Testimony of Dr. Aprile L. Pilon, Ph.D.*
Committee on Small Business & Entrepreneurship
United States Senate

Field Hearing – Rockville, MD – June 22, 2009

Thank you for the opportunity to speak today, Senator Cardin. I am Dr. Aprile Pilon, President and CEO of Clarassance, Inc. and APC Biotechnology Services, Inc., two small biotechnology companies based in Rockville, MD. Clarassance is developing biologic protein drugs to treat respiratory and immunologic disease, focusing on a new treatment to prevent chronic lung disease in premature infants. APC Biotech provides consulting and laboratory services, and is also developing a novel manufacturing platform for the production of biologic drugs and vaccines under a current NIH SBIR grant. My companies are located in the Montgomery County Business incubator, in which over 40 small businesses reside, over half of which are biotechnology companies. For months, I've watched fellow biotechnology companies give up space, lay off employees, try to sell their equipment, move out, and finally close their doors. Investment capital is not available and small biotechnology companies are in dire need of economic assistance in order to survive.

I have significant experience utilizing the SBIR program at NIH to build healthcare technology assets and facilitate their commercialization. I have personally written and submitted 23 SBIR grant applications since 1995, of which 8 have been funded for a total of over $2 million. These grants were submitted on behalf of 3 different small businesses and supported a total of 8 full time scientists and 6 part time scientists during the funding periods over a period of 14 years. Our lead drug candidate in Clarassance attracted over $9 million in equity financing to fund 2 Phase 1 clinical trials, is poised to enter Phase 2 clinical trials, and was partially funded in the pre-investment early stage using $1.1 million in SBIR funding from the NIH. These SBIR grants added value to my companies beyond simply the dollar amount of the grant award in that they provide a third party opinion of the technology and research plan by qualified experts (reviewers), thus facilitating investment by angel and small institutional investors who may lack the resources to perform technical due diligence on their own.

Basic discoveries made at academic institutions, government labs, or even in small companies, must be evaluated for reproducibility and product feasibility and de-risked to the point where either institutional investment or corporate partnering is possible. A significant amount of high-risk, specialized R&D must typically be conducted in order to evaluate and reproduce basic discoveries and to explore product ideas to assess commercial potential. Typically, small companies are

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the only ones willing to take these risks. This is an especially long and expensive process for the development of healthcare technologies. The NIH SBIR program, therefore, fills a vital intermediate seed-stage funding gap between basic discoveries and commercially-enabled healthcare technologies. The NIH SBIR program, and the small businesses that it supports, are essential components of the "food chain" that develops new healthcare technologies and creates sustainable jobs in the biotech industry. Early stage, commercially-directed R&D is thus complementary to the basic research conducted at academic and government labs and a necessary stage of the commercialization process.

The NIH basis for requesting the SBIR program exclusion from the stimulus and position that the SBIR program is underutilized and that poor quality applications, so-called "junk science", would receive funding under the SBIR/STTR program at the expense of higher quality academic applications is unfounded. Indeed, the reverse may be the case. The NIH's position is based on its funding criteria established for academic institutions and does not respect the very purpose of the SBIR program, nor take into account the situation with small businesses. It has grown increasingly difficult to obtain grant funding through the NIH SBIR program. According to the SBIR/STTR program funding data (see attached table), the number of SBIR applications decreased by 41% from 2004 to 2007. This is no surprise, since the SBIR Phase 1 success rate decreased from the 30% range in 2001-2002 to about 20% in 2005. Likewise, the Phase II success rate decreased from the 50% range in 2001-2002 to 35% in 2005.

The decrease in the number of applications can be directly attributed to the decrease in the application success rate. The preparation of a grant proposal requires an enormous amount of time and energy, representing both an economic cost and an opportunity cost, that significantly depletes the resources of small businesses. Also, the relatively small seed-stage amounts of the NIH SBIR awards ($100,000 for Phase 1 and $750,000 for Phase II) is also taken into account in the company's decision to allocate resources to grant preparation and some decide that their resources are better spent trying to secure other types of funding. Therefore, small businesses must carefully select and plan high quality scientific projects before considering writing and submitting any grant proposal. Often the basic research has been done, to provide some measure of confidence in a successful outcome, and the technology to be developed has already received some form of limited financial support other than grant dollars (ie. founder investment, etc.) The economic cost of failure to receive grant funding can be lethal to a small biotech business. I, therefore, believe that the higher investment of small businesses in proposal writing and the higher cost of failure to secure grant funding justifies a significantly higher success rate for the SBIR program compared to other grant mechanisms tailored for academic institutions.

A recent National Research Council report[1] in which survey responses were obtained from nearly 400 NIH SBIR award recipients, stated that the decrease in the number of NIH SBIR proposals between 2002-2005 was directly attributed to 3 primary causes, including;

1. the high level of competition,
2. concerns about the selection mechanism (ie. qualify of reviews), and
3. funding delays.

I have personally experienced each of these three primary issues during my 14 years of submitting SBIR grants to the NIH. (As an aside, the issue of venture ownership (of more than 51% of the small business) accounted for just 3% of companies that abandoned the SBIR program between 2002-2005.)

When the competition is high and the success rate decreases, small businesses are not able to devote resources to unproductive activities. NIH review committees are comprised primarily of academics who, in my experience, generally resent the intrusion of small business into what they consider their domain (ie. NIH funding) and often do not consider translational R&D conducted by small businesses to be either innovative or meritorious. Given these prejudices, the NIH's position that small businesses are eligible to compete for non-SBIR grant awards under most of the other RFA's planned under the ARRA is disingenuous. Reviews of SBIR grants are often unfairly negative, academic reviewers are often uninformed about the SBIR review criteria (versus academic review criteria) resulting in applications being rejected for erroneous reasons, and inconsistency from review panel to review panel (ie. recommendations to change the research plans from one panel are criticized and rejected by the next panel that reviews the grant). Another issue that is difficult to manage and results in lower grant scores for small businesses is the fact that the company may not be able to reveal all of its technical rationale and data to justify pursuing a particular line of research, due to the confidential nature of the information, especially before a patent is filed. Most academic reviewers have little patience for missing information and will downgrade the application on that basis. This is a significant problem when the academic review process is applied to the SBIR program so poorer scores under these conditions do not necessarily correspond to poorer science. Therefore, set asides for small business are essential to insuring that some R&D funding flows to companies. In addition, while the small business community applauds the new RC3 mechanism aimed at enabling small businesses to conduct pivotal translational research, recently announced by NIH, the $40 million allocation is a far cry from the ~$230 million that would have been allocated to small businesses if the funding had gone to the SBIR program.

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1. Venture Funding and the NIH SBIR Program. Prepublication copy. Charles W. Wessner, Editor, The National Research Council of the National Academies. The National Academies Press, Washington, DC. 2009.

Moreover, the SBIR/STTR program is significantly more efficient at directing R&D funds towards actual R&D spending. Nearly every dollar of R&D grant funding awarded to a small company is spent directly on the R&D, whereas academic institutions typically receive between $1-$1.50 for every $1 actually spent on R&D to cover their overhead. Indirect cost rates for small businesses are often not tolerated by SBIR budget review committees, and if they are, they are typically less than 25%; while NIH tolerates indirect cost rates of up to 175% from academic institutions.

Thus, we have an economic stimulus to support NIH-mediated development of healthcare solutions that completely excludes small companies and subsidizes low risk product development for large companies. The purpose of the ARRA is to stimulate the economy and stimulate job growth, primarily through supporting the health and growth of small businesses. There is no question that small businesses are more efficient at converting research dollars into economic growth under the SBIR program. Small businesses are the principle vehicle for the development of technology into marketable healthcare products and services, sustainable new jobs, and sustainable economic growth.

I urge the NIH to recognize and embrace the SBIR program as a catalyst for transforming basic biomedical research into healthcare solutions and to offer more opportunities like the RC3 mechanism to fund translational and clinical research.

I urge the Senate to pass S. 1233 in its present form and to expand the SBIR program to 5% of the NIH R&D budget, and to reverse the exclusion of the SBIR program from the NIH economic stimulus funding.

Thank you for your consideration.

NIH Data

Statement of Request:

Update table of FY 1995 - 2007 SBIR applications by FY and phase

FY	All SBIR				Phase 1				Phase 2			
	Number Reviewed	Number Awarded	Success Rate	Amount Awarded	Number Reviewed	Number Awarded	Success Rate	Amount Awarded	Number Reviewed	Number Awarded	Success Rate	Amount Awarded
1995	3,744	831	22.2%	$131,554,136	3,200	619	19.3%	$58,508,040	544	212	39.0%	$73,046,096
1996	3,316	696	21.0%	$111,804,628	2,808	524	18.7%	$50,998,428	508	172	33.9%	$60,806,200
1997	3,108	1,023	32.9%	$177,545,919	2,568	742	28.9%	$72,425,919	540	281	52.0%	$105,120,000
1998	2,964	928	31.3%	$155,251,782	2,503	703	28.1%	$69,474,761	461	225	48.8%	$85,777,021
1999	3,758	1,153	30.7%	$210,168,503	3,173	874	27.5%	$94,944,070	585	279	47.7%	$115,224,433
2000	4,171	1,177	28.2%	$215,876,258	3,582	946	26.4%	$113,468,347	589	231	39.2%	$102,407,911
2001	3,629	1,230	33.9%	$262,655,129	2,972	885	29.8%	$112,826,747	657	345	52.5%	$149,828,382
2002	4,095	1,265	30.9%	$279,031,110	3,411	930	27.3%	$124,423,577	684	335	49.0%	$154,607,533
2003	5,135	1,370	26.7%	$307,181,916	4,384	1043	23.8%	$151,079,961	751	327	43.5%	$156,101,955
2004	6,109	1,334	21.8%	$319,429,001	5,299	1032	19.5%	$161,415,416	810	302	37.3%	$158,013,585
2005	5,380	1,118	20.8%	$289,911,889	4,511	806	17.9%	$126,216,067	869	312	35.9%	$163,695,822
2006	4,580	1,080	23.6%	$309,217,486	3,723	725	19.5%	$119,285,839	857	355	41.4%	$189,931,647
2007	3,613	975	27.0%	$266,131,441	2,947	696	23.6%	$118,796,366	666	279	41.9%	$147,335,075