Commercialization by Design

Meaningful Measurement and Social Impact of University Technology Commercialization

March 23-25, 2015
Tucson, Arizona

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Focus IP Group, LLC
Lecturer
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What Is The Impact
Of
The Commercialization Of Academic Research?

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What Do We Mean By Impact?

- Who's asking?
- Financial?
  - Revenues
  - Profits
  - Capital raised
  - Capital formation
- Social?
  - Employment
  - Economic development
  - People helped
  - Lives saved
  - Affordability
- All of the above?

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Why's It So Difficult To Measure Impact?

- Which impact?
- Who wants to know?
- And why?

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Do We Make a Good Return on Investment?

- Total Return from Licensing $2.6 billion
- Total Investment in Research $65.1 billion
  - i.e., 4.0%
    - Truly pathetic – shut it down
- Wait a minute
  - The government didn't fund that research to develop new technologies and products
  - They did it to:
    - Increase the nation's base of scientific knowledge; and
    - Train the next generation of scientists
- So what is the real investment?
  - Investment in patenting -- $351 million? ➔ 715% return
  - Net investment in patenting -- $157 million? ➔ 1,675% return
    - Much better!

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Some of the Challenges

- University-linked innovation / entrepreneurship is typically only a small part of the total innovation / entrepreneurship activity in a region
  - Hard to detect university-based economic development from macro-economic data
- Need to peel the onion carefully:
  - Multiple layers of activity with increasingly loose linkage to the university
    - University-owned technologies
    - Professor-originated (i.e., know-how based)
    - Student-based
    - Alumni-based

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Some Examples

- University-owned technology
  - Google, Akamai, Medivation
- Know-how
  - Netscape, Cisco, SAS
- Student
  - Microsoft, Dell, Yahoo, Under Armour, Facebook
- Alumni
  - Hewlett-Packard, Campbell Soup

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Some Challenges

- Whose job is it to collect the data?
  - AUTM and OTL's focus is on the university-owned IP start-ups
    - It's our job to do the deals
      - Hopefully we keep good data
    - Arguably our job to document impact
  - Incubators collect some of the other categories
    - If they go through the "official" incubator
  - Economic development agencies interested in the rest
    - But no particular focus on university-linked
  - Alumni office
    - Probably only the successes that are good for a donation!

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Some Approaches to Measuring Impact

- Development phase impact
- Product sales based approaches
- Sectoral analyses
- Start-up company analyses
- Triple Helix analyses

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Development Phase Impact

- 43,295 active licenses in 2013
  - 9,925 generating running royalties on product sale
  - 33,370 still in development
- Lot of economic activity associated with the development effort

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Development Phase Impact

- Research done by Lori Pressman, Lita Nelsen *et al* at MIT in 1995
- Survey of MIT exclusive licensees
  - 18 physical sciences
  - 19 biotech
- Broken down by size of company:
  - Start-up
  - Small
  - Large
- Asked for the total investment in developing the technology
  - Generated average investment per year by company size
    - Biotech 3x physical sciences ($3.24 vs $1.33 million/year)
    - Start-ups 5-10x small companies ($2.24 vs $0.406 million/year)

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Development Phase Impact

- $1 billion impact
  - 20% of product sales impact at the time
- Study replicated and confirmed
  - U. Penn
  - OSU

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Product Sales Based Approaches

- Originated in 1993
  - Driven by the first AUTM Survey
    - $200+ million income predicted for 1992
      - Politically sensitive
- Asks the question:
  - What level of product sales does it take to generate royalty income of $x million?
    - Not a sophisticated analysis!
  - Private and very confidential survey yielded an average royalty rate of 1.7%
    - AUTM / MIT published an economic impact analysis using this approach in 1996
      - $20.6 billion product sales
      - 212,500 jobs
      - $3 billion in tax revenues (federal, state, local)

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THE ECONOMIC CONTRIBUTION OF UNIVERSITY/NONPROFIT INVENTIONS IN THE UNITED STATES: 1996-2013

PREPARED FOR
THE BIOTECHNOLOGY INDUSTRY ORGANIZATION
BY LORI PRESSMAN, DAVID ROESSNER, JENNIFER BOND,
SUMIYE OKUBO AND MARK PLANTING, MARCH 2015

MARCH 17, 2015

Bio Biotechnology Industry Organization

Product Sales Based

- AUTM Annual Survey
  - Starting in 2011, asked for product sales from royalty reports
    - Low compliance
      - ~34% of respondents reported ~$35 billion in product sales
    - Two ways to extrapolate to entire survey base:
      - Number of Licenses Generating Running Royalties
      - License Income from Running Royalties
    - Precisely confirmed the 1996 royalty rate estimate!
    - Yields ~$80-100 billion in product sales

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Sectoral-based Analyses -- Healthcare

SPECIAL ARTICLE

The Role of Public-Sector Research in the Discovery of Drugs and Vaccines

Ashley J. Stevens, D.Phil., Jonathan J. Jensen, M.B.A., Katrine Wyller, M.B.E., Sabarni Chatterjee, M.B.A., Ph.D., and Mark L. Rohrbaugh, Ph.D., J.D.

ABSTRACT

BACKGROUND

Historically, public-sector researchers have performed the upstream, basic research that elucidated the underlying mechanisms of disease and identified promising points of intervention, whereas corporate researchers have performed the downstream, applied research resulting in the discovery of drugs for the treatment of diseases and have carried out development activities to bring them to market. However, the boundaries between the roles of the public and private sectors have shifted substantially since the dawn of the biotechnology era, and the public sector now has a much more direct role in the applied-research phase of drug discovery.

METHODS

We identified new drugs and vaccines approved by the Food and Drug Administration (FDA) that were discovered by public-sector research institutions (PSRIs) and classified them according to their therapeutic category and potential therapeutic effect.

RESULTS

We found that during the past 30 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in PSRIs. These drugs included 93 small-molecule drugs, 36 biologic agents, 15 vaccines, 8 in vivo diagnostic materials, and 1 over-the-counter drug. More than half of these drugs have been used in the treatment or prevention of cancer or infectious diseases. PSRI-discovered drugs are expected to have a disproportionately large therapeutic effect.

CONCLUSIONS

Public-sector research has had a more immediate effect on improving public health than was previously realized.

From the Institute for Technology Entrepreneurship and Commercialization (A.J.S.) and Office of Technology Development (A.J.S., J.J.J.), Boston University School of Management, Boston; the Norwegian Radium Hospital Research Foundation, Oslo (K.W.); and the Office of Technology Transfer, National Institutes of Health, Bethesda, MD (S.C., M.L.R.). Address reprint requests to Dr. Stevens at Boston University School of Management, 53 Bay State Rd., Boston, MA 02215, or at astevens@bu.edu.

N Engl J Med 2011;364:535-41.

Criteria for Inclusion

- Products which have received FDA approval by either:
  - Center for Drug Evaluation and Research (CDER) or
  - Center for Biologics Evaluation and Research (CBER)
- A license to intellectual property was signed (or enforced by the Courts)
- US Public Sector Research Institutions only
  - National Laboratories
  - Universities
  - Hospitals
  - Non-profit Research Institutes
- Each BLA/NDA resulting from that IP

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Criteria for Inclusion

- Includes:
  - Vaccines
  - Small molecule drugs
  - Biologics
  - *In vivo* diagnostics
- Excludes:
  - Platform technologies that contribute to the development of whole classes of drugs
    - Cabilly
    - Axel
    - etc.
  - Nutritionals

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Sources for Study

Primary:

- FDA – Orange Book, CDER and CBER databases
- SEC – EDGAR database
- ReCap / ReCapIP
- USPTO
- CRISP
- iEdison

Secondary:

- AUTM Surveys (e.g. Better World Report)
- University of Virginia Patent Foundation research
- Press articles
- Lawsuits
- Personal communications, etc.

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Number of Products

Type of Product	Number
New Chemical Entity	93
Biologic	36
Vaccine	15
Over the counter	1
In-vivo diagnostic	8
Total	153

Therapeutic Categories

Therapeutic Area	Number
Hematology/Oncology	40
Infectious Disease	36
Cardiology	12
Metabolic	12
CNS	12
Dermatology	7
Renal	7
Ophthalmology	6
Immunology	6
Gastroenterology	4
Women's Health	3
Allergy	2
Pulmonary	2
Urology	2
Anaesthesiology	1
Dental	1
	153

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Discovering Institution	Number
National Institutes of Health	22
U. of California	11
Sloan Kettering	8
Emory University	7
Yale University	6
Children's Hospital, Boston	5
MIT	5
Salk Institute	5
Wisconsin Alumni Research Foundation	5
Columbia University	4
New York University	4
U. of Michigan	4
U. of Minnesota	4
U. of Texas	4
Brigham & Women's	3
Dana-Farber Cancer Institute	3
Harvard	3
Massachusetts General Hospital	3
Oklahoma Medical Research Foundation	3
Rockefeller University	3
Scripps	3
State University of New York	3
Tulane University	3
U. of Cincinnati	3

Initial Developers

Type of Entity	Number	%
Large Entity	65	42.5%
Small Entity	65	42.5%
Start-Up	23	15.0%
Total	153	

Current Marketer	Number
GlaxoSmithKline	12
J&J	9
Bristol-Myers Squibb	8
Merck	8
Pfizer	8
Eli Lilly	6
Genzyme	6
Novartis	6
AstraZeneca	5
Wyeth	5
Amgen	4
Bayer Healthcare	4
Eisai	4
Roche	3
Abbott	3
Baxter Healthcare	3
BiogenIdec	3

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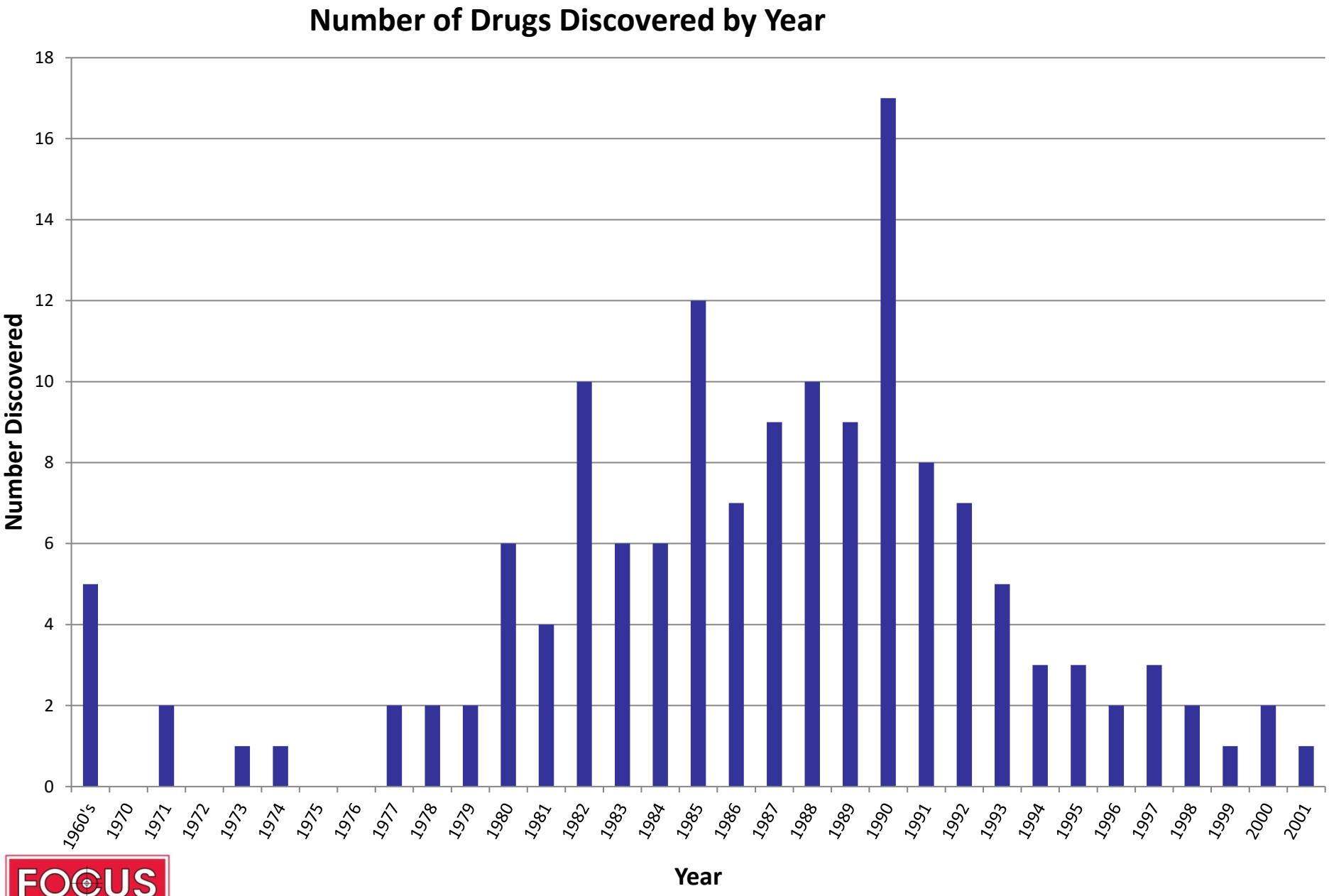

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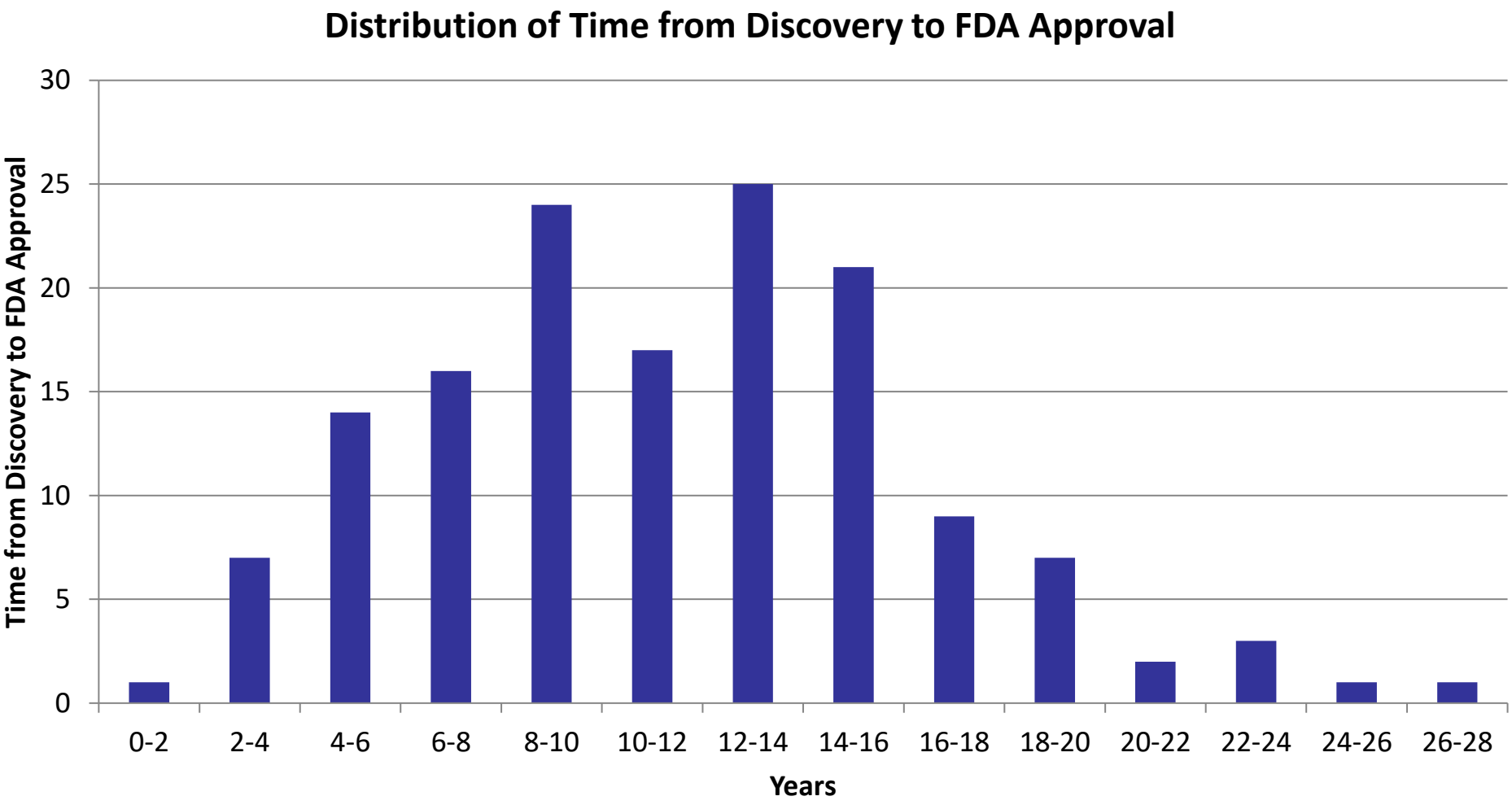

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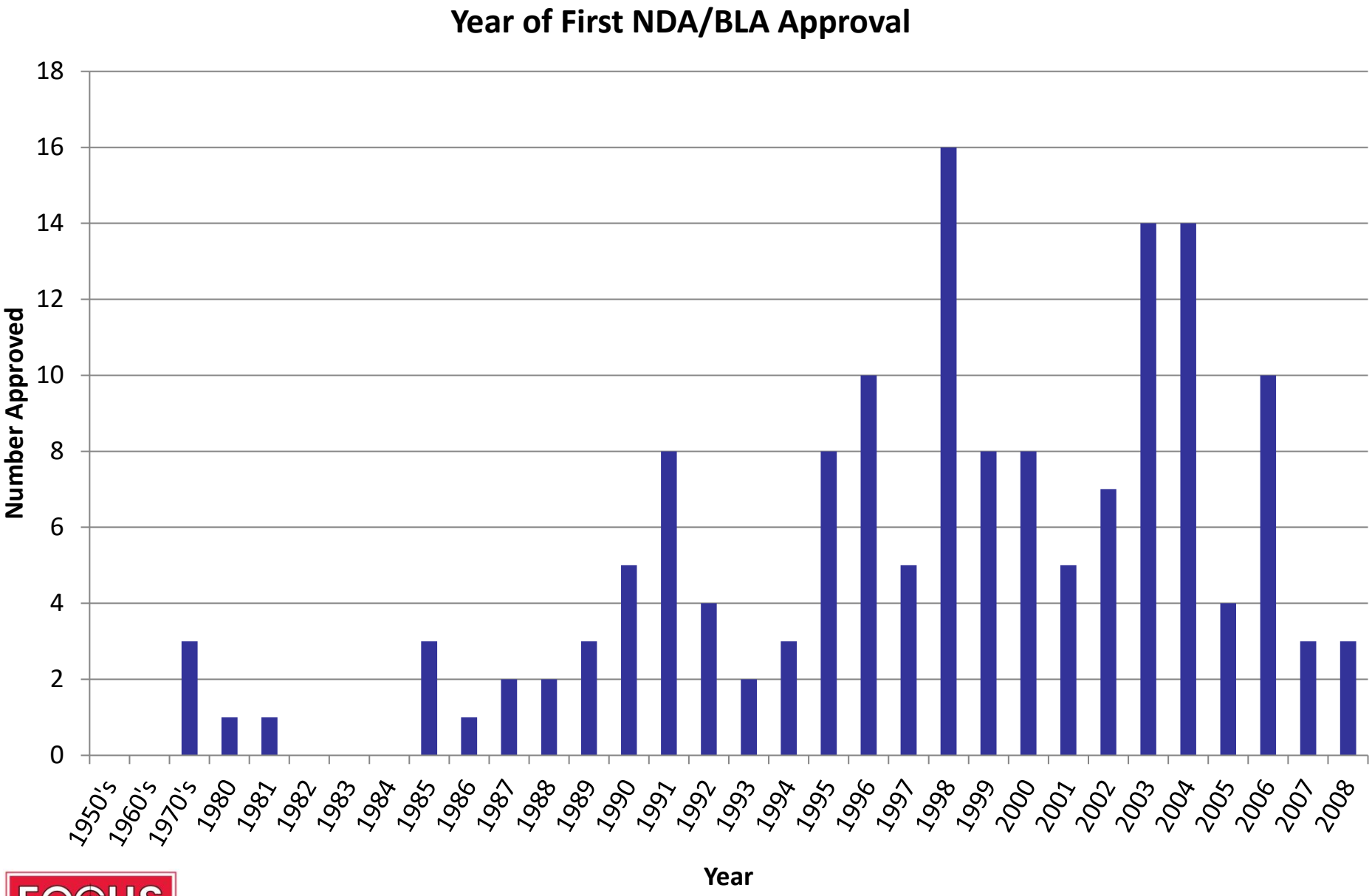

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Commercialization Pathways

- Found that the classical models for commercialization of public sector research:

PSRI ➔ Large Pharma ➔ Market

and

PSRI ➔ Biotech ➔ Large Pharma ➔ Market

are considerable over-simplifications

- There are frequently one or more additional transactions both pre- and post-FDA approval.

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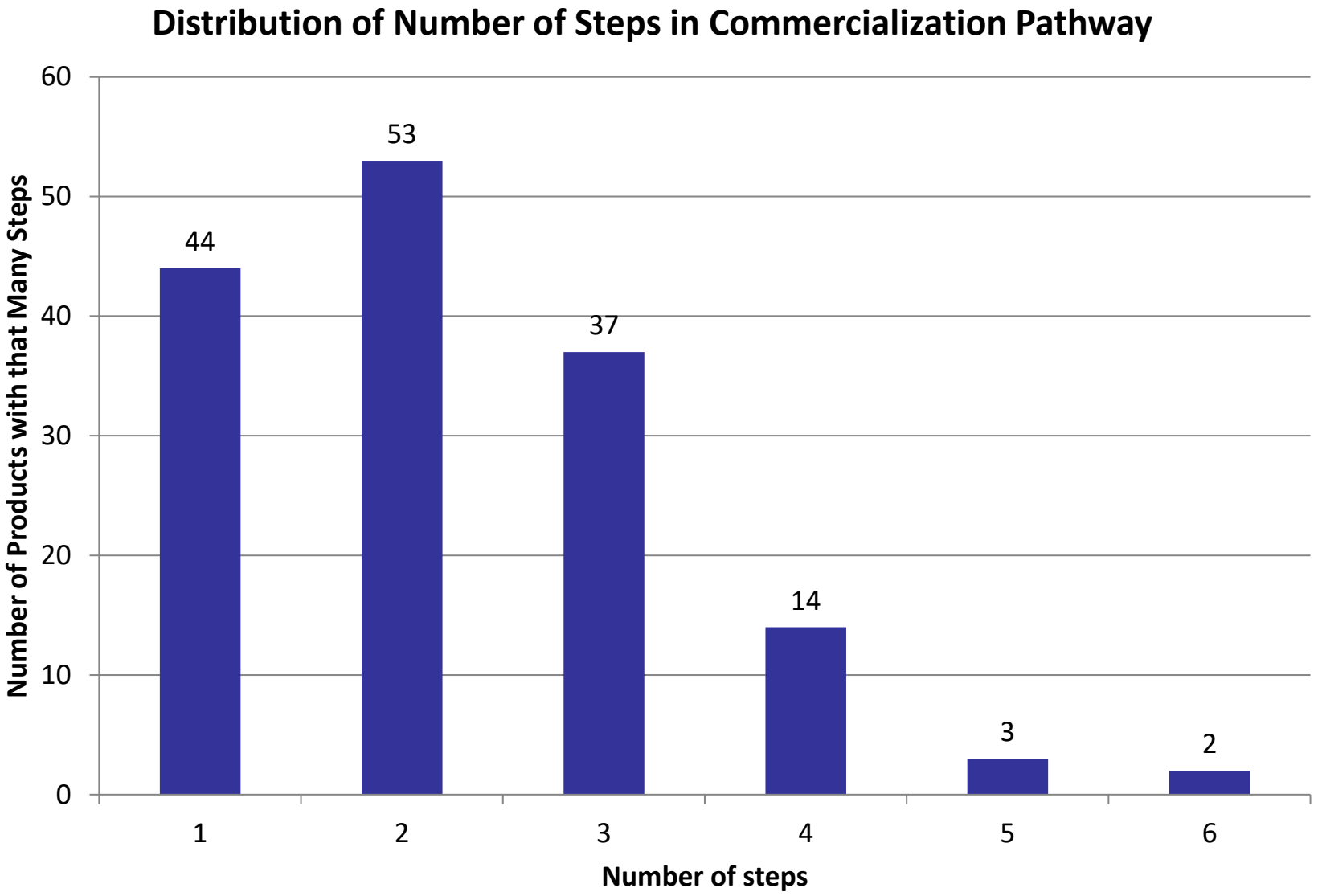

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Commercialization Pathway vs. Initial Developer

No. of Steps	1	2	3	4	5	6
Large Entity	39	14	10	1	1	0
Small Entity	4	31	18	10	1	1
Start-Up	1	8	9	3	1	1

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Economic Impact

- Inventor
- Developer
- Marketer

Impact on Inventing Institutions

- Royalty sales
- 35 transactions 1990 – 2013
- $4.051 billion in revenues

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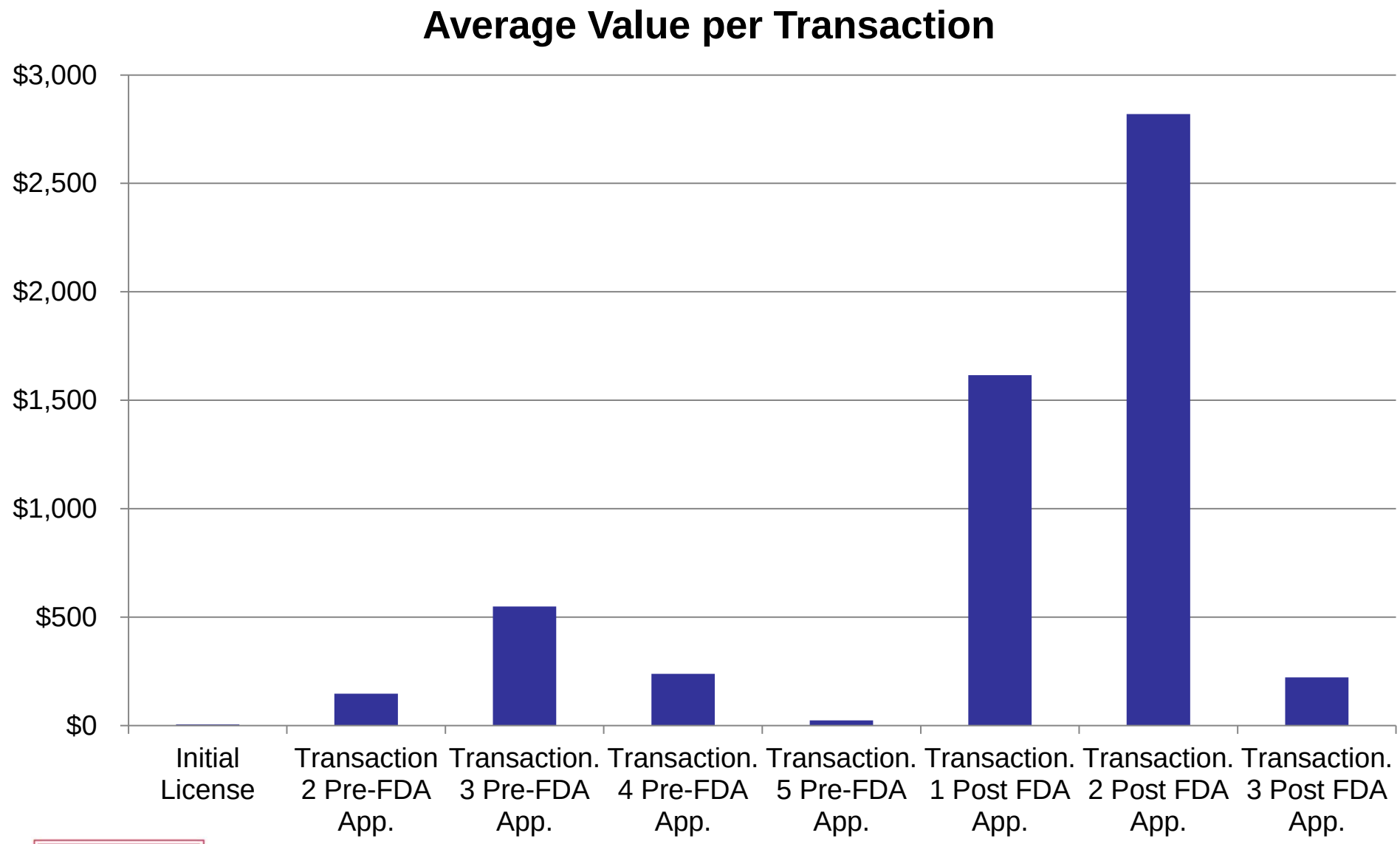

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Developer

Transaction	Number	Value	Average Value
Pre-FDA Approval		($mm)	($mm)
Initial License	23	$99.0	$4
Transaction 2	51	$9,634.7	$189
Transaction 3	11	$5,522.0	$502
Transaction 4	5	$1,194.0	$239
Transaction 5	1	$24.0	$24
Post FDA Approval			
Transaction 1	54	$70,308.4	$1,302
Transaction 2	20	$56,002.2	$2,800
Transaction 3	2	$443.0	$222
Total	167	$143,227.3	

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2008 Sales

	US ($ billion)	Global ($ billion)	%
PSRI	39.9	102.7	37.7%
All drugs	291.5	773.0	
	13.7%	13.7%	

Source: IMS Health, Company Reports

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Medical Devices

- Study underway
- Impact even greater
  - Virtually all medical device categories originated with an MD observing and tinkering

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The Internet

W3C World Wide Web consortium	CERN
NCSA Mosaic	University of Illinois Urbana-Champaign
Eudora By Qualcomm	University of Illinois Urbana-Champaign
Yahoo!	(Stanford)
Lycos	Carnegie-Mellon
Akamai	MIT
Google	Stanford
f	(Harvard)

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Start-Up Company-Based Analyses

- 9,960 formed 1980-2013
  - 75% located in same state as institution
    - Every state except Alaska
      - 12.3% from California institutions*
      - 11.8% from Massachusetts institutions*
      - 389 by MIT
      - 624 by University of California System
      - 210 by University of Utah
  - 45% still active in 2013

AUTM Annual Licensing Activity Survey 1994-2013

* Through 2010

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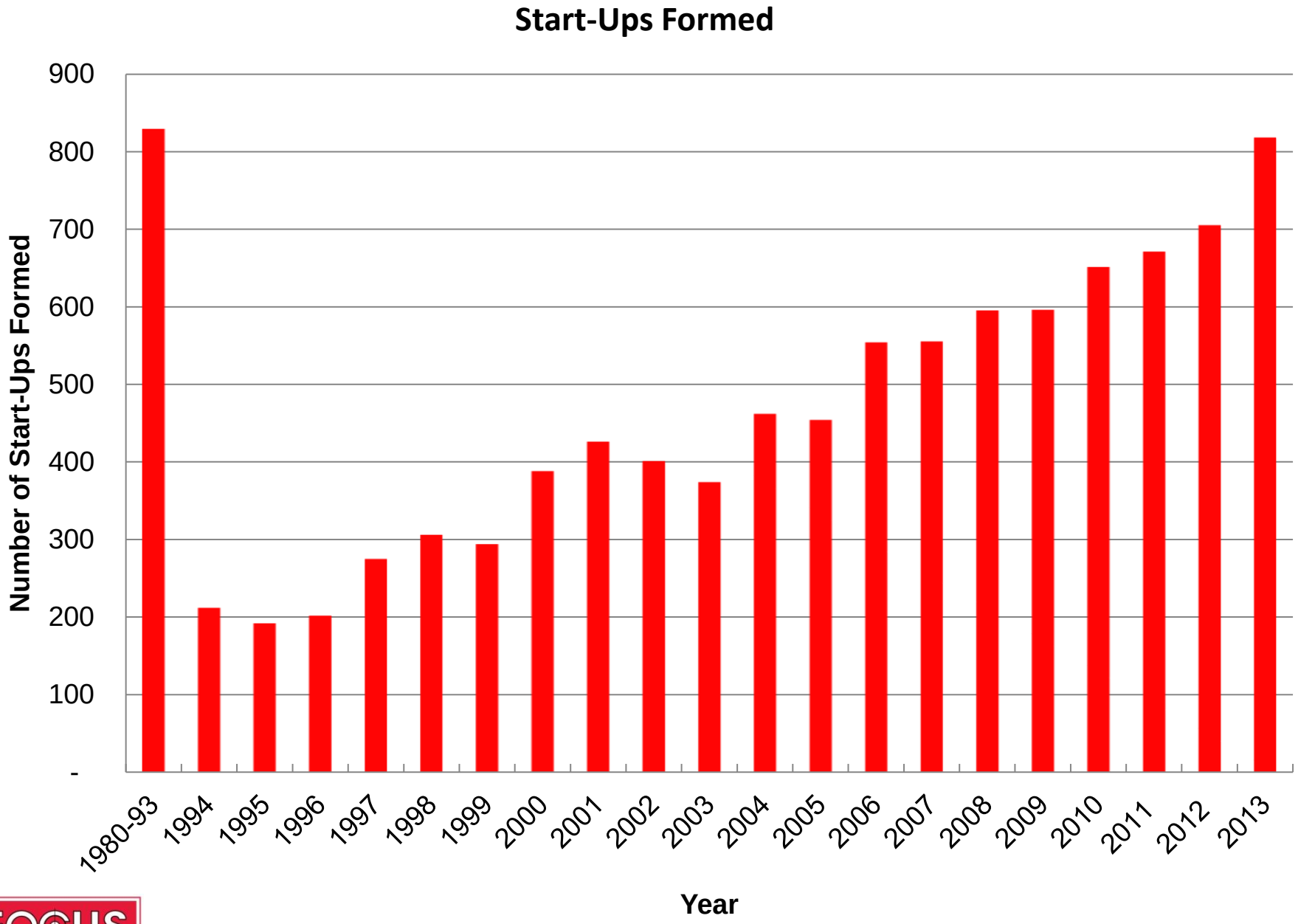

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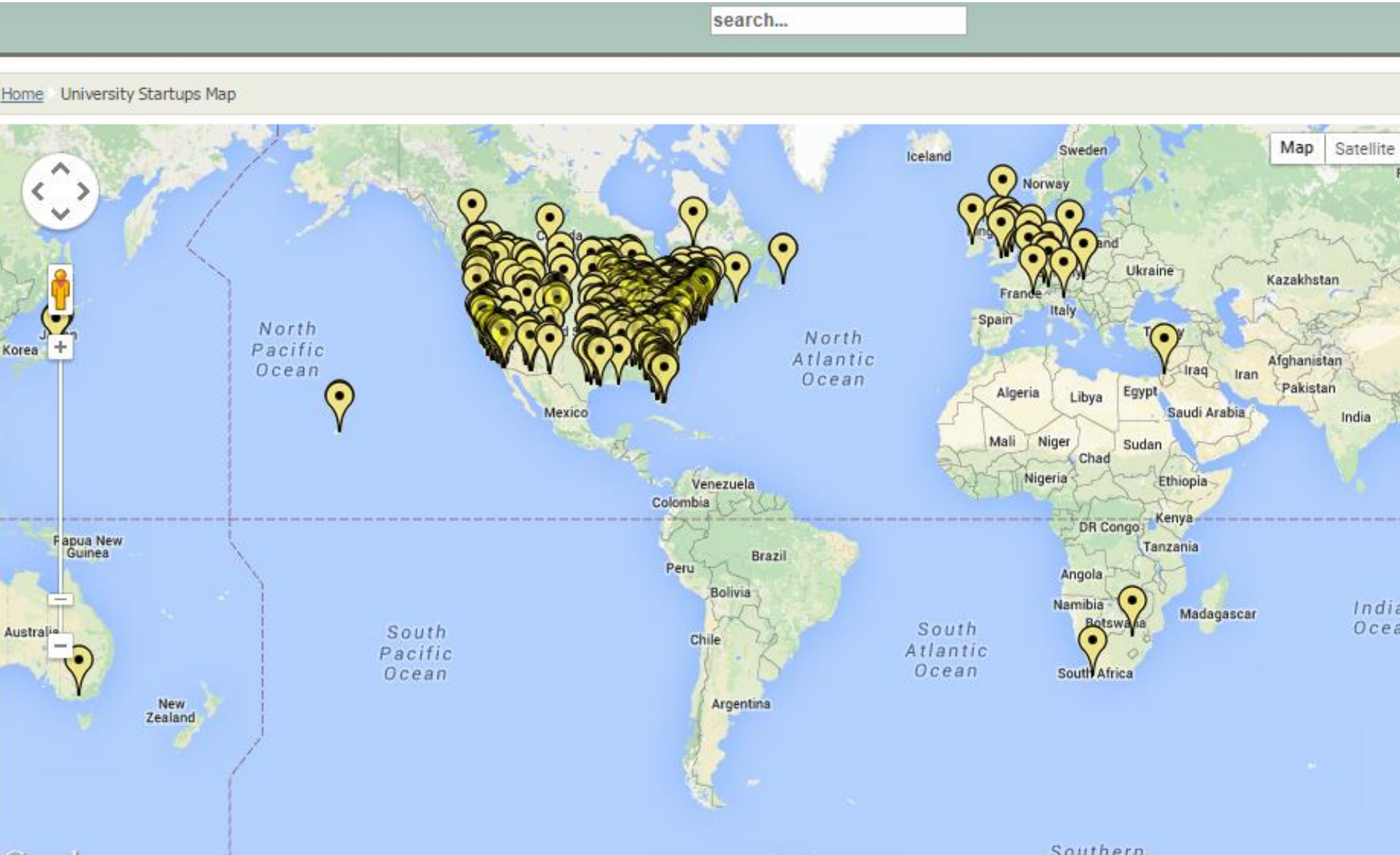
The AUTM-NCET Start-Up Map



100 SUCCESS STORIES

GOVERNMENT FUNDING

+

UNIVERSITY RESEARCH

=

INNOVATION, COMPANIES, JOBS

SPARKING ECONOMIC GROWTH

How federally funded university research creates innovation, new companies and jobs

THE SCIENCE COALITION

APRIL 2010

www.sciencecoalition.org

AUTM Studies

- Spin-out employment question asked since 2011
- ~35% response rate
- Generates low numbers
  - 15,335 total reported
    - Only NC State (7,516) and U. of Michigan (2,050) reported more than 1,000 employees
    - Only 20 institutions reported more than 100 employees
  - Average 11 employees per start-up
  - Extrapolates to only 46,000 employees
    - Google has 65,000 alone!
- Need to reboot this survey!

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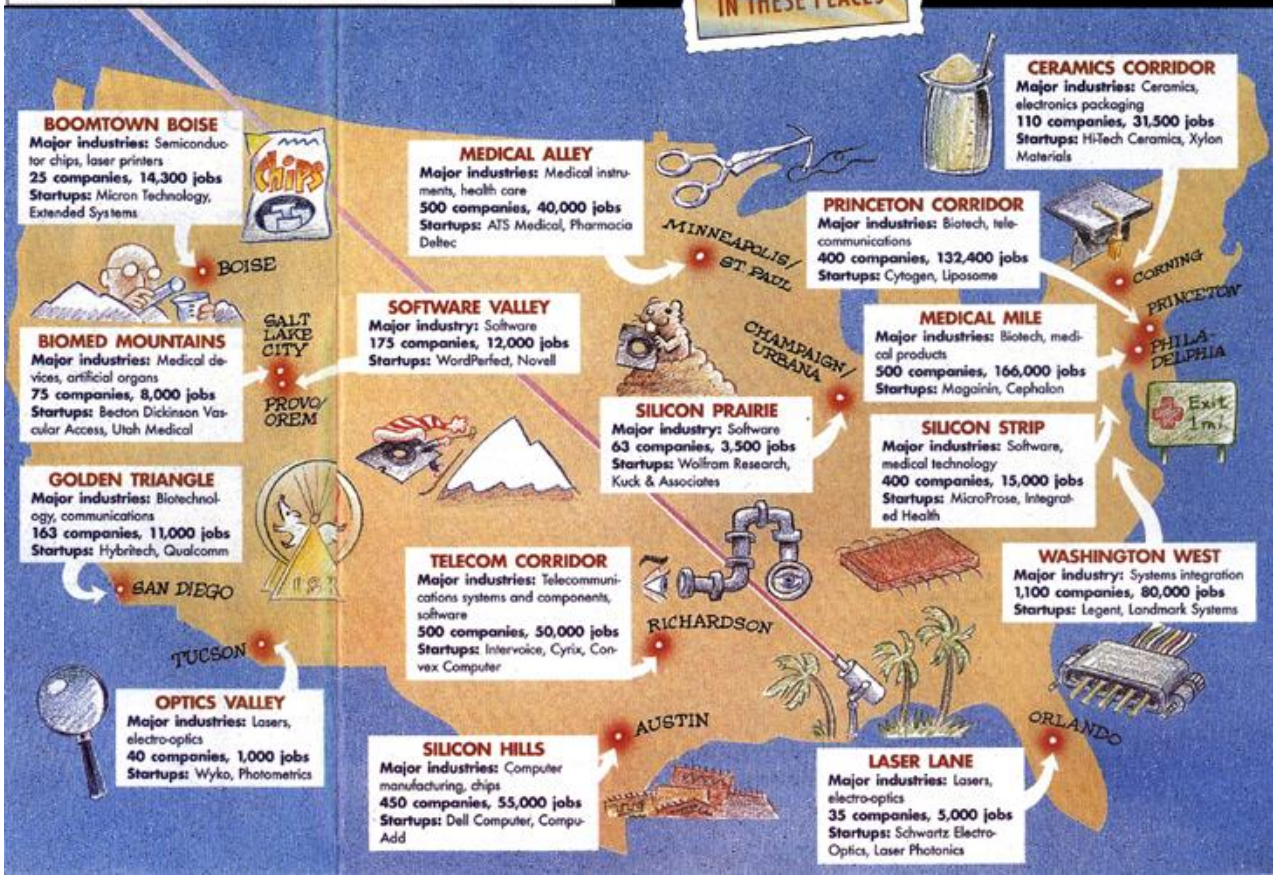
Triple Helix Analyses

October 19, 1992

HOT SPOTS

AMERICA'S NEW GROWTH REGIONS ARE BLOSSOMING DESPITE THE SLUMP

AT LEAST 600,000 PEOPLE HOLD HIGH-TECH JOBS IN THESE PLACES



Ingredients of a High Tech Cluster

- A major research university
- Quality of life
- Build on local industry
- Cooperation between local university, business and government.
- Technology transfer from the university
- Funding sources -- state, VC, angels
- Incubators

<u>Phases of Economic Development</u>

- Start-ups
- New division of major US company
- Foreign companies move in
- Export led growth

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Prime Example: The Pharmaceutical Industry in Massachusetts

The Ecosystem

- Universities
  - Pioneers in life sciences research
  - Most NIH funding in any Congressional District
  - 10 Nobel Prizes 1960-1980
  - Leaders in developing TLO's
- Funding
  - Massachusetts was the birthplace of organized venture capital
    - 1947 – American Research and Development Corporation
  - Substantial number of VC firms to fund the start-ups
  - Proximity to Wall Street a plus

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The Academic Medical Centers

Harvard	Massachusetts General Hospital
	Brigham & Women's Hospital
	Beth-Israel Deaconess Medical Center
	Children's Hospital
	Dana-Farber Cancer Institute
	Mass Eye and Ear Hospital
	Joslin Diabetes Center

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1970's and 80's – The University Spin-Outs

- In 1975, one pharmaceutical company in Massachusetts
  - US Headquarters of Astra AB of Sweden
- 1978 – Biotech companies started to spin out of Harvard, MIT, BU, Tufts
  - Biogen
  - Genetics Institute
  - Genzyme
  - Seragen
    - By and large, know-how spin-outs

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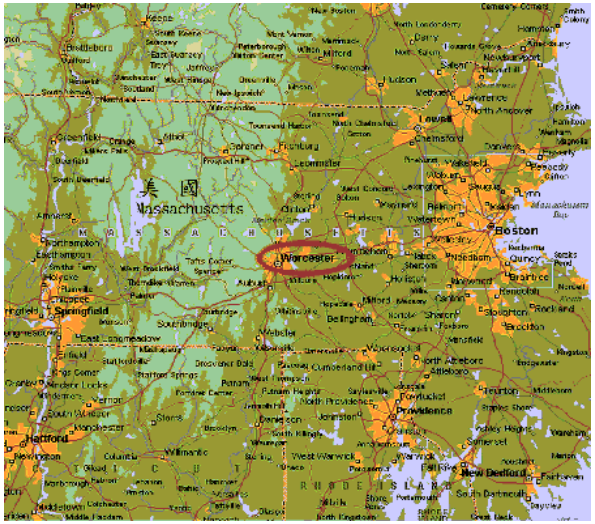
The Massachusetts Biotechnology Research Park

- 1984 – Massachusetts Biotechnology Research Park established in Worcester
  - First biotech-specific research park in the world
  - Across the street from U. Mass Medical Center
- First building:
  - Cambridge Biotechnology Corporation on floors 1 and 2
  - Incubator on floor 3



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1980's – The First Big Pharma's

- BASF was first major corporation to move to Massachusetts (1989)
  - Massachusetts Biotechnology Research Park
  - Highly restrictive recDNA rules in [illegible] 3 abroad
  - Invented Humira in Worcester
    - Abbott bought BASF Pharma
- An [illegible] Products acquire

BASF → Abbott → [illegible]

Wyeth → [illegible]

1995 – Rise of Biopharmaceutical Manufacturing

- Genzyme received substantial incentives to produce its first major product in Massachusetts

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biogen idec
gsk
GlaxoSmithKline
Alkermes
ALGETA
Celgene
Takeda
AMGEN
ARIAD
IMMUNOGEN, INC.
Eisai
AsahiKASEI
AstraZeneca
DSM
SUNOVION
Healthy bodies, healthy lives
Bristol-Myers Squibb
Ironwood
ENANTA
Pharmaceuticals
AMAG
PHARMACEUTICALS
MERCK
SERONO
CUBIST
PHARMACEUTICALS
KERYX
BIOPHARMACEUTICALS, INC
MERCK
Research Laboratories
abbvie
sanofi aventis
L'essentiel c'est la santé.
Shire
IPSEN
Innovation for patient care
pSivida
corp
Baxter
Johnson&Johnson
VERTEX
Pfizer
NOVARTIS
Meaningful Measurement and Social Impact of University Technology Commercialization

Summary

- Different impact methodologies all seem to lead to large numbers
  - ~$100 billion in current impact
    - Non-overlapping sectors
      - Total is probably significantly higher
  - For perspective, net farm income in 2013 was $120 billion

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Some Favorites

- Biggest impact on the greatest number of people:
  - Dead heat
    - Google
    - Mosaic
    - Eudora
  - Runner Up
    - Akamai
- Biggest financial impact:
  - Cabilly
  - My estimate of product sales: $143 billion
    - All chimerized antibodies till 2006
    - All synthetic antibodies 2001-2018

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Thank you for listening.

Questions?

astevens@fipgllc.com

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