MEMORANDUM

March 16, 2018

TO:

County Council

FROM:

Robert H. Drummer, Senior Legislative Attorney

SUBJECT:

Bill 41-17, Economic Development Fund – Small Business Innovation Research

and Small Business Technology Transfer Matching Grant Program - Established

PURPOSE:

Action on Bill - Roll call vote required

Planning, Housing & Economic Development Committee recommendation (3-0): enact the Bill with a sunset provision

Bill 41-17, Economic Development Fund – Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program – Established, sponsored by Lead Sponsor Councilmember Leventhal and Co-Sponsors Council President Riemer, Councilmembers Rice, Elrich, Berliner, Katz, Council Vice-President Navarro and Councilmembers Hucker and Floreen, was introduced on December 12, 2017. A public hearing was held on January 16 and a Planning, Housing and Economic Development Committee worksession was held on March 5.

Bill 41-17 would establish a Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program and define eligibility for the Program.

Background

The Small Business Innovation Research Grant (SBIR) and the Small Business Technology Transfer Grant (STTR) are two different congressionally-mandated grant programs for U.S. small businesses who engage in research and development that has a strong potential for commercialization. Bill 41-17 would establish a County matching grant for those County-based small businesses that receive either a Phase I or Phase II grant under either the SBIR or the STTR from the National Institutes of Health. The County grant would be limited to 25% of a Phase I grant up to \$25,000 or 25% of a Phase II grant up to \$75,000. A grantee would be limited to 1 County matching grant each year and a total of 5 County matching grants under this Program.

The grant program would be administered by the Director of Finance out of the Economic Development Fund, subject to appropriation.

All 8 witnesses supported the Bill. Robert Nelson, former Deputy Program Manager for the SBIR and STTR Programs at NASA, testified that County seed money would be helpful for small businesses seeking additional SBIR/STTR grants. See ©10. The rest of the witnesses represented a company that would potentially benefit from this grant program. Anthony Saleh of MiRecule, represented a company that has received SBIR/STTR grants and testified that his company could hire 1 or 2 additional people if they received a County matching grant. Dr. Irving Weinberg of Weinberg Medical Physics, Inc. represented a company that has received SBIR/STTR grants and supported the Bill. Indira Poola, President of Silbiotech, Inc., also supported the Bill. See ©11. Silbiotech has received \$1.96 million in SBIR grants to develop *in vitro* diagnostic test technology to identify candidates for therapy and prevention of breast cancer. Bruce Weintraub, MD, President, CEO & Cofounder of Trophogen (©12-14), David Setlin, Mock V. Solutions, Inc., Ashwin Kulkarni, and Dr. Stephen Hoffman also supported the Bill.

March 5 PHED Committee Worksession

In addition to all 3 Committee members, Councilmember Rice attended the worksession. Gene Smith, Legislative Analyst, and Robert Drummer, Senior Legislative Attorney, represented the Council staff. The Committee discussed the usefulness, cost, and limited scope of the matching grant program that the Bill would establish. The Committee requested additional information on the possibility of adding grants to County based companies that have entered into a Cooperative Research and Development Agreement (CRADA) with the Federal government. The Committee may consider an amendment to add a CRADA grant program to the Bill before Council action. The Committee amended the Bill to add a sunset provision after 7 years and recommended (3-0) approval of the Bill with the sunset provision.

Issues

1. What is the fiscal and economic impact of the Bill?

OMB estimated that the matching grant program would cost the County an average of \$850,000 per year. See, FEIS at ©5-9. The estimate is based upon a review of the number of SBIR/STTR grants awarded by NIH to County businesses in the last 3 years. The estimate assumes an average of 20 matching grants each year at the maximum grant amount. Finance concluded that the matching grant program created by Bill 41-17 is likely to have a positive impact on the County's economy, but that it is difficult to measure any positive effect on the County's employment and personal income.

2. Is this a good use of limited County economic development resources?

Economic development is important to the County. The biotech industry is a strategic industry sector that is an important part of the County's economy. The testimony from the SBIR/STTR grant recipients at the public hearing indicated that this small matching grant program would help small businesses obtain future funding for their companies. The Phase II SBIR grant requires an applicant to provide a commercialization plan and the ability to secure substantial independent third-party investor funds. The County matching grant program could help a small business secure a Phase II SBIR grant.

Council staff notes that this program may duplicate other initiatives already funded by the County.

- Biotech Investment Incentive Tax Credit Supplement (§20-76A of the County Code). This program provides a grant to investors that invest in County biotech businesses and qualify for the State's companion program. The Council has approved an appropriation of \$500,000 since FY11.
- <u>BioHealth Innovation, Inc. (BHI)</u>. The County provides annual funding to BHI to facilitate economic development by identifying market-relevant biohealth products, connecting those products with funding, and assisting businesses in marketing and growth. The Council appropriated \$750,000 in FY18 for BHI.
- <u>Life Science Initiative</u>. The County provides funding to the Montgomery County Economic Development Corporation (MCEDC) to provide grants to biotechnology businesses that receive funding through TEDCO. MCEDC's budget included \$200,000 for this initiative and others for FY18.

The Bill would provide a matching grant of up to \$25,000 for a Phase I grant and up to \$75,000 for a Phase II grant. At the request of Council staff, MCEDC provided comments on this proposal before the Bill was introduced. See, MCEDC memorandum dated November 14, 2017 at ©15. MCEDC pointed out that 41 Montgomery County businesses received more than \$49 million in SBIR Phase I/II grants in 2016. Although each of the potential grant recipients at the public hearing stated that the County matching grants would make a difference, it is fair to wonder if these grants would be large enough to make a small business of this type successful or encourage a small business to re-locate or stay in the County.

MCEDC suggested that the Council consider opening this grant program to all product-based SBIR/STTR grant recipients in any industry or consider adding additional funding to some of the programs that already exist under the Economic Development Fund. See MCEDC comments at ©15. MCEDC also suggested that it might be more beneficial to increase funding for Phase III companies that must secure their own non-SBIR funding.

3. Should the Bill contain a sunset provision?

The Bill does not currently include a sunset provision. Therefore, the program would continue until the Council enacts legislation ending it. Council staff believes that all new grant programs without a track record of success should be evaluated after a certain period. A sunset provision in the law would ensure that an evaluation of the merits of the program takes place. Committee recommendation (3-0): amend the Bill to sunset the law in 7 years. See line 47 of the Bill at ©3.

4. Should the Bill be amended to authorize grants to a Cooperative Research and Development Agreement (CRADA) recipient?

A CRADA is a contract vehicle between a Federal laboratory and a private entity. The U.S. Congress established CRADAs to promote national technological competitiveness and rapid transfer of innovation to the marketplace. In brief, CRADAs allow for a private entity to access tax-supported research or equipment for commercializing a technology into a useful, marketable product. CRADAs are not limited to intellectual property and may also include Government facilities (including equipment) or collaborative interactions with expertise at the Federal

laboratory. There is no central authority or agency that manages CRADAs; rather, CRADAs are developed and managed by agency-specific Technology Transfer Offices (TTO).

Bill 41-17 would establish a program in the EDF to provide a grant to County biotech businesses that receive SBIR/STTR Phase I or II grants. During the PHED Committee's discussion about Bill 41-17, the question was raised whether the bill should be amended to include CRADAs. There is a natural connection because both CRADAs and SBIR/STTR grants are Federal programs designed to accelerate commercialization of useful, marketable products.

CRADAs lack a clear nexus for the County's grant. The current intent of Bill 41-17 connects the County funding with the awarding of a Phase I or II SBIR/STTR grant. The County would be supplementing the Federal grant. This process requires minimal discernment from the County. Businesses that receive SBIR/STTR grants all went through a similar application, review, and award process. CRADAs do not have the same unified process, and businesses execute CRADAs for a variety of reasons. CRADAs are individualized contract vehicles. For example, one business may execute a contract to use a specialized piece of equipment to conduct research once a week for one hour and another business might execute a contract to work with the Federal employee who discovered a new molecule to see if it has commercial applications for 10 hours a week. The lack of uniformity makes it impossible to create a uniform calculation to provide a grant. A business may enter into a CRADA before receiving a SBIR/STTR grant or after receiving a grant.

There is no central clearinghouse for CRADAs. Data for SBIR/STTR grants is all published and maintained through the Small Business Administration. CRADAs have no such clearinghouse, which makes it challenging for Finance to validate and administer a grant using CRADAs as the metric. CRADAs are developed and managed by agency-specific TTO. No TTO provides information about specific CRADAs it has executed, and there is significant variation between each TTO in terms of the data that is shared. The NIH TTO does provide summary data. For 2015, 2016, 2017, NIH executed an average of 109 CRADAs a year. No details were provided about the location of the businesses/individuals that executed these CRADAs. Council staff looked at NIH because of the parameters of Bill 41-17. Other agencies in the County (ARL, DOE, NRL, etc.) did not publish summary data.

CRADAs would dilute the intent of Bill 41-17. Finance estimates a fiscal impact of \$850,000 if the County provides the maximum grant for all businesses awarded a SBIR/STTR from NIH. Other programs in the EDF have historically received appropriations of \$500,000 annually. SBIR/STTR grants provide sufficient demand for the County's resources that the inclusion of CRADAs (an unknown universe) would only serve to dilute the impact of Bill 41-17. Council staff recommendation: do not amend Bill 41-17 to add CRADAs as a metric for a grant.

5. Should the Bill be enacted?

The grant program established by Bill 41-17 would be subject to an appropriation from the Council. If the Council enacts the Bill, the question of funding would have to be decided during the Council's annual budget deliberations. The Council would have to consider funding for this program along with all the other items in the operating budget. At this point, it is difficult to determine if this program would be a good use of the County's limited resources. For this reason, Council staff recommends that a sunset provision requiring an evaluation of the program be added

if the Council decides to enact the Bill. **Committee recommendation (3-0):** enact the Bill with a sunset on July 1, 2025.

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Bill No.	41-		
Concerning:			
Fund -	Small B	usiness	<u>Innovation</u>
			<u>Business</u>
Technolo	ogy Trans	fer Mato	hing Grant
Program	- Establis	hed	
Revised: Ma	rch 5, 201	8 Draft	No. <u>4</u>
Introduced:			
Expires:	June 1	2, 2019	
Enacted:			
Executive:			
Effective:			
Sunset Date:	July 1,	2025	
Ch I	aws of Mo	ont. Co.	

COUNTY COUNCIL FOR MONTGOMERY COUNTY, MARYLAND

Lead Sponsor: Councilmember Leventhal

Co-Sponsors: Council President Riemer, Councilmembers Rice, Elrich, Berliner, Katz, Council Vice-President Navarro and Councilmembers Hucker and Floreen

AN ACT to:

- (1) establish a Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program;
- (2) define eligibility for the Program; and
- (3) generally amend the law governing the Economic Development Fund.

By adding

Montgomery County Code Chapter 20, Finance Section 20-76E

Boldface
Underlining
Added to existing law by original bill.

[Single boldface brackets]
Double underlining
Added by amendment.

[[Double boldface brackets]]

* * *

Heading or defined term.

Added to existing law by original bill.

Added by amendment.

Deleted from existing law or the bill by amendment.

Existing law unaffected by bill.

The County Council for Montgomery County, Maryland approves the following Act:

1	Sec. 1	. Section 20-76E is added as follows:
2	20-76E. Sm	<u> Aall Business Innovation Research and Small Business Technology</u>
3	Transfer M	atching Grant Program.
4	<u>(a)</u>	Definitions. As used in this Section:
5		Director means the Director of Finance or the Director's designee.
6		<u>Small Business Innovation Research Grant or SBIR means the</u>
7		congressionally-mandated set-aside program by that name for U.S. small
8		businesses to engage in research and development that has a strong
9		potential for commercialization.
10		Small Business Technology Transfer Grant or STTR means the
11		congressionally-mandated set-aside program by that name for U.S. small
12		businesses to engage in research and development that has a strong
13		potential for commercialization.
14	<u>(b)</u>	Grant Program. The Director of Finance must pay, subject to
15		appropriation, a SBIR or STTR Matching Grant to each business who
16		meets certain eligibility standards.
17	<u>(c)</u>	Eligibility. A business is eligible to receive the matching grant if the
18		business:
19		(1) has been awarded a SBIR or STTR Phase I or Phase II grant during
20		the current calendar year by the National Institutes of Health; and
21		(2) conducts at least 51% of its research and development operations
22		at a physical location in the County.
23	<u>(d)</u>	Regulations. The Executive may adopt regulations under Method (2) to
24		implement this Section.
25	<u>(e)</u>	Amount of grant.
26		(1) An eligible business may receive:

27			<u>(A)</u>	a match of 25% of a SBIR or STTR Phase I grant, up to a
28				maximum of \$25,000; or
29			<u>(B)</u>	a match of 25% of a SBIR or STTR Phase II grant, up to a
30				maximum of \$75,000.
31		<u>(2)</u>	an el	igible business may receive only:
32			<u>(A)</u>	one County matching grant under this Program each year;
33				and
34			<u>(B)</u>	a total of five County matching grants under this Program.
35	<u>(f)</u>	<u>Adm</u>	inistra	tion.
36		<u>(1)</u>	The !	Director must administer the Program.
37		<u>(2)</u>	<u>The</u>	Director must require a business to pay back any grant
38			payn	nents received if the business does not remain in the County
39			for a	t least 2 years after receiving the grant payment.
40		<u>(3)</u>	Gran	nts must be awarded on a first-come, first-served basis.
41		<u>(4)</u>	<u>An</u> e	eligible business that does not receive a grant due to lack of
42			<u>avail</u>	able funding may be awarded a grant in the following year.
43		<u>(5)</u>	The	Director must reserve 50% of the appropriated funds for
44			<u>eligi</u>	ble businesses receiving a Phase I grant and 50% of the
45			appr	opriated funds for eligible businesses receiving a Phase II
46			gran	<u>t.</u>
47	(g)	<u>Suns</u>	et. Th	is Section is not effective after July 1, 2025.
48				
49	Approved:			
50			• •	
	Hans D. Rier	ner, Pre	sident,	County Council Date

LEGISLATIVE REQUEST REPORT

Bill 41-17

Economic Development Fund - Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program – Established

DESCRIPTION:

Bill 41-17 would establish a Small Business Innovation Research and Small Business

Technology Transfer Matching Grant Program and define eligibility for the Program.

PROBLEM:

The County needs to encourage economic development in the County.

GOALS AND

The goal is to encourage small businesses who receive a federal grant under these

programs to locate operations in the County.

OBJECTIVES:

COORDINATION: Department of Finance

FISCAL IMPACT: Office of Management and Budget

ECONOMIC

IMPACT:

Department of Finance

EVALUATION:

n/a

EXPERIENCE

ELSEWHERE:

n/a

SOURCE OF

Robert H. Drummer, Senior Legislative Attorney

INFORMATION:

APPLICATION

WITHIN

MUNICIPALITIES: n/a

PENALTIES:

n/a

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MEMORANDUM

January 12, 2018

TO:

Hans Riemer, President, County Council

FROM:

lennifer A. Hughes, Director, Office of Management and Budget

Ten Alexandre A. Espinosa, Director, Department of Finance

SUBJECT:

FEIS for Bill 41-17, Economic Development Fund - Small Business Innovation

Research and Small Business Technology Transfer Matching Grant Program -

Established

Please find attached the fiscal and economic impact statements for the above-referenced legislation.

JAH:fz

cc: Bonnie Kirkland, Assistant Chief Administrative Officer Lisa Austin, Offices of the County Executive Joy Nurmi, Special Assistant to the County Executive Patrick Lacefield, Director, Public Information Office David Platt, Department of Finance Dennis Hetman, Department of Finance Pofen Salem, Office of Management and Budget Felicia Zhang, Office of Management and Budget

Fiscal Impact Statement

Bill 41-17, Economic Development Fund – Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program - Established

1. Legislative Summary

Bill 41-17 would establish a Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program. The Small Business Innovation Research Grant (SBIR) and the Small Business Technology Transfer Grant (STTR) are two separate congressionally-mandated grant programs for small businesses engaging in research and development with the potential for commercialization.

Bill 41-17 proposes to establish a County matching grant for those County-based small businesses that received either a Phase I or Phase II grant under either the SBIR or the STTR from the National Institutes of Health (NIH). The County grant would be limited to a 25 percent matching grant up to \$25,000 for Phase I and \$75,000 for Phase II. A grantee would be limited to one County matching grant each year and a total of five County matching grants under this Program.

2. An estimate of changes in County revenues and expenditures regardless of whether the revenues or expenditures are assumed in the recommended or approved budget. Includes source of information, assumptions, and methodologies used.

Bill 41-17 stipulates that the County's matching grant would be limited to a 25 percent of the NIH SBIR/STTR grants with a maximum of \$25,000 for Phase I and \$75,000 for Phase II. If NIH continues to give SBIR/STTR grants to County businesses at the rate they did from 2015 to 2017, 20 companies would be eligible for the County's matching grant based on an average of companies eligible between 2015 and 2017. Of these, 13 would be Phase I and 7 Phase II grantees. All of them would receive the maximum match, or close to it. As the following table illustrates, this would require an annual average of \$850,000 in expenditures for implementation of Bill 41-17. Note that some awardees may relocate from other jurisdictions to Montgomery County as a result of the proposed legislation, which could further increase the estimated annual expenditures.

Montgomery County Businesses Received SBIR/STTR Grants between 2015 and 2017

			,		——		·		_	
SBIR/STTR Grants	2015		2016		2017		Average of 2015-2017		Estimated Annual County Expenditures	
	No. of Total		No. of		No. of		No. of			
	Awards	Amount	Awards	Total Amount	Awards	Total Amount	Awards	Total Amount		
Phase I	17	\$ 3,367,221	5	\$ 5,238,983	17	\$ 4,813,998	13	\$ 4,473,401	\$	325,000
Phase II	5	\$10,643,865	8	\$ 15,579,234	8	\$ 6,575,501	7	\$ 10,932,867	\$	525,000
Total	22	\$14,011,086	13	\$ 20,818,217	25	\$ 11,389,499	20	\$ 15,406,267	\$	850,000

Note: The data come from the National Institute of Health database at <u>www.sbir.aav</u>. The estimated County grant is based on \$25,000 for Phase I and \$75,000 for Phase II.

An explanation of how the addition of new staff responsibilities would affect other duties.
 Not applicable.

9. An estimate of costs when an additional appropriation is needed.

It is estimated that \$850,000 would be needed in the first full year of implementation in order to serve grantees at the average rate indicated in #2 above.

10. A description of any variable that could affect revenue and cost estimates.

Several variables could affect expenditure and revenue estimates, including

• Unanticipated growth or decline in the number, amount, and type of awards made by the NIH for Phase I and Phase II; and

1/11/18

- The number of County-based businesses receiving the NIH grant awards.
- 11. Ranges of revenue or expenditures that are uncertain or difficult to project.

Not applicable.

12. If a bill is likely to have no fiscal impact, why that is the case.

Not applicable.

13. Other fiscal impacts or comments.

Not applicable.

14. The following contributed to and concurred with this analysis: Ruth Semple, Department of Finance Robert Hagedoorn, Department of Finance Pofen Salem, Office of Management and Budget

Jennifer A. Hughes, Director

Office of Management and Budget

Economic Impact Statement

Bill 41-17, Economic Development Fund – Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program - Established

Background:

Bill 41-17 would establish a Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program. The Small Business Innovation Research Grant (SBIR) and the Small Business Technology Transfer Grant (STTR) are two separate congressionally-mandated grant programs for small businesses engaging in research and development that has potential for commercialization. Bill 41-17 establishes a County matching grant for those County-based small businesses that received either a Phase I or Phase II grant under either the SBIR or the STTR from the National Institutes of Health (NIH). The legislation provides for a 25 percent matching grant with a maximum of \$25,000 for Phase I and a maximum of \$75,000 for Phase 2.

1. The sources of information, assumptions, and methodologies used.

Sources of information include the Division of Fiscal Management, Department of Finance and the NIH database. There are no assumptions and methodologies used in the preparation of the economic impact statement.

From the NIH database, Finance reviewed three years of awards: 2015, 2016, and 2017. From that review:

- 2015 17 awardees for Phase 1 and 5 awardees for Phase 2 (total 22). Using the matching amount in Bill 41-17, that would generate \$424,939 for Phase 1 and \$375,000 for Phase 2 for a total amount of \$799,939
- 2016 5 awardees for Phase 1 and 8 awardees for Phase 2 (total 13). Using the matching amount in Bill 41-17, that would generate \$125,000 for Phase 1 and \$600,000 for Phase 2 for a total amount of \$725,000
- 2017 18 awardees for Phase 1 and 9 awardees for Phase 2 (total 27). Using the matching amount in Bill 41-17, that would generate \$450,000 for Phase 1 and \$675,000 for Phase 2 for a total amount of \$1,125,000
- With the exception of one awardee who received less than the maximum (\$24,939 instead of \$25,000), everyone received the maximum amount under Bill 41-17 (either \$25k or \$75k)
- Using an average of the period 2015-2017, this suggests 13 awardees for Phase 1
 \$325,000 and 7 awardees for Phase 2 = \$525,000 for a total = \$850,000 for 20 awardees.

2. A description of any variable that could affect the economic impact estimates.

The variables that could affect the economic impact estimates are the number of awards and the maximum amount of the award. Based on the review of the NIH database from 2015 to 2017 discussed in paragraph #1, there were an average total of 20 awards per year and an average of \$850,000 in grants between 2015 and 2017.

Economic Impact Statement

Bill 41-17, Economic Development Fund – Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program - Established

3. The Bill's positive or negative effect, if any on employment, spending, savings, investment, incomes, and property values in the County.

Since the goal of Bill 41-17 is to encourage more small-life science companies to locate in Montgomery County, the number of awards and amount would increase. Bill 41-17 could have a positive impact on employment and incomes. However, without specific data on the number of companies willing to locate in the County, it is difficult to measure with any certainty the amount of such a positive effect on the County's employment and personal income.

4. If a Bill is likely to have no economic impact, why is that the case?

Bill 41-17 could have a positive economic impact.

5. The following contributed to or concurred with this analysis: David Platt and Rob Hagedoorn, Finance;

Alexandre Espinosa, Director

Department of Finance

12/22/2017



Robert Nelson's Testimony to the Montgomery County Council in Support of the Bill 41-17, "Economic Development Fund Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program" January 16, 2018

My name is Robert Nelson from the Upcounty and I'm here today to speak in favor of Bill 41-17. In order for Montgomery County to continue to thrive, there needs to be investment in our economic future. Nationally 70% of new jobs are created by small businesses and the development of new technology is key to global success. The SBIR and STTR Programs afford small businesses a vehicle to develop new technologies utilizing federal funding and retain the intellectual property rights for future commercialization. I had the opportunity to meet many entrepreneurs during the nine years that I served as Deputy Program Manager for the SBIR and STTR Programs at the National Aeronautics and Space Administration. We balanced the amount of funding allocated to Phases 1 and 2 versus the number of new contracts that could be awarded. So the proposed funding in Bill 41-17 will be very helpful in providing Montgomery County small businesses to be in a better position to compete in the nationwide competition for SBIR/STTR contracts and grants. Many firms have their initial experience with Federal government contracting through the SBIR/STTR Programs. Since competition in contracting requirements are satisfied in Phases 1 and 2, sole-source contracts may be awarded in any amount in Phase 3. SBIR/STTR is a gateway for a business to receive millions of dollars in additional contracts and expand their business. We cannot rely on traditional established businesses to provide the future employment growth needed in Montgomery County. Seed funding from Economic Development Funds is likely to spur much more investment in our county's future. I urge you to approve Bill 41-17.

Yesterday we commemorated Martin Luther King, Jr's birthday and April 4 marks five decades since his death. This morning there was a sobering County Council discussion about factors driving the cost of government. Let me close with a quote from Reverend Dr. King: "The ultimate measure of a man is not where he stands in moments of comfort and convenience, but where he stands at times of challenge and controversy." [Strength to Love, 1963]

Robert Nelson, Goshen

Testimony on Montgomery County Public Hearing: Bill 41-17, Economic Development Fund - Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program

My name is Indira Poola, Ph.D

I am the founder and President of Silbiotech, Inc. Located in Gaithersburg, MD 20879

Our company has been in business for five plus years in Montgomery County

I have had three SBIR awards, Two Phase I awards and one Phase II award. Total awarded: \$1.96Million. One Phase I from NSF (\$150,000), another Phase I from NCI, NIH (\$230,000) and one Phase II (\$1.58Million) from NCI, NIH.

All the SBIR awards are for developing an *In Vitro* Diagnostic Test technology to identify candidates for therapy and prevention of breast cancer.

This program, if established, would be the first local SBIR/STTR matching funds program in the nation and would help attract and retain Biotech Companies right here in Montgomery County.

The program could also help leverage the State of Maryland to create a similar program, which has been done in several states including Kentucky, Michigan, Massachusetts, etc.

The extra matching dollars will be utilized towards commercialization of our technology.

The total potential revenue per year of our clinical test is \$400 Million /year. We hope to achieve at least 10% market penetration by the end of year 5.

Re: Bill 41-17, Economic Development Fund - Small Business Innovation Research and Small Business Technology Transfer Matching Grant Program. Testimony by Bruce D Weintraub, MD, President, CEO & Cofounder, Trophogen, 9430 Key West Ave, Suite # 120 Rockville, MD 20850, Tel 301-717-8935, bweintraub@trophogen.com, www.trophogen.com

Dear Council President Riemer, Councilmember Leventhal, sponsor of Bill 41-17 and my longtime esteemed colleague, other Councilmembers and Guests:

I wish to speak in strong support of Bill 41-17 as an Economic Development Fund SBIR Matching Grant Program specifically for biotech companies in the County. I am the President, CEO and Cofounder of Trophogen established in 2001, a small but highly regarded so -called "emerging" local biotech company in Rockville that develops new recombinant or DNA-based therapeutics for human and animal health. I have been a resident of Montgomery County since 1968 or 50 years (!) and am the most senior entrepreneur speaking today and among the most experienced. I first came to the County to work at the NIH immediately after graduating from Harvard Medical School, then medical residency and ultimately an assistant professorship at the two most prestigious Harvard teaching hospitals, the Brigham and Mass. General. After training as a fellow in endocrinology at NIH, I was invited to be the first tenured Head of the Endocrine Training Program at NIH and first Chief of the Molecular Endocrinology Branch where I served a full 26 year career, in the United States Public Health Service (USPHS) from which I retired as a Captain in 1995. I then served for 5 years as a Professor at the University of Maryland Medical School and its Biotechnology Institute.

Even in my youth I knew I wanted to be a physician to develop new drugs to advance human health, and did extensive medical research and published several important research papers in high school at Roswell Park Cancer Hospital in Buffalo, as an undergraduate at Princeton and at Harvard Medical School. I was among the first scientists at NIH to take advantage of the Federal Technology Transfer Law of 1984 which allowed federal scientists to patent inventions and receive royalties for themselves and their Institutes on inventions of new drugs. My co-invention was one of the first recombinant DNA -based patented drugs called biologics, which

have recently emerged as most exciting therapeutics in pharma and the basis of the biotech industry. It was the first recombinant form of thyroid – stimulating hormone or TSH called Thyrogen by our biotech partner Genzyme that has revolutionized the diagnosis and treatment of thyroid cancer and has been a great commercial success with annual sales of over \$200 million since 1998.

With my extensive research background, the commercial success of Thyrogen and many new inventions with my new NIH coinventor and partner, Mariusz Szkudlinski, we were finally able to find the appreciable venture capital needed, ultimately \$8 million, to start a therapeutics company, Trophogen in 2001, requiring many years of drug development plus long and expensive clinical trials. We had many options of possible venues for our company but chose Rockville and Montgomery County because of its strong early commitment to and nurturing of biotech, its proximity to NIH and the exciting new campuses of University of Maryland and Johns Hopkins at Shady Grove. In our early years in biotech Montgomery County and the I 270 Biotech Corridor was the 3rd largest such center in the Country after Silicon Valley and later LA and San Diego in California and Boston- Cambridge in Massachusetts. However soon thereafter Research Triangle in North Carolina made many overtures to biotech and overtook our 3rd position and recently other states have also overtaken us and by the most recent surveys of the regions most successful and nurturing to biotech by SBIR matching grants we are discussing today and many other overtures Montgomery County and Maryland had fallen to 5th or 6th. Using SBIR matches and many other local and state overtures, many other regions and states will also soon overtake us unless this County and this State take immediate action. Even worse most surveys of venture capital available for biotech show our region as only 17th or worse because most venture capitalists do NOT think of us as hubs of biotech innovation they are seeking but mostly as just government contractors, and do not choose to locate near here. After receiving series A venture capital in 2001, and since the recession in 2008-2009 it has been very difficult for our company and most others in the region to receive series B or C venture capital or to go public in a declining IPO market for biotech. Most of us are still struggling to obtain much too long and expensive FDA approval for our biotech drugs or medical devices and instead must rely on these highly competitive SBIR grants with a success rate per submission of only 10-20% as judged by our most expert peers. My company has been very successful in raising 13 such grants for over

\$12 Million but we must continually raise more SBIR funding to be successful and even viable.

A County SBIR matching program with an initial yearly fund of \$1 Million, my colleagues and I suggest and estimate should be able to provide about \$25,000 for phase 1 and \$50,000 additional matching funds for phase 2. Though that is not a lot of funding for a match compared to other states it is a very good beginning and I will be meeting with State Senator Brian Feldman later this week to discuss his continuing support for an even greater State match which I conceive as a vitally needed and unique Montgomery County- Maryland Biotech "leveraged partnership"!

The entire federal SBIR program is entirely merit based, not need based, and its review process depends solely on expert peers using 6 highly objective well validated review criteria. I feel very strongly that this County should not delay or attempt to change the will of Congress by introducing any other need criteria in a second County review by non-experts. Instead any company which feels it does not need the match may refuse it to help others and if the fund miscalculates allotments in one fiscal year with not enough funds for companies in Q 4 of any year, then those companies should be the first to receive matching funds in Q1 of the following year. In that following year this Council may either allocate more funds or instead recalculate a lower matching amount.

In summary, this Council has a unique opportunity to take a small but very important first step to begin reversing our County's recent fall, most importantly in national perception, as an innovative leader in biotech that it once had because of County visionaries decades ago. With our unique resources and brilliant minds at NIH, the Universities and Incubators at Shady Grove and the Hopkins Plan for development of a "Science City" at the site of the former Belward Farm, this unique new County- State SBIR matching "Leveraged Partnership" that I envision should take our County to future new heights as a world class, highly innovative biotech hub!



SUBJECT: SBIR Matching Grant Program Proposal

TO: Gene Smith

FROM: MCEDC Staff

DATE: November 14, 2017

Thank you for inviting MCEDC to comment on the proposed creation of a Small Business Innovation Research (SBIR) matching-grant incentive program for Montgomery County's biohealth companies. As you know, SBIR encourages small businesses to engage in federal research and R&D that has the potential for commercialization. The SBIR program is structured in three phases:

- The objective of Phase I is to establish the technical merit, feasibility, and commercial potential of the proposed R&D efforts. SBIR Phase I awards normally do not exceed \$150,000.
- The objective of Phase II is to continue the R&D efforts initiated in Phase I. Funding is based on the results achieved in Phase I, the scientific and technical merit of the project, as well as the project's commercial potential. SBIR Phase II awards normally do not exceed \$1,000,000.
- The objective of Phase III is for the small business to pursue commercialization resulting from the Phase I/II R&D
 activities. SBIR does not fund Phase III, so small businesses must secure funding in the private sector or from other
 non-SBIR Federal agencies.

As the County Council explores whether to allocate limited resources to support a new incentive program, we ask that the following items be taken into consideration:

- In 2016, over \$49 million was awarded to 41 Montgomery County-based companies via SBIR Phase I/II. This funding
 was awarded to biohealth and non-biohealth companies.
- The amount of SBIR Phase I/II funding awarded to local companies could make it difficult for the County to make meaningful matching investments in all of the awardees.
- Because Phase III companies are required to secure their own non-SBIR funding, the County's financial support of
 those entrepreneurs could be critical. MCEDC could work with Council (and other stakeholders) to determine a
 reasonable structure for supporting companies in the post-Phase II commercialization stage.
- MCEDC recognizes the need to facilitate the creation of product-based companies across industries in order to grow
 a sustainable local economy. County Council could consider a local funding program to complement TEDCO's new
 Gap Investment Fund. The Gap Investment Fund provides funding that falls between seed and venture investments.
 Gap investments of up to \$500,000 help technology companies solidify strategic partnerships and gain customer
 traction. If the Council were to create a similar local program, the companies could be vetted by investment experts at
 TEDCO.
- If the Council chooses to reward companies who receive SBIR Phase I/Phase II grants, we ask you open the
 program to all product-based companies, regardless of their industries. For example, because biohealth is a strategic
 industry, our entrepreneurs have support through other funding streams, like the Life Sciences Impact Grant, which
 automatically provides \$25,000 to local companies selected for TEDCO's Life Sciences Investment Fund.

MCEDC can provide additional comments, answer questions or explore these issues more fully with the Council staff, at your convenience. Thank you for your continued commitment to strengthening the local economy.

