Putting Patients Before Bureaucracy

November 9, 2005

The Honorable J. Dennis Hastert
The Honorable Nancy Pelosi
U.S. House of Representatives
Washington, DC 20515

The Honorable Bill Frist
The Honorable Harry Reid
U.S. Senate
Washington, DC 20510

Dear Speaker Hastert, Majority Leader Frist, Minority Leader Reid and Minority Leader Pelosi:

With time running out on this session of Congress, we call on you to help eliminate a regulatory interpretation stifling promising research that could improve the health and lives of people suffering from many diseases. As 60 patient groups, medical health advocates, biotechnology and medical device organizations, we urge you to pass and make law the "***Save America's Biotechnology Innovative Research (SABIR) Act***" (H.R. 2943 & S.1263) before Congress completes its 2005 legislative business. The bipartisan ***SABIR Act***, authored by Congressman Sam Graves and Senator Kit Bond, is critically necessary in order to restore the eligibility for Small Business Innovation Research (SBIR) grants to majority venture capital–backed biotechnology and medical device companies that provide promise and hope for millions of American patients.

Under the SBIR program, federal research and development grants are awarded to small-business applicants. Unfortunately, recent changes in the Small Business Administration's (SBA) interpretation of eligibility standards for SBIR grants now disqualify many start-up biotech and medical device companies. Specifically, SBA regulations require that, to be eligible for a grant, a small company must be at least 51 percent owned by one or more "individuals." The SBA has recently re-interpreted "individuals" to exclude venture capital, thereby disqualifying many bioscience and device companies from receiving these important grants. For the first decades of the SBIR program, the term "individuals" was interpreted to allow venture capital backed biotech and device companies to participate in the SBIR program. Only recently has this interpretation changed.

U.S. biotech and medical device companies are working to develop drugs, vaccines, diagnostics and devices that target more than two hundred diseases, including various cancers, heart disease, Alzheimer's disease, diabetes, multiple sclerosis, AIDS, arthritis and a whole host of rare diseases. Many of these companies use the SBIR program to provide critical early-stage funding for innovative research and development (R&D). These small companies are the ones that take significant risks and develop the breakthrough research that leads to the "miracle" treatments we have come to expect from the medical technology revolution. It must be understood, however, that SBIR grants in no way sustain emerging biotech or device companies over the course of the 10 to 15 years of development required to bring a product to market. Most biotech and device companies must rely heavily on outside investors, primarily venture capital, in order to sustain their R&D efforts.

Although recent regulatory action by the SBA to clarify the issue of affiliation sought to allow participation of some companies' majority owned by other entities, it does not address the fundamental obstacle to participation of small biotech and device companies in the SBIR program. Given the critical role SBIR grants play in helping emerging biotech and device companies, it is imperative that Congress intervene.

In closing, your leadership is needed now to help innovative research move forward in order to foster breakthrough cures. On behalf of America's patients, medical technology and biotechnology, we urge you to pass the bipartisan ***SABIR Act*** (H.R. 2943 & S.1263) in both the U.S. House and U.S. Senate before Congress wraps up business for 2005 so the President can sign it into law.

Respectfully,

AdvaMed
AIDS Vaccine Advocacy Initiative
Alliance for Aging Research
Alpha-1 Foundation
American Autoimmune Related Diseases Association
American Federation for Aging Research
American Gastroenterological Association
The Amytrophic Lateral Sclerosis Association
Arizona BioIndustry Association
Association of American Medical Colleges
BIOCOM
BioGroup of Rhode Island Tech Collective
BioIdaho
Biotechnology Council of New Jersey
Biotechnology Industry Organization
C3: Colorectal Cancer Coalition
California Healthcare Institute
Children's Tumor Foundation
Christopher Reeve Paralysis Foundation
Colorado BioScience Association
Crohn's & Colitis Foundation of America
Cystic Fibrosis Foundation
Donald Danforth Plant Science Center
Faster Cures
Genetic Alliance
Georgia Biomedical Partnership
Hawaii Life Science Council
Huntington's Disease Society of America
Illinois Biotechnology Industry Organization
Infectious Diseases Society of America
Institute for the Study of Aging
Iowa Biotechnology Association
Juvenile Diabetes Research Foundation
Kansas City Life Science Institute
Kidney Cancer Association
Leukemia & Lymphoma Society
Marti Nelson Cancer Foundation
Massachusetts Biotechnology Council
Muscular Dystrophy Association
National Alliance for the Mentally Ill
National Multiple Sclerosis Society
National Organization for Rare Disorders
New York Biotechnology Association
North Carolina Biosciences Organization
Omeris
Palmetto Biotechnology Alliance
Parkinson's Action Network
Puerto Rico Industry University Research Consortium
Research!America
RetireSafe
Society for Women's Health Research
SMA Foundation
St. Louis Coalition for Plant and Life Sciences
Technology Council of Maryland
Tennessee Biotechnology Association
Texas Healthcare & Bioscience Institute
Us TOO International Prostate Cancer Education and Support Network
Utah Life Science Association
Washington Biotechnology & Biomedical Association
Wisconsin Biotechnology and Medical Device Association