The Quadruple Aim: Working Together, Achieving Success
Terry Irgens RPh MS CAAMA
26 January 2011
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(Re)Generating the Future of Therapy

26 JAN 2011

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Director
AFIRM
AFIRM Mission

Discover, develop, and translate regenerative medicine technologies having both near term and far-term translation potential

To provide cutting-edge medical capabilities to heal and reset our warriors who have catastrophic traumatic injuries and disabilities

2011 MHS Conference
AFIRM Strategy

Use a combination of investments > $300M for 5 years

Assemble the best tissue engineering, stem cells and biomaterials experts in the U.S

Rapidly translate promising regenerative medicine capabilities to our wounded warriors

- Core Service and eDHP investments
- University-donated endowments
- Inter-Agency contributions
- Congressional Special Interest (CSI)
- Industry partners contributions
- Other DOD Programs, e.g., JIEDDO/OTT.

Having ready reach into the nascent regenerative medicine industrial base

- Clinical trials that demonstrate safety, benefit
- Access to commercialized technologies
Top US Institutes & Researchers
(2001-2007)

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<th>US Rank</th>
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<tr>
<td>1</td>
<td>David Kaplan</td>
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AFIRM
2011 MHS Conference
All major scientific approaches to tissue regeneration are utilized in the development of regenerative therapies for the wounded service members.
Regenerative Medicine Product Development

- **PRODUCT DISCOVERY**
  - Cells
  - Scaffolds
  - Bioreactors
  - Growth Factors
  - Combination
  - 3-7 Yr
  - $100-130M

- **PRE-CLINICAL**
  - 20 Products
  - .5 - 2 Yr
  - $60-70M

- **IND, IDE (PMA, 510k) SUBMITTED**
  - 5 Products
  - 1-2 Yr
  - $70-100M

- **Clinical Trials**
  - HUMANS PHASE I 10-20 Volunteers
  - HUMANS PHASE II 50-100 Volunteers
  - HUMANS PHASE III 100-200 Volunteers
  - 1-2 Yr
  - 2-3.5 Yr
  - 2.5-4 Yr
  - $70-100M
  - $130-160M
  - $190-220M

- **FDA REVIEW**
  - NDA, BLA SUBMITTED
  - 1-2 Years
  - $18-20M

- **LARGE-SCALE MANUFACTURING / PHASE IV**
  - FDA Approved Product
  - 1-2 Years
  - $18-20M

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Ref. AFIRM 2010. Estimated Time in Stage - Total = 10-20.5 Years
Estimated Cost per Stage - Total = $568-700M

2011 MHS Conference
To Heal our Wounded Warriors

Five Areas of Emphasis

- Burn Repair
- Healing Without Scarring
- Cranio-Facial Reconstruction
- Compartment Syndrome
- Limb and Digit Salvage and Reconstruction
FY 2010 Clinical Trials

Cell Spraying to Reduce Burn Scarring & scar revision

ReCell
Avita Medical

Before

After

Wake Forest – Pittsburgh Consortium (WFPC)

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FY 2010 Clinical Trials

Hand Transplants

Face Transplants

Wake Forest–Pittsburgh Consortium (WFPC)

Rutgers-Cleveland Clinic Consortium (RCCC)

2011 MHS Conference
FY 2011 Clinical Trials
Engineered Skin

Autologous Engineered Skin

Allogeneic Engineered Skin

Rutgers-Cleveland Clinic Consortium (RCCC)

Wake Forest - Pittsburgh Consortium (WFPC)
Fat Injections to Fill Facial Defects

Clinical trial uses patient's own fat and fat derived stem cells for filling in dents in the face.

Wake Forest – Pittsburgh Consortium (WFPC)
CT scan showing 10% increase in quadriceps mass (white arrow) at 4 months post surgery.
AFIRM – Industry Partnership

- Expertise in product development, marketing, regulatory, manufacturing
- Resources for clinical trials
- Licensing technology or Financial investment
- Provide a mechanism to advance combat casualty care
- Studies focus on questions of interest to the military but most of the products have commercial application
- Advances improve both military and civilian care
Other Promising Products on the Horizon

Transplantation Tolerance

Tissue Donor Cell  Transplant Recipient Cell

Rutgers-Cleveland Clinic Consortium (RCCC)

Skin Printer

Wake Forest – Pittsburgh Consortium (WFPC)
Other Promising Products

- Burn Treatment with P12 peptide
- Burn Treatment with KeraHeal, keratin based gel
- Injectable bone void filler, Plexur-LV to repair cranial and long bone defects.
- Fracture resistant tissue stent grafts to repair vascular trauma

- Skin bioreactor, in vitro tissue expander
U.S. Army Medical Materiel Development Activity

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LEST WE FORGET WHY WE ARE HERE

FREEDOM