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To our Honorable Members of Congress:

In partnership with the Unite 2 Fight Paralysis organization, advocates from around the world are meeting with members of congress and their staff today to share their personal stories and the promise Regenerative Medicine (RM) has for the treatment of spinal cord injuries.

Over the last two days, advocates attended the Working 2 Walk conference and had an opportunity to learn of recent advancements from some of the top spinal cord injury researchers in the country. They are eager to educate policy makers on this promising research and ask for their support of ***The Regenerative Medicine Promotion Act of 2011*** (HR1862).

This bill supports the development of a federal framework, increased funding for research and commercial development of products, and development of a regulatory environment that enables rapid approval of safe and effective products.

Paralysis is a progressive condition and the complications from it are life threatening. The physical, emotional and financial burdens of paralysis are enormous. If the personal burdens of living with paralysis are not enough to convince you to support this bill, the financial aspects of spinal cord injury will. In particular, spinal cord injury most often strikes young people who are just beginning their productive adult lives and for most of them, their injury takes them out of the work force forever. After one year of injury only 11.6% are employed and by 20 years post-injury 35.2% are employed.

The potential savings from regenerative medicine treatments for the United States is approximately \$250 billion a year (2007 dollars). This figure reflects the direct costs associated with chronic diseases that show possible cures from RM, including late-stage Parkinson's disease, new cases of spinal cord injury, heart failure, stroke, and insulin-dependent diabetes. The stories of the individuals visiting congressional offices today will help to explain the personal toll of surviving paralysis.

Thank you for taking the time to meet today to discuss this bill and the urgent issues it supports. Regenerative Medicine has never been more promising and the individuals it has the potential to help deserve your support of ***The Regenerative Medicine Promotion Act of 2011***.

Sincerely,

A handwritten signature in cursive script that reads 'Marilyn A. Smith'.

Marilyn A. Smith, Executive Director
Unite 2 Fight Paralysis

Regenerative Medicine Economic Impact Data

(courtesy Alliance for Regenerative Medicine)

Regenerative medicine represents a huge potential in healthcare costs savings with its potential to decrease cost savings, reduce costs in chronic care, reduce premature deaths, and increase worker productivity.

Regenerative medicine and stem cell therapies cause two types of economic impacts: *health-related benefits* – cost savings in healthcare, increases in productivity, and the reduction of premature deaths – all of which have a positive effect on the economy; and *attributable economics benefits* that are focused on local and regional economic development, including the economic impact of public expenditures (increases in GDP, tax revenues, etc), the expansion of the biotechnology industry (employment, attraction of private funding), and potential revenues from intellectual property, etc.

Health-Related Benefits: Healthcare cost savings and productivity gains

Productivity gains from introducing a cure to juvenile diabetes five years earlier—such as in 2030 instead of 2035—are estimated at \$12.5 billion in total and studies show there are other possible gains from early introduction of cures.[1]

The California Institute of Regenerative Medicine (CIRM), created by Proposition 71, projected that by 2014, savings produced by reduced health care costs from CIRM-funded discoveries, along with tax revenue generated by research funding, should exceed Proposition 71's costs to the state's general fund that year. In the years prior to 2014, tax revenue alone is projected to cover the interest costs on its bonds.

The potential savings from regenerative medicine treatments for the United States in terms of the direct costs associated with chronic diseases that show possible cures from RM – late-stage Parkinson's disease, new cases of spinal cord injury, heart failure, stroke, and insulin-dependent diabetes – is approximately \$250 billion a year.[2]

Current Costs of Five Diseases with Potential RM Treatments

Disease	Cost/Year (2007)	Patients (millions)
Heart failure	\$50.7 billion	5.2
Insulin dependent diabetes	\$125.1 billion	5.8
Stroke	\$62.7 billion	5.7
Parkinson's disease	\$23 billion	.65
Spinal cord injury	\$37.2 billion	.25

Economic Development: Job creation, increased tax revenue, biotech industry growth

Attributable economics benefits are estimated on local and regional scales (generally at the state level), and include the impact of public expenditures (increases in GDP, tax revenues, etc.), the expansion of the biotechnology industry (employment, attraction of private funding), and potential revenues from sales, intellectual property, etc.[3] While reports vary, the economic benefits are consistently projected as a function of the size of the investment.

CIRM is estimated to create over 13,000 new job-years per year in construction alone from its \$270 million investment in facilities; which will also generate nearly \$100 million in tax revenue; and has already increased the number of stem cell researchers employed in the state by over 400%.The state also expects to see benefits from new intellectual property produced.

By 2007, 11 states appropriated a total of over \$4 billion for stem cell research, with eight creating state-level institutions to accompany these funds.[4]

The regenerative medicine industry is estimated to employ more than 6,000 full-time employees with 10,000+ indirect jobs.[5]

The Diabetes Example: Understanding the Promise of Regenerative Medicine

According to the American Diabetes Association (ADA), 23.6 million American children and adults, 7.8% of the U.S. population, have diabetes. Furthermore, research published by the University of Chicago in 2009 concluded that in the next 25 years, the number of Americans living with diabetes will nearly double. Spending on diabetes is predicted to nearly triple from \$113 billion to \$336 billion, even with no increase in the prevalence of obesity.

People with diabetes require regular injections of insulin, monitoring equipment, regular doctor visits and have higher healthcare costs due to inherent risks of complications that include cardiovascular disease, stroke, blindness, kidney failure and damage to the nervous system. Because of their ability to differentiate into different types of functioning cells, stem cells are one of the best hopes for reducing the threat of diabetes. Scientists believe they can develop a stem cell-based therapy capable of replacing the islet (insulin-producing) cells in the pancreas, allowing for better glucose control or even providing a cure for the disease. This ability to renew biologic function in the body is what distinguishes regenerative medicine from other areas of medicine. According to the ADA web site:

“Scientists from across the United States and throughout the world – including those involved with the American Diabetes Association – believe that stem cell research, especially embryonic stem cell research, holds great promise in the search for a cure and better treatments for diabetes.”

Simply *reducing the impact* of diabetes through stem cell therapy would yield important economic benefits from decreased healthcare costs and increased productivity.

[1] Longaker, M., Baker L., and Greely, H., (2007), Nature Biotechnology. Volume 25 Number 5.

[2] Mason C. and Dunnill P., (2008), The strong financial case for regenerative medicine and the regen industry, Regen Med: 3 (3), 351-363.

[3] Seneca, JJ, and Irving, W, (2007), Updated Economic Benefits of the New Jersey Stem Cell Capital Projects and Research Bond Acts. Newark: Rutgers University.

[4] Lieutenant Governor Elizabeth Roberts, (2007), Discovering Rhode Island's Stem Cell Future. Government of Rhode Island.

[5] Lysaght, M.J., Jaklenec, A., Deweerd, E. (2008), “Great expectations: private sector activity in tissue engineering, regenerative medicine and stem cell therapeutics,” Tissue Engineering, Vol. 12 No.2, 305-15.

Regenerative Medicine Industry Facts (courtesy Alliance for Regenerative Medicine)

- Market estimated to be between \$2-\$5 billion [1] - + 1.2M+ patients treated with RM products[2]

Global Market

- Depending on the definition of regenerative medicine, estimates for global market size vary widely. The global market for regenerative medicine products is forecasted to be \$11 billion by 2015. [2] According to recent studies it could reach up to \$15-\$20 billion over the next 15 years.

United States

Market Size

- U.S. sales of commercially available stem cell therapies were \$15.2 million in 2007 and \$16.5 million in the first two quarters of 2008.[2]
- 173 companies had products in US clinical trials in 2008.[3]
- 55% of regenerative medicine, tissue engineering, and stem cell therapeutic companies are based in the U.S.[4]

Financial Information of Public Companies

- Using available databases, the Alliance estimates that there are 31 public companies in regenerative medicine, that have an aggregate revenue of \$493 million with a market capitalization of \$4.7 billion in 2011.

Number of Companies

- While estimates vary, the Office of Life Sciences for the U.K. Department of Health estimates that there is a total of 391 companies in regenerative medicine. 357 are reported to be small to medium sized enterprises focused on developing therapies and 34 are large pharmaceutical companies.

Number of Regenerative Medicine Companies by Region – July 2011 [5]	
North America	183
Europe	145
East Asia	37
Other	26

Clinical Trials

- Growth in the industry is also indicated by the large number of clinical trials underway. There are currently more than 275 therapeutic companies with 240 cell-based therapies in the market or in clinical development.[6]

Number of RM Clinical Trials Per Development Phase – January 2011[6]	
Phase I	77
Phase II	89
Phase III	27
Commercial Products	44

Number of Commercial RM Clinical Trials Per Indication – January 2011	
Heart Disease	23
Stroke	10
Diabetes (Type 1 and 2)	6
Spinal Cord Injury	8
ALS	6
Parkinson's	3

[1] Regenerative Medicine: Industry Briefing, (2009), Commercial Opportunities and Ontario's Strengths. MaRS Advisory Services.

[2] Lysaght, M.J., Jaklenec, A., Deweerd, E. (2008), "Great expectations: private sector activity in tissue engineering, regenerative medicine and stem cell therapeutics," Tissue Engineering, Vol. 12 No.2, 305-15.

[3] Lysaght, M.J., Jaklenec, A., Deweerd, E. (2008), "Great expectations: private sector activity in tissue engineering, regenerative medicine and stem cell therapeutics," Tissue Engineering, Vol. 12 No.2, 305-15.

[4] Lysaght, M.J., Jaklenec, A., Deweerd, E. (2008), "Great expectations: private sector activity in tissue engineering, regenerative medicine and stem cell therapeutics," Tissue Engineering, Vol. 12 No.2, 305-15.

[5] "Taking Stock of Regenerative Medicine in the United Kingdom." Office of Life Science. U.K. Department of Health. July 2011

[6] Buckler, Lee, (2010), Cell Therapy Industry Overview.

Regenerative Medicine Promotion Act of 2011

H.R.1862

Sponsor:

Rep Bilbray, Brian P. [CA-50] (introduced 5/12/2011)

Cosponsors:

Rep Butterfield, G. K. [NC-1] - 5/12/2011

Rep Capuano, Michael E. [MA-8] - 6/21/2011

Rep DeGette, Diana [CO-1] - 5/12/2011

Rep Dent, Charles W. [PA-15] - 5/12/2011

Rep Eshoo, Anna G. [CA-14] - 6/2/2011

Rep Farr, Sam [CA-17] - 9/21/2011

Rep Fudge, Marcia L. [OH-11] - 5/12/2011

Rep Gerlach, Jim [PA-6] - 5/12/2011

Rep Holt, Rush D. [NJ-12] - 5/12/2011

Rep Langevin, James R. [RI-2] - 5/12/2011

Rep LaTourette, Steven C. [OH-14] - 6/21/2011

Latest Major Action: 5/13/2011 Referred to House subcommittee. Status: Referred to the Subcommittee on Health.

SUMMARY AS OF: 5/12/2011--Introduced.

Regenerative Medicine Promotion Act of 2011 - Requires the Comptroller General to submit to Congress a report identifying all ongoing federal programs and activities regarding regenerative medicine.

Directs the Secretary of Health and Human Services (HHS) to establish a Regenerative Medicine Coordinating Council in the Office of the Secretary, the duties of which shall include: (1) preparing a national strategy to support research into regenerative medicine and the development of drugs, biological products, medical devices, and biomaterials for use in regenerative medicine; (2) identifying sources of funding for research into regenerative medicine and areas where such funding is inadequate; and (3) making recommendations regarding federal policies to support development and marketing of regenerative medicine products.

Authorizes the Secretary, acting through the Director of the National Institutes of Health (NIH), to make grants for: (1) basic or preclinical research into regenerative medicine; (2) research and development of drugs, biological products, medical devices, and biomaterials for use in regenerative medicine; and (3) the making of an investigational new drug application or an investigational device exemption application within four years of receiving such grant.

Amends the Public Health Service Act to authorize the Director of NIH to award grants, contracts, or cooperative agreements to accelerate the development of high need cures through the development of medical products and behavioral therapies for use in regenerative medicine.

Authorizes the Secretary, acting through the Commissioner of Food and Drugs, to: (1) conduct, support, or collaborate in regulatory research to assist the Food and Drug Administration (FDA) in performing its functions with respect to regenerative medicine; or (2) make grants to fund regulatory research for such purpose.