

ALLIANCE_{for} *Regenerative Medicine*

Online at www.alliancerm.org

Who We Are

The Alliance for Regenerative Medicine (ARM) is a Washington, DC-based non-profit organization that promotes legislative, regulatory and reimbursement initiatives necessary to facilitate access to life-giving advances in regenerative medicine. ARM also works to increase public understanding of the field and its potential to transform human healthcare, and provides services to support the growth of its member companies and organizations. Prior to the formation of ARM, there was no advocacy organization operating in Washington, DC to specifically represent the interests of regenerative medicine companies, research institutions, investors, and patient groups supporting more rapid adoption of technologies in our field.

About Regenerative Medicine

Regenerative medicine is a rapidly evolving interdisciplinary field in health care that translates fundamental knowledge in biology, chemistry, and physics into materials, devices, systems, and therapeutic strategies which augment, repair, replace or regenerate organs and tissues. It differs from other fields of medicine in the array of disciplines it brings together and its ability to harnesses the body's own restorative capacity to accelerate the healing process.

What We Do

Alliance members work together to:

- introduce and support policies that pave the way for development of therapies, medical devices and diagnostics based in regenerative medicine
- coalesce multiple, diverse stakeholders to ensure the healthcare system supports ready access to regenerative medicine products (i.e., U.S. and international government agencies, private insurers, providers, consumer groups, private healthcare enterprises)
- promote government and private funding of research and development in regenerative medicine
- create visibility for advances in the field
- encourage more rapid clinical translation of regenerative medicine technologies
- develop sustainable business models and improve access to capital
- provide broad-based education about regenerative medicine
- encourage a global dialogue about the new meaning of treatment, prevention and healthcare, and the evolving prospects for human health that derive from regenerative medicine

Members

Regenerative medicine represents enormous potential for transforming health and extending life, involving every one of us in our capacity as patients and consumers of healthcare. That's why ARM's membership is so diverse, representing university-based and non-profit organizations, patient advocacy groups, leading regenerative medicine life sciences companies and investor organizations.

Members of the Alliance will benefit from:

- more effective advocacy for policies that benefit regenerative medicine
- meeting with key congressional, administration, regulatory, and reimbursement officials
- working with colleagues to identify challenges and solutions to advancing regenerative medicine
- networking with thought leaders and peers in the regenerative medicine community
- access to prospective partners and investors committed to our field
- building an effective vehicle for educating the public about the benefits of regenerative medicine

Please join us.

Issues in Regenerative Medicine

Regulatory Pathway

The regulatory pathway for regenerative medicine products remains largely untested and undefined, and the process for reviewing such multidisciplinary products will need to be refined to assure approvals are timely.

Funding

Historically, scientific discovery in the United States has primarily been funded by the government. Regenerative medicine has not benefitted from this funding infrastructure, having received more than ten times as much private as government funding. Further, the U.S. research industry relies on government-funded basic research for innovation, obtaining licenses to develop products only once a technology has been demonstrated in the lab. Without government funding for regenerative medicine, this core underpinning of US-conducted research is at risk.

Reimbursement & Market Access

In order to succeed commercially, regenerative medicine products need to be incorporated into the insurance system. However, the process for obtaining reimbursement acceptance by private insurers and The Centers for Medicare and Medicaid Services (CMS), the largest insurer in the nation, is still unclear due to the emerging state of the industry. As the regenerative medicine industry matures, companies will need a consolidated source for information, support and advocacy to navigate the reimbursement and market hurdles.

Education

Awareness and understanding of regenerative medicine is essential to its success. ARM believes that everyone from patients to policymakers must understand current and future applications of regenerative medicine in order to maximize the number of safe, effective and innovative products brought to market.

ARM's Agenda for Change

ARM's agenda comprises action specific to regenerative medicine, as well as weighing in on broader issues that influence the field such as health care reform and comparative effectiveness research. ARM's advocacy strategy includes:

- Research into funding policies that support necessary research in universities as well as in private companies;
- Promoting responsible, predictable regulatory policy that ensures safe and effective products reach patients as soon as possible; and
- Working toward a market-based reimbursement system that rewards innovation and facilitates patient access to new products.

Research Agenda

- Engaging with the Department of Health and Human Services, National Institutes of Health (NIH), Department of Defense (DoD) and other agencies to identify and recommend research priorities
- Advocating for Congress to provide increased federal appropriations and programmatic support
- Supporting state initiatives to provide increased investment in regenerative medicine.

Regulatory Agenda

ARM will work with FDA to resolve specific questions about the regulatory pathway for regenerative medicine products, including:

- whether regenerative medicine technologies should be regulated like other biologics and devices (and if not, defining relevant differences);
- use of existing and developing clinical testing and imaging techniques and technologies to determine the product safety
- standards for safety and efficacy
- importance of the proposed clinical indication for new products on the regulatory pathway.

Reimbursement Agenda

As regenerative medicine matures, a favorable reimbursement climate will become increasingly important to facilitate coverage by Medicare and private insurers. ARM intends to:

- clarify the types evidence of improved care and cost effectiveness sought by payers when making coverage and payment decisions
- provide input on evaluations for coverage/payment
- develop strategies for companies to obtain information about product evaluations prior to market launch

Executive Committee

Dr. Anthony Atala, Director, Wake Forest Institute for Regenerative Medicine
Dr. Leona Brenner-Gati, Vice President, Corp. Office of Science and Tech., J&J
Ray Cypess, President and CEO, ATCC
Doug Doerfler, President and CEO, MaxCyte
Ed Field, President & COO, Aldagen
Gary Kurtzman, Vice President, Life Sciences, Safeguard Scientifics
Alan Lewis, President, Juvenile Diabetes Research Foundation
Martin McGlynn, President and CEO, StemCells Inc.
John McNeish, Executive Director, Regenerative Medicine, Pfizer
Dr. George Muschler, Vice Chair, Orthopedic and Rheumatologic Inst., Cleveland Clinic
Dr. Steven Nichtberger, President and CEO, Tengion
Jon Obermeyer, Executive Director, Regenerative Medicine Foundation
Dr. Tom Okarma, President and CEO, Geron
Dr. Beth Seidenberg, Partner, Kleiner, Perkins, Caufield, and Byers
Bernard Siegel, Executive Director, Genetics Policy Institute
Dean Tozer, Senior Vice President, Advanced BioHealing
John Walker, President and CEO, iPierian
Scott Wolchko, Chief Financial Officer, Fate Therapeutics

To fill out a membership application, go to: http://www.alliancerm.org/arm_application.pdf

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