86
7.2 Functionalities Needed To Drive Informatics In Tissue Engineering .................................................................87
7.3 Maturity of Informatics Components Worldwide ...................................88
7.4 Data Products of Relevance to Tissue Engineering ..............................89
7.5 Table of Representative Companies in the Continuum of Bioinformatics Companies (Sample) .........................................................90
7.6 State of Progress in the United States, Europe, and Japan .......................94
8.1 Key FDA Documents Re: Regulation of Human Tissue and Cell Therapies ..............................................................................104
8.2 European Regulatory Classification ......................................................112