

**BACKGROUND**  
**Comments by the**  
**Cystic Fibrosis Foundation for**  
**Capitol Hill Briefing on**  
**Small Business Innovation Research (SBIR) Grants**  
**Wednesday, November 9, 2005**

The Cystic Fibrosis Foundation supports “*Save America’s Biotechnology Innovative Research (SABIR) Act*” which reinstates the eligibility for Small Business Innovation Research (SBIR) grants to majority venture capital-backed biotechnology companies. H.R. 2943 and S.1263 - sponsored by Representative Sam Graves and Senator Christopher S. Bond respectively - will restore initial rules to once again facilitate government support for promising research at these biotech companies that could improve the quality of life for people with cystic fibrosis (CF).

Development of a new drug in the United States takes approximately 15 years, which is almost one-half of the 35-year life expectancy for those living with CF today. The current drug development process is simply not acceptable for many living with CF, a rare, genetic disease. Consequently, the CF Foundation launched its own Therapeutics Development Program to encourage and support an extensive pipeline of potential new therapies. Through this program, the CF Foundation has been working closely with biotechnology and pharmaceutical industries to support cutting-edge lifesaving research.

Over the past eight years, the CF Foundation has entered into 38 agreements with biotechnology companies, some of which receive venture capital funding. Since 2000, the CF Foundation has committed \$112 million to both discovering compounds and developing treatments for CF in many scientific areas. These small biotechnology companies must be eligible for SBIR grants from the National Institutes of Health without which they will be unable to continue their critical research.

In 2001, the Small Business Administration ruled that firms must be at least 51 percent owned and controlled by individuals, and have no more than 500 employees, including affiliates, in order to be eligible to obtain SBIR grants.<sup>1</sup> This ruling also determined that the definition of “individuals” no longer included venture capital-backed companies. Many biotech companies that are majority-owned by venture capital firms have since been denied access to grant money or have opted to delay SBIR submissions.

Already, a Gaithersburg company, Intronn Inc., terminated a CF research program as well as employees after it lost SBIR support due to financing received through venture capital, which made

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<sup>1</sup> Appeal No. 4423 (2001)

**National Office**

the company ineligible for SBIR grants. The inability of NIH to fund research at these small biotechnology companies seeking cures for life threatening diseases is inappropriate.

According to Robert J. Beall, Ph.D., president and CEO of the CF Foundation, “We believe it is essential that biotech companies with venture capital support be eligible for SBIR grants. The lives of people with CF and many other diseases are harmed when there are regulatory barriers to funding this lifesaving drug research.”

*The Cystic Fibrosis Foundation, headquartered in Bethesda, Md., is a donor-supported, nonprofit organization committed to finding therapies and ultimately a cure for cystic fibrosis (CF), and to improving the lives of those with the disease.*

*CF is a life-threatening genetic disease that causes lung infections and digestive problems and affects approximately 30,000 children and adults in the United States. For more information, visit <http://www.cff.org> or call (800) FIGHT CF.*

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