

Should the NIH Reevaluate its Priorities?

NIH Scientific Review Board
Panel I, Small Business Community Discussion
October 3, 2012

Robert N. Schmidt, Chairman
BS, MS, MBA, JD, Prof. Engr., Patent Attorney
Cleveland Medical Devices Inc.

Rschmidt@CleveMed.com

216-619-5925

4415 Euclid Ave., Suite 400
Cleveland, OH 44106



Cleveland Medical Devices Inc.

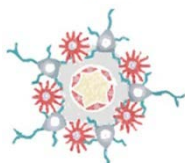
- Founded in December, 1990
- Use the Thomas Edison Model, Invention Factory
- Commercial sales around the world, profitable
- Awards
 - **Inc. 500, 2000, 812% five year growth**
 - **Inc. 5000, 2007/8/9/10** 5,000 fastest growing companies in US
 - **Inc. Inner City 100**, 2000 (34), 2001 (15), 2002 (27)
 - **Weatherhead 100**, (NE Ohio), 1999, 2000/01/03/04/05/06
 - **Edison Award, 2012, SleepView**, along with Apple iPhone 4s
 - **Ohio Emerging Technology Award**
 - **Tibbetts Award**, Best SBIR Companies (2002/2006)
 - **NIH Success Story** (NIH Website)
 - **Stevie Award** (American Business Awards) Best Product Developer Category for PSG@Home 2007
 - **Leading Edge Award** from Entrepreneurs EDGE, top 101 middle market companies in Northeast Ohio that create great value for their community, 2006, 2007, 2008, 2009, 2010,
 - **Best Neuro Product in America**, Kinesia, Neurotech Business Reports, 2008



Our Products- Sold on Seven Continents

CleveMed

Cleveland Medical Devices Inc.



In-Lab & Home Sleep Monitoring
–Crystal Monitor Series & SleepView®



Flocel

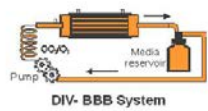


Orbital Research Inc.



Flocel
www.flocel.com

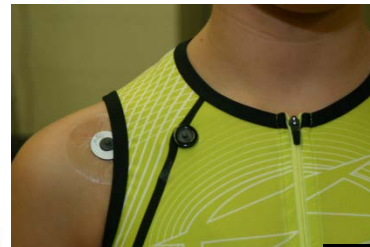
Dynamic In Vitro
 Blood Brain Barrier Model



DIV- BBB System



Cross Section of A single lumen



NeuroWave

HARNESSING THE POWER OF EEG

Anesthesia Monitoring & Seizure Detection

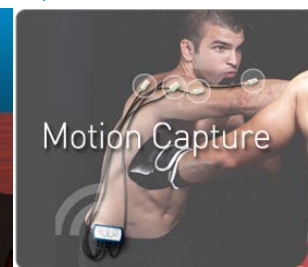
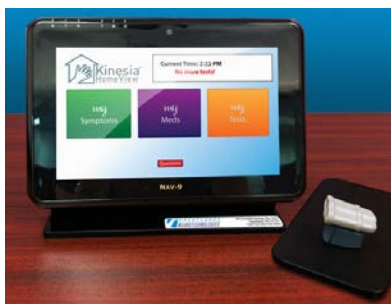
– NeuroSENSE® & NeuroFAST™



GREAT LAKES NEUROTECHNOLOGIES

Movement Disorders & Education

Kinesia HomeView™, KinetiSense™, BioRadio®



Motion Capture



Orbital Research Inc.

NIH Scientific Review Board, Oct. 3, 2012

CleveMed

Cleveland Medical Devices Inc.

I Believe: NIH Policies Should Promote

Deliver Better Health-Faster

- Get technologies into the market place as fast as possible
- Basic research remains important, but next focus should be on technology transition

Job Creation

- Fund programs that will create the most jobs now
- Coordinate with other Government agencies to speed approvals & increase funding

Wealth Creation

- Increase wealth will help pay national debt
- Patents are the number one wealth creator
- Encourage patents



S-Curve, Where Should the NIH Invest?

Investing more in later stage technology provides:

1. More delivered healthcare now
2. More Jobs
3. More Wealth to America, now

Technology
Maturity,
Sales \$

**MORE NEAR TERM
BANG FOR THE BUCK (>10x)**



Basic
Research

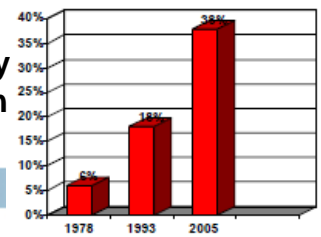
Technology
Transition

Time



Are Our Priorities Correct?

Percent of U.S. Scientists and Engineers Employed by Companies with Fewer than 500 Employees



Small Business employs 38% of the scientist and engineers in the US, but gets just 4.3% of the R&D Funding.

Figure 1. Percentage of Scientists and Engineers Employed In Government, Academia and Business (NSF 2003)

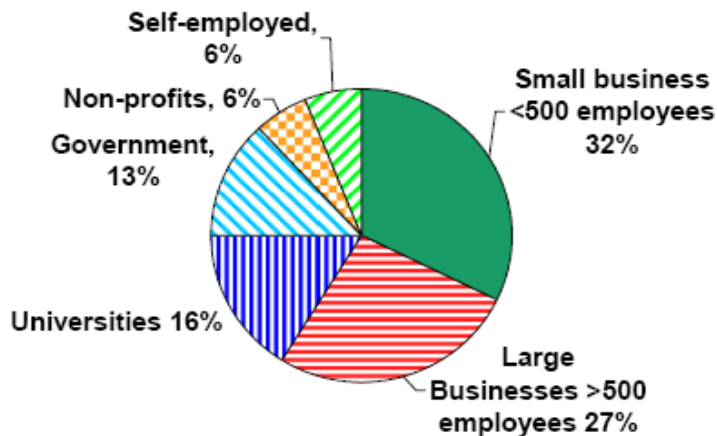
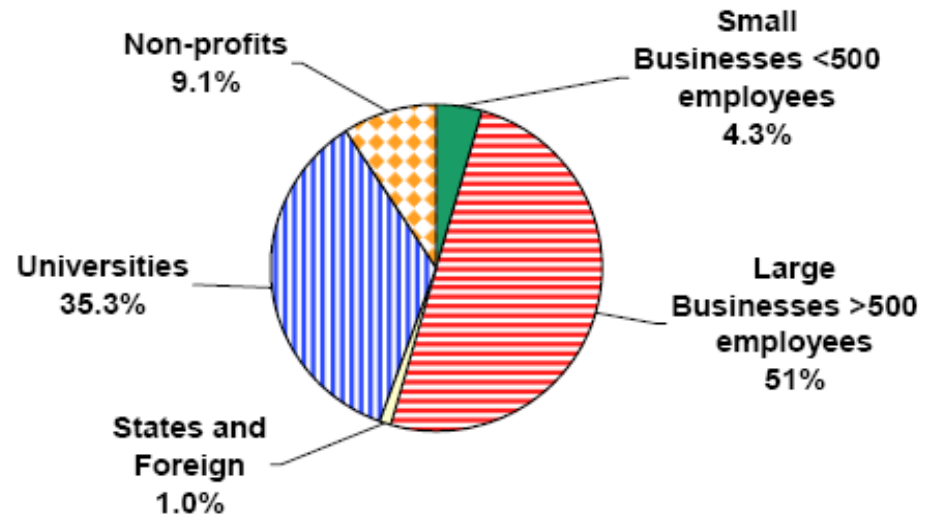


Figure 2. Percentage of Total Extramural Federal R&D Expenditures Received by Academia and Businesses \$81.7 Billion (NSF FY-2005)



SMALL BUSINESSES CREATED 93% OF THE NET NEW JOBS FROM 1989 TO 2005

- Small businesses are by far the most effective instrument for helping the nation grow new jobs.
- From 1989 to 2005, small businesses created 22.9 million of the total of 24.6 million of the net new jobs, **93%**
- SBA Office of Advocacy, from data provided by the U.S. Bureau of the Census, Statistics of U.S. Business. See:http://www.sba.gov/advo/research/dyn_b_d8905.pdf. Data from 1989 through 2005

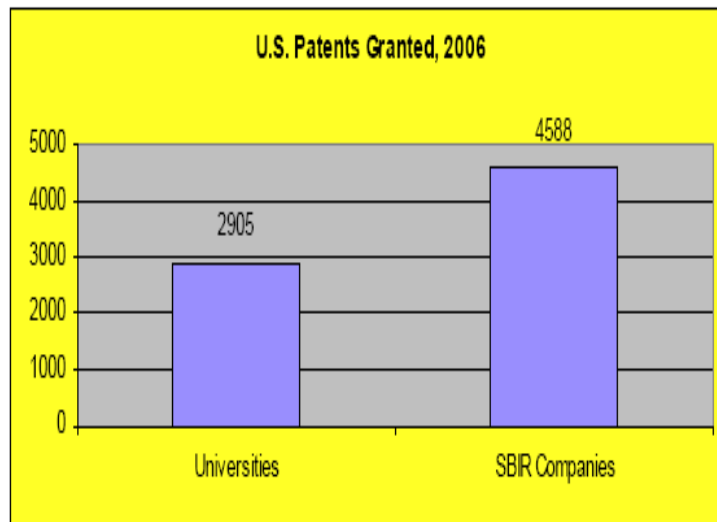


Small Business Produces Patents and Innovation

- 30 Years Ago, Small Technology Companies Created 2.5 Times as Many Innovations per Employee as Large Companies¹
- By 2002-2006 the SBA found that the small firms producing over 15 patents in that five year period produced 13–14 times more patents per employee than did the large firms, and these patents were cited in applications more often than average patents, thus likely making them more valuable.²

¹ NSF Study, 1982 that lead to SBIR Act.

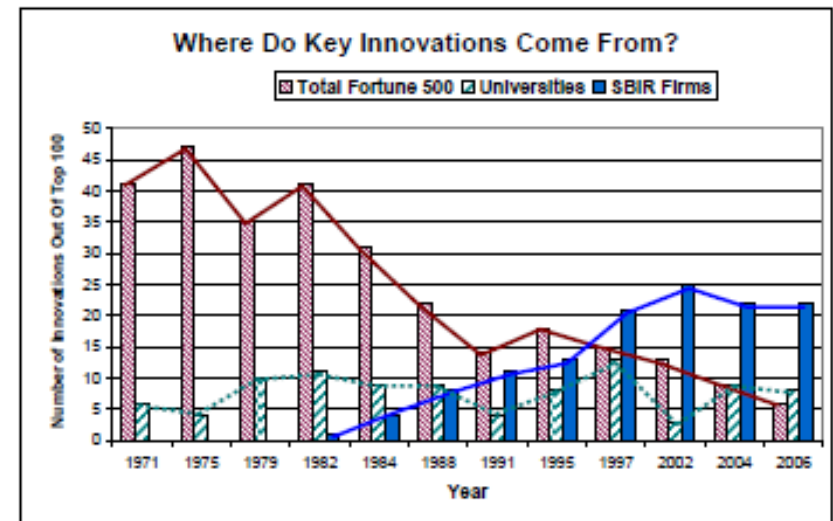
² Diana Hicks, *Small Serial Innovators: The Small Firm Contribution to Technical Change*, CHI Research, 2003, produced under contract to the Small Business Administration, contract SBA01C-0149.



56% more patents on 12% of the funding, 13X the Value



Orbital Research Inc.



4.4x the R&D 100 Awards on 8% of the funding, 55X the Value

CleveMed
Cleveland Medical Devices Inc.

Recommendations to NIH

Increase Funding for Tech Transfer

- More Gap Funding
- Increase % to 5-10%
- Step by Step to \$5-10 million (Ph II b,c,d,e)

Pay for Patents

- US or International only?
- Limit amount?
- Consistent with FAR!



Recommendations to NIH

Establish
Interagency
Committees

- Work with FDA to speed approvals to market

Establish
Interagency
Committees

- Work with DoD, FDA, CMS, and VA to speed development and commercialization

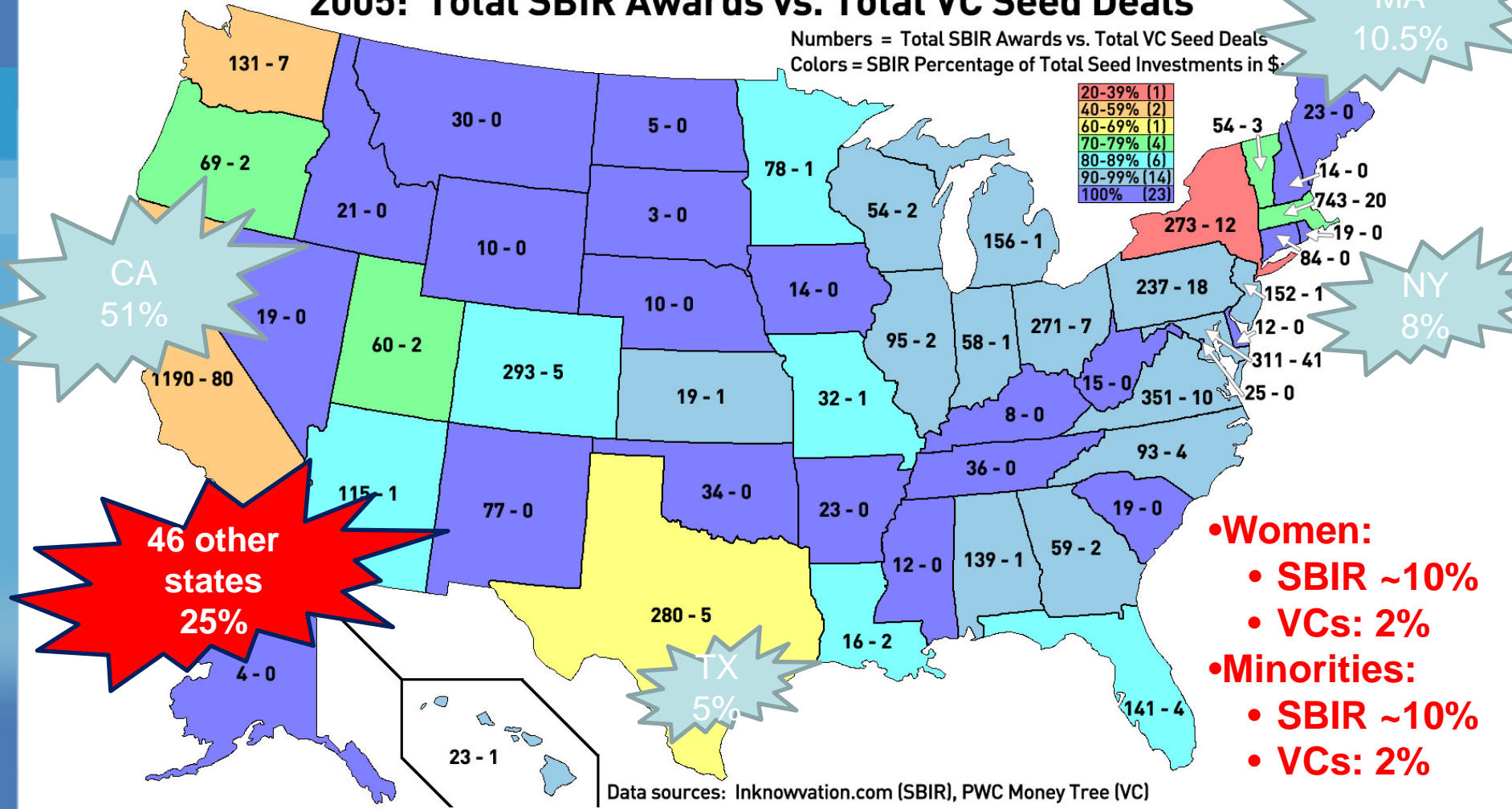


75% of Venture Capital Goes to 4 States 25% Goes to 46 States, ~ 0.5% per State

2005: Total SBIR Awards vs. Total VC Seed Deals

Numbers = Total SBIR Awards vs. Total VC Seed Deals
Colors = SBIR Percentage of Total Seed Investments in \$

20-39%	(1)
40-59%	(2)
60-69%	(1)
70-79%	(4)
80-89%	(6)
90-99%	(14)
100%	(23)



- **Women:**
 - SBIR ~10%
 - VCs: 2%
- **Minorities:**
 - SBIR ~10%
 - VCs: 2%

**46 other states
25%**

Data sources: Inknowvation.com (SBIR), PWC Money Tree (VC)



Other issues beyond the scope of the panel

The following legislation is having significant impact on stunting the growth of small businesses in the US:

- **America Invents Act:** Increasing cost of Patent Protection- you can't raise money until you get a patent, and you can't get a patent until you raise money.
 - Sec. 3(l), SBA never completed required report for effect on Small Business
 - Act was opposed by IEEE, NSBA, NVCA, 80% of patent attorneys, & others
- **Jobs Act:** No clear path as to what a Qualified Investor is, shutting down Angels. SEC appears to be ending self-certification of Qualified Investors.
- **Medical Device Tax:** Taxes many (most) medical device manufacturers more than their profits, hurting R&D and job creation.
- **FDA needs reform:** Need balance, saving lives in equation.

National Association of Manufacturers (NAM) recent poll of SB found:

- **55 percent say they would not start a business** today given what they know now and in the current environment.
- **67 percent say there is too much uncertainty** in the market today to expand, grow or hire new workers.
- **69 percent** of small business owners and manufacturers **say current federal regulatory policies have hurt American small businesses** and manufacturers.
- **54 percent say other countries like China and India are more supportive** of their small businesses and manufacturers than the United States



QUESTIONS



Robert N. Schmidt, CEO
Cleveland Medical Devices Inc.

Rschmidt@CleveMed.com

216-619-5925

4415 Euclid Ave., Suite 400
Cleveland, OH 44106



Orbital Research Inc.

NIH Scientific Review Board, Oct. 3, 2012

CleveMed
Cleveland Medical Devices Inc.

Why Universities Benefit from SBIR/STTR

1. Small businesses (SB) pay very small royalties, usually covering the patent costs.
2. SB hire students part-time during their education, allowing them to obtain valuable work experience.
3. SB frequently hire those students when they graduate.
4. Graduates staying in town working for those same SB tend to be more active in alumni activities, and contribute more to the university.
5. SB hire faculty part-time, subsidizing their income, making them happier and providing more research opportunities.
6. That extra research can lead to more research for the university.
7. SB subcontract research, testing, and equipment use from the university, helping the school's bottom line and keeping facilities utilized.
8. Eventually, some of those licenses will hit "big time" and get licensed to large businesses, which will pay large license fees to the universities for the inventions.
9. Finally, the SB entrepreneurs will die some time, and think kindly of the university (aka: Hewlett-Packard model).



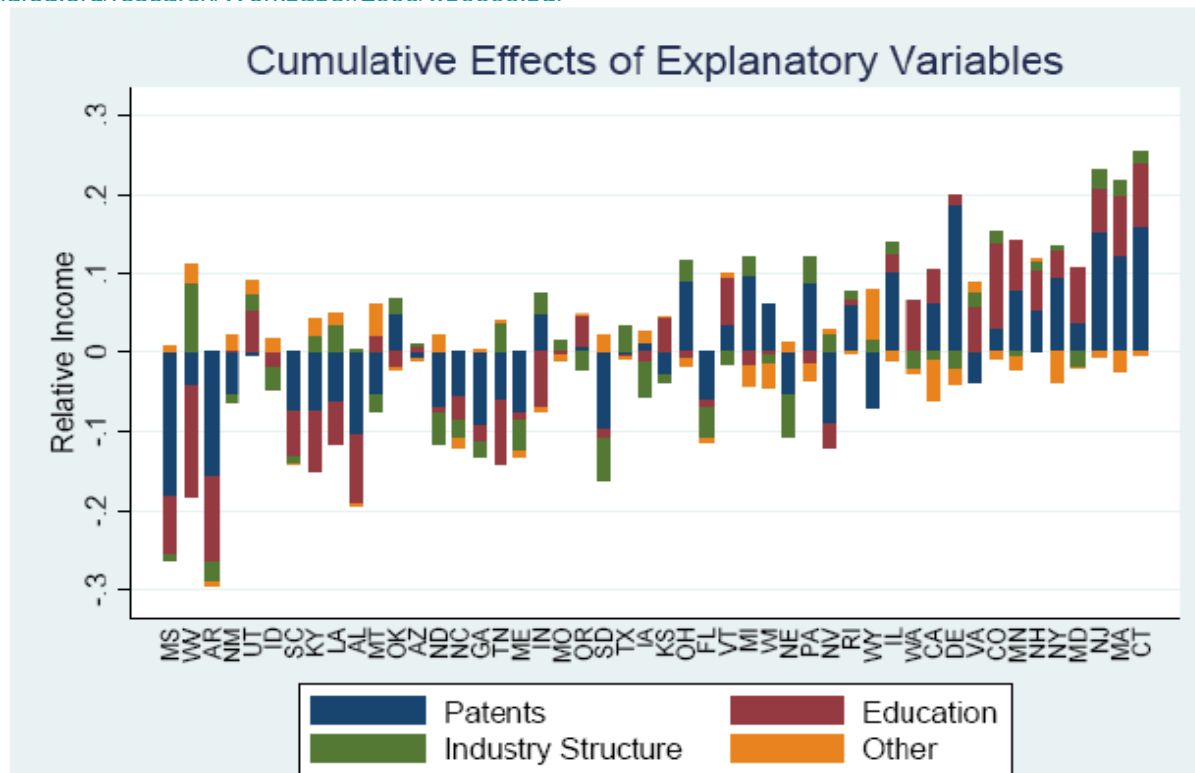
Patents Produce Wealth

Patents are the Number 1 Indicator of Regional Wealth¹

¹ Federal Reserve Bank Study, 2006

"Altered States: A Perspective on 75 Years of State Income Growth," Federal Reserve Bank of Cleveland, *Annual Report 2006*. For more detail, see Paul Bauer, Mark Schweitzer, Scott Shane, *State Growth Empirics: The Long-Term Determinants of State Income Growth*, Working Paper 06-06, Federal Reserve Bank of Cleveland, May 2006.

<http://www.clevelandfed.org/research/Workpaper/2006/wp0606.pdf>



Issues for NIH- Difficulty of Commercialization

- Steps toward commercialization, ~% of costs
 - 5% with engineering prototype: form, fit, function,
 - 10% when manufacturable product,
 - 25% for FDA,
 - 50% with CMS,
 - Last 50% for commercial introduction
- Need \$10 million minimum for development to start product introduction (about 10 SBIR Ph I & 11)
- Time from conception to standard of practice is ~17 years (likely 10-20 years or more)



Issues for NIH- Difficulty of FDA Approval

- FDA needs reform
 - 2 pages 510k 25 years ago, to
 - 650 page 510k not enough today
- NIH-FDA-CMS Must have committee to work with other groups to speed commercialization



Issues for NIH- Stimulus for small business?

- Lack of stimulus for SB in ARRA
- *“Provided further, That the funds provided in this Act to the NIH shall not be subject to the provisions of 15 U.S.C. 638(f)(1) and 15 U.S.C. 638(n)(1)”*
- PL111-5 ARRA, NIH Page 62 eliminating about \$200-\$250M from small business SBIR/STTR.



Other Myths Worth Debunking

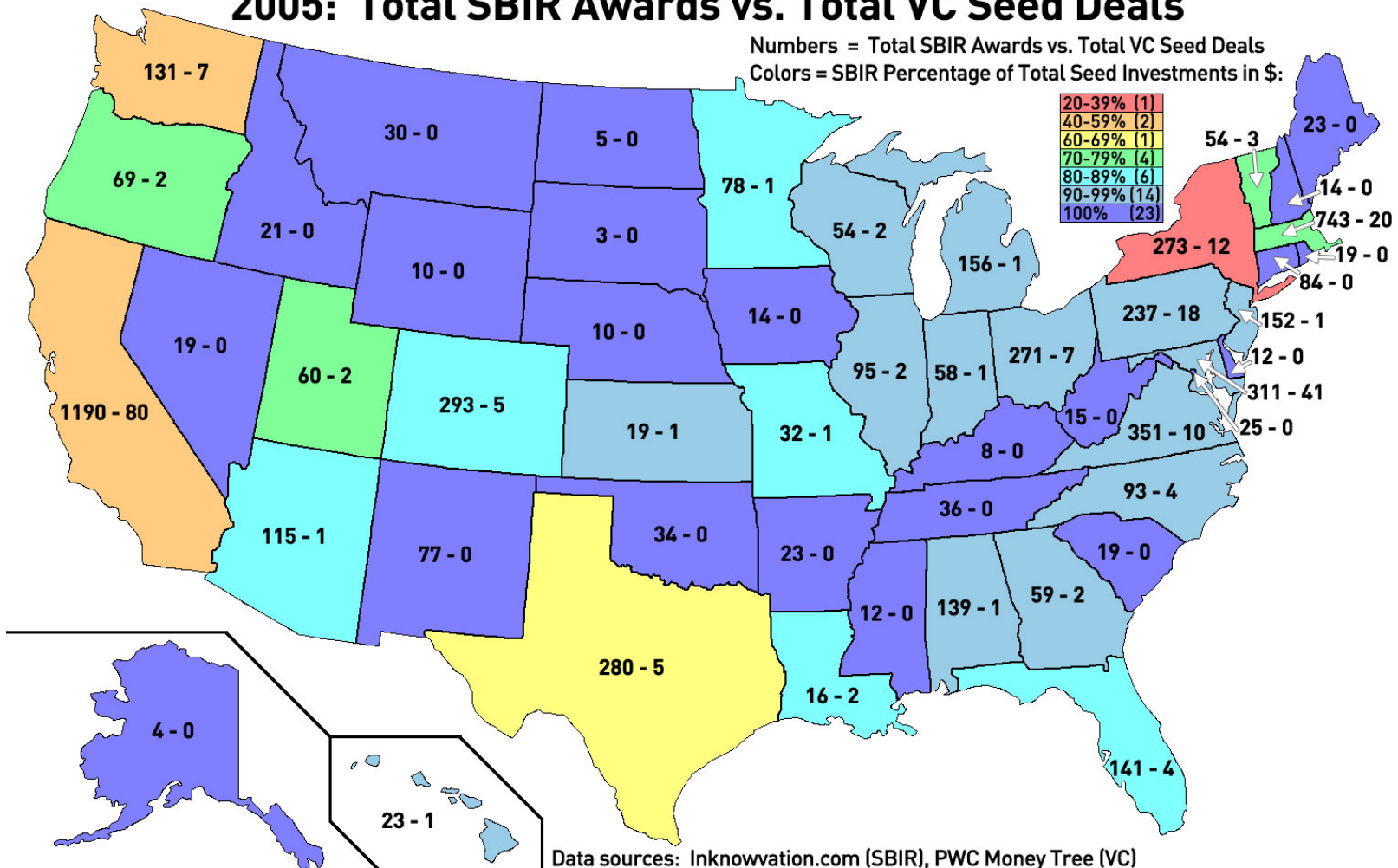
- SBIR Mills
- Duplication of efforts
- Waste, Fraud, and Abuse
 - Tiny fraction
 - All examples by Inspector Generals personnel involved universities.
 - Investigations looking to find a problem, not to solve one.



2005: Total SBIR Awards vs. Total VC Seed Deals

Numbers = Total SBIR Awards vs. Total VC Seed Deals
 Colors = SBIR Percentage of Total Seed Investments in \$:

20-39%	(1)
40-59%	(2)
60-69%	(1)
70-79%	(4)
80-89%	(6)
90-99%	(14)
100%	(23)



Data sources: Inknowvation.com (SBIR), PWC Money Tree (VC)



WHY SMALL HIGH TECH COMPANIES ARE AMERICA'S BEST INVESTMENT

- Patents are the number one indicator of regional wealth (education is # 2).
- The SBIR program is delivering 58% more patents than *all U.S. universities combined*.
- Smaller companies produce about **5 times more patents per employee than large firms and 20 times more than universities**.
- Small firms patents are more important (more often cited) than large firm patents.
- Small technology firms employ **>38% of all scientists and engineers** in America (54.8 percent of all industrial scientists and engineers). Yet these nearly 6 million scientists and engineers work with only **4.3 percent of the government R&D dollars**. In contrast, firms with more than 500 employees account for only 27% of all scientists and engineers, but receive 50.3 percent of government R&D funds. Universities employ 16% of the scientists and engineers and receive 35.3 percent, non-profit research institutions 9.1 percent, and states and foreign countries 1.0 percent.

See Federal Reserve Bank of Cleveland, "Altered States: A Perspective on 75 Years of State Income Growth," Annual Report 2005. For more detail, see Paul Bauer, Mark Schweitzer, Scott Shane, State Growth Empirics: The Long-Term Determinants of State Income Growth, Working Paper 06-06, Page 46, Federal Reserve Bank of Cleveland, May 2006, www.clevelandfed.org/research/Workpaper/2006/wp0606.pdf
SBIR patent database, Innovation Development Institute, www.innovation.com
Small Serial Innovators: The Small Firm Contribution To Technical Change, CHI Research, Inc, under contract to the U.S. Small Business Administration, March 2003, www.sba.gov/advo/research/rs225tot.pdf.
Ibid page 12. "a patent from a small firm is more than twice as likely to be found among the top 1% highest impact patents than is a patent from a large firm."
Science Foundation, Science and Engineering Indicators, 2006 (Figures are for 2005.)



Tax on Large, Profitable Medical Device Companies is 50%, More than 100% on Smaller Firms

THE TAX BREAKDOWN
A TYPICAL MEDICAL DEVICE COMPANY

2.3% tax on revenues = **10-15%** tax on profits

↓

Combined with **35%** corporate & state corporate taxes

↓

End up paying a **50%** tax rate (in most jurisdictions)

Source: Evan Bayh, Former Senator (D-IN)

FOX NEWS
com



80% of Medical Device companies have 50 or fewer employees

Orbital Research Inc.

Cleveland State University, April 20, 2010

CleveMed
Cleveland Medical Devices Inc.

Are you sure you want to start a company? Here are my Starting a Company Rules of Thumb.

1. Never quit a good job to start a company.
2. This is the best way to lose your house.
3. If you are lucky and don't go bankrupt, be prepared to starve for 5-10 years.
4. It takes 7-10 years and 10 million dollars to make a medical device product. Lots more if it is a drug. 15-20 years to penetrate the market.
5. If you have an engineering prototype (form, fit and function), then you may be as much as 5% of the way to commercialization.



Successful Product Launch

<u>Product or Service</u>	<u>Cost to Launch</u>	<u>Time (Years)</u>
Simple Service	\$100K to \$1M	1-3
Simple Product	\$5M+	2-10
Most Products	\$5 M to \$50 M	7-15
Drug	\$1 billion +	10-20

Capital Financing Needs per the Biotechnology Industry Organization

<u>Company Stage</u>	<u>Private investment per company</u>
Proof of Concept	\$25,000 – \$100,000
Pre-seed	\$50,000 – \$500,000
<u>Seed</u>	\$150,000 – \$2 million
<u>Early-stage</u>	\$1 million – \$5 million
Expansion-stage	Up to \$10 million
Mezzanine	Up to \$20 million
Successful Product Launch:	<u>10-15 years - \$1 billion+</u>

The Cleveland Medical Economy Growth Model

The Schmidt Model

- Start 10 companies per year with \$0.5 M ea, 2 employees ea.
- After 2 years, $\frac{1}{2}$ are broke
- 5 companies in Yr 3 need \$1.5 M ea and have 5 employees
- By Yr 4 only 3 companies survive. They need \$4 M each and have 8 employees
- By Yr 7 only 2 companies survive. They need \$5 M each and have 10 employees.
- In Yr 9, one company will be worthy of an additional \$9M.
- By Yr 10 one company will be at 27 employees and will grow rapidly.
- The other company will have 10 employees and will grow slowly.

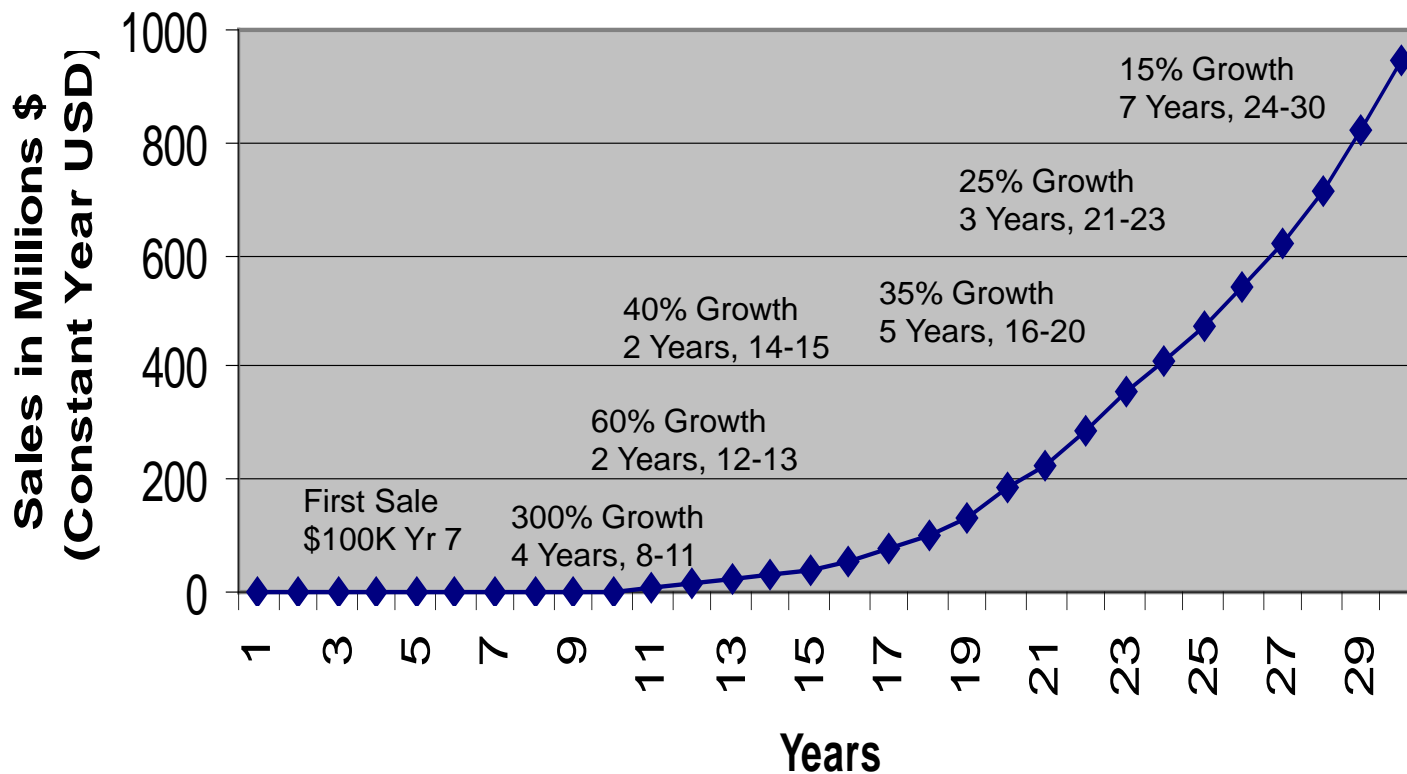


Assumed Curve for Best of Investments

YR Sales \$M % Growth

YR	Sales \$M	% Growth
1	0	0
2	0	0
3	0	0
4	0	0
5	0	0
6	0	0
7	0.1	0
8	0.3	3.00
9	0.9	3.00
10	2.7	3.00
11	8.1	3.00
12	12.96	1.60
13	20.76	1.60
14	29.03	1.40
15	40.64	1.40
16	54.87	1.35
17	74.07	1.35
18	100	1.35
19	135	1.35
20	182.2	1.35
21	227.8	1.25
22	284.8	1.25
23	355.9	1.25
24	409.3	1.15
25	470.7	1.15
26	541.3	1.15
27	622.6	1.15
28	715.9	1.15
29	823.3	1.15
30	946.8	1.15

Sales from Best of 10 Investments



Model Can Be Achieved

Steris Vs. Schmidt Model

