

# Launching the Alliance for Regenerative Medicine: Organizational Issues and Corporate Status

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# What is the Alliance for Regenerative Medicine?

- The first advocacy organization exclusively dedicated to representing the regenerative medicine community
- A group of companies, university-based research organizations, independent research organizations and service organizations with the shared goal of advancing cell-based therapies, biomaterials and tissue engineering products to the marketplace.
- A 501©4 organization
- The political voice of the regenerative medicine community
- A source of information about the field of regenerative medicine for policy makers, the media, and the general public

# Why Must We Act Now?

- Issues affecting the future of RM being debated now in context of Healthcare Reform, comparative effectiveness, HIT
- No industry organization exists to focus exclusively on policy priorities for RM
- Broader industry organizations represent too many competing interests . Other organizations are too narrowly focused.
- If we wait, we will likely see multiple smaller organizations emerge to claim status as primary RM voice
- Regulatory agencies need single point of contact representing RM to discuss regulatory agenda
- No single reliable source for information exists to inform dialogue about challenges and potential for RM

# Advocacy Advantages of Alliance

- Provides single, credible voice to represent regenerative medicine community in healthcare policy decisions
- Unlike larger trade organizations, Alliance maintains credibility because of central role of research institutions.
- Enables recruitment of diverse membership
- Leverages geographic breadth of RM community for political advantage
- Operates in day-to-day health care policy making circles
- Provides more options for representation than one company or one institution
- Significantly enhances ability to raise funds

# Consequences of Inaction

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**“Struggling UK Stem Cell Said in Need of Therapy”**

- Demonstrates the need to organize and focus on advocacy, regulatory/reimbursement challenges, and collaborations

# Mission

- Provide credible voice for Regenerative Medicine community to influence policy outcomes
- Use close link between research institutions and companies to emphasize potential of science
- Educate key decision makers about potential of regenerative medicine
- Address regulatory requirements to create clear path to commercialization
- Establish link between science and achievable, measurable clinical outcomes
- Provide networking opportunity to set stage for collaborations

# Definition of Regenerative Medicine

- The National Institutes of Health define **Regenerative Medicine** as the process of creating living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage, or congenital defects.
  - Regenerating damaged tissues and organs in the body by stimulating previously irreparable organs to heal themselves.
  - Use stem cells to grow cells, tissues and organs to repair damaged or destroyed cells and tissue the body cannot heal by itself.
  - Solve the problem of the shortage of organs available for donation compared to the number of patients that require life-saving organ transplantation

# Elements of Advocacy Agenda

- Healthcare Reform Strategy
- Congressional Strategy
- Comprehensive RM regulatory framework
- Influence national research agenda
- RM Reimbursement agenda
- PR and Education Strategy

# RM and Health Care Reform

- Health care reform is happening NOW!
- “President Obama Hosts Health Reform Summit”  
March 05, 2009, *US News & World Report*
- “Health Care Industry in Talks to Shape Policy”  
February 19, 2009, *The New York Times*
- US House expects legislation this summer
- We need to educate Congress and the Administration about the promise of regenerative medicine in the context of health reform

# Develop Congressional Strategy

- Congress has been legislating for a decade on some RM issues (embryonic and adult stem cells)
- RM community has the opportunity to seek gains from Congress to create a long-term favorable environment:
  - Health Reform provides an opportunity for education and influence
  - NIH funding issues are being developed
  - Scientific advances provide opportunity to highlight the power of this technology
  - Congressional strategy will supplement regulatory and reimbursement strategy

# Develop RM Regulatory Agenda

- Analyze the regulatory landscape and develop a strategy
- Regulatory issues for ARM to address are likely to include:
  - Ensuring a regulatory approval pathway that appropriately balances risk and benefit re: clinical trial design, data requirements, etc.
  - Ensuring that FDA has the necessary scientific expertise to evaluate new technologies
- The RM community as a whole should establish a dialogue with FDA to ensure communication and input into agency actions

# Influence Research Agenda

- Identify what research is needed to advance RM
- Influence the comparative effectiveness agenda
  - Over \$1 billion appropriated among AHRQ, NIH, and Office of HHS Sec'y
  - Work with agencies to fund research relevant to RM
- Work with NIH to promote a RM basic research agenda
  - Influence NIH funding priorities
  - Identify stimulus funding opportunities (NIH Challenge grants being developed now)

# Develop RM Reimbursement Agenda

- As more and more RM products get closer to market, the community needs to lay the groundwork for a favorable reimbursement climate
- Analyze the reimbursement landscape for Medicare as well as private insurers and develop the necessary strategy
- Issues are likely to include:
  - Determining what evidence of improved care and cost effectiveness payers will be looking for when making coverage and payment decisions
  - Providing input into those evaluations and develop strategies to obtain that information prior to marketing
- Establish a dialog with CMS and private insurers to ensure input into agency/insurer decisions

# Develop PR and Education Strategy

- Develop broad media education campaign (linked to activities of Foundation)
- Conduct regular briefings for policymakers on state of science and challenges to clinical implementation
- Advise RM scientists and other thought leaders on how to speak to media
- Establish RM “list of experts” to be available for comment
- Prepare basic RM educational material

# Next Steps

- Recruit founding members
- Convene founders meeting to discuss and approve 1<sup>st</sup> year operating plan, approve advocacy priorities, and set by-laws
- Launch July 1
- First year budget goal -- \$1 million
- Announce Regenerative Medicine meetings/Fly-Ins