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Bioeconomy for New Solutions in Medical Technology: Massachusetts Experience

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Topics

- Profile of life sciences in Massachusetts
- Institutional landscape
- Policy issues and programs
- Observations and forward perspective

Biotech/MedTech Interface

- Arsenal Medical
- 480 Biomedical
- Semprus BioSciences
- BIND Biosciences for;
- T2 Biosystems for.

- nanofiber-based drug delivery
- resorbable scaffolds for tissue growth
- medical device coatings;
- targeted nanoparticle-based therapeutics
- nanoparticle-based diagnostics

Biotech/MedTech Interface

- MicroCHIPS
- Combinent Biomedical Systems
- Momenta Pharmaceuticals
- Seventh System Biosystems
- silicon-chip-based drug delivery
- transvaginal drug delivery
- for complex sugar-based therapeutics
- microneedle patch for drawing blood outside clinical settings

Prof. Robert Langer, MIT

President Barack Obama awards MIT biomedical engineer Robert Langer the National Medal of Technology and Innovation in 2013 in Washington, D.C. Photo: Brendan Hoffman/Getty Images Amy Nordrum, IBT Times, 2015

Life Sciences in Massachusetts

- Biopharma companies: 550
- Medical device companies: 400
- Active CMO’s and CRO’s for outsourcing R&D
- VC funding 2014 $1.9 billion; 2015 $2 billion
- 110,000 in life science workforce
- 122 Colleges and universities
- Over $2 billion yearly in competitive NIH funding

Source: MLSC, 2016

Institutional Landscape

- Government agencies, legislative committees
- Hospitals, universities, research centers
- Professional services
- Press and communications media
- Public interest groups
- Patient advocacy groups
- Investment community
- Big pharma, big medtech, SMEs
- Trade associations and cluster organizations
- International presence

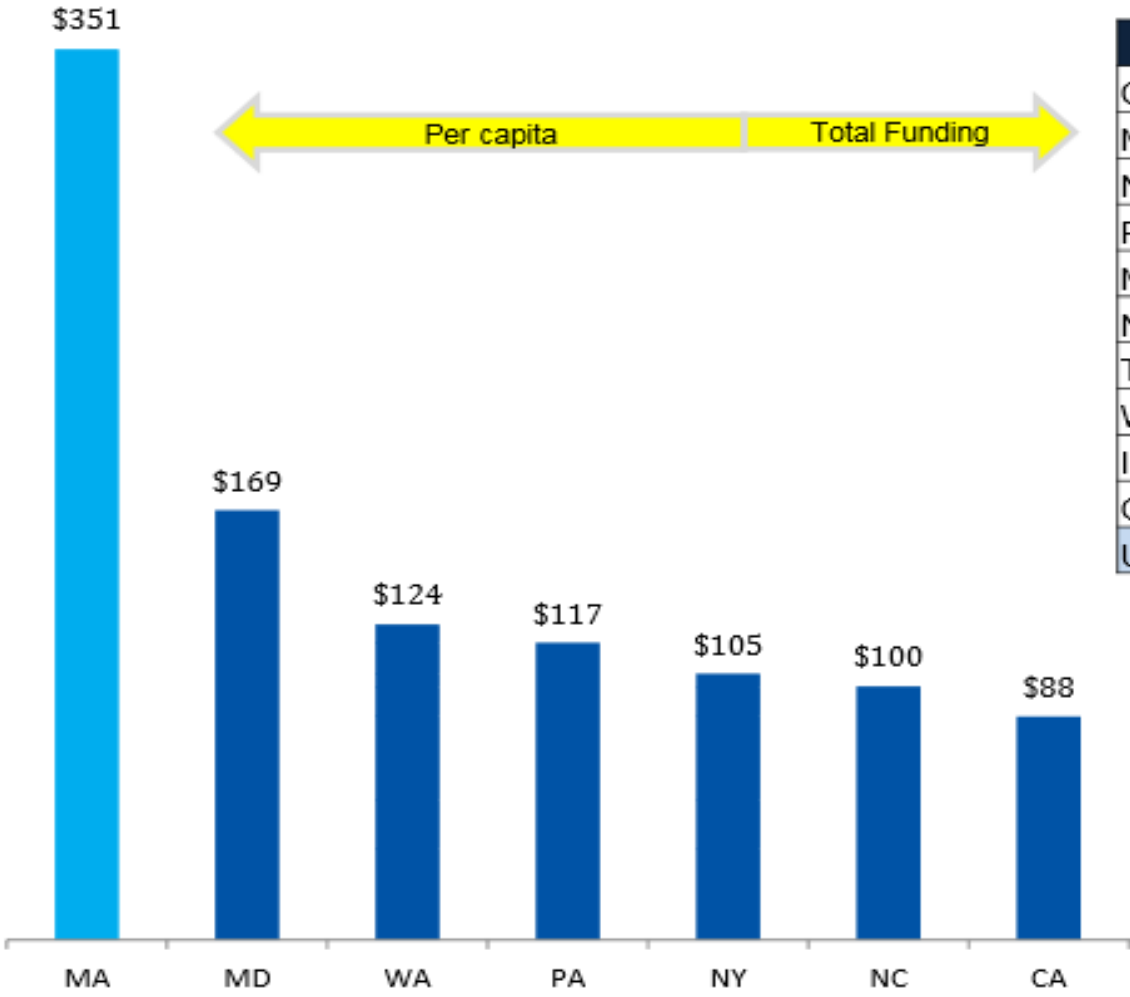
Growth in number of biopharma firms Massachusetts

- 1980: 5 firms
- 1985: 25 firms
- 1990: 115 firms
- 1995: 150 firms
- 2000: 250 firms
- 2004: 280 firms
- 2016: >550 firms

US federal agencies involved

- Health Human Services
- National Institutes of Health
- National Science Foundation
- Environmental Protection Agency
- Food and Drug Administration
- Department of Defense
- Department of Energy
- Department of Agriculture
- Department of Commerce
  - NIST
  - EDA

NIH funding per capita



Per capita | Total Funding

State	Funding
California	$3,410,496,236
Massachusetts	$2,364,750,629
New York	$2,069,300,604
Pennsylvania	$1,496,869,899
Maryland	$1,010,931,562
North Carolina	$991,876,570
Texas	$972,156,544
Washington	$876,933,041
Illinois	$710,197,186
Ohio	$633,220,134
US	$22,251,657,294

Source: NIH, Research Portfolio Online Reporting, U.S. Census Bureau

NIH Funding of US Research Hospitals

Organization	City	State	Awards	Funding
Massachusetts General Hospital	Boston	MA	770	$349,524,060
Brigham & Women's Hospital	Boston	MA	558	$319,409,432
Children's Hospital Corporation	Boston	MA	301	$122,949,506
Dana-Farber Cancer Inst.	Boston	MA	207	$122,652,215
Children's Hospital of Philadelphia	Philadelphia	PA	192	$112,146,779
Beth Israel Deaconess Medical Center	Boston	MA	240	$108,156,442
Cincinnati Childrens Hosp Med Ctr	Cincinnati	OH	251	$97,854,412
St. Jude Children's Research Hospital	Memphis	TN	89	$48,650,426
New York State Psychiatric Institute	New York	NY	99	$46,903,956
Seattle Children's Hospital	Seattle	WA	84	$39,068,563
Boston Medical Center	Boston	MA	85	$38,130,340
Cedars-Sinai Medical Center	Los Angeles	CA	76	$34,423,825
Tufts Medical Center	Boston	MA	45	$27,737,457
McLean Hospital	Belmont	MA	81	$25,413,803

Source: NIH, Research Portfolio Online Reporting

Venture Capital Funding in Massachusetts (Sample Year 2014)

Biotechnology	$ 1,822,294,200
Software	$ 1,059,746,500
Medical Devices	$ 338,705,300
IT Services	$ 233,346,600
Retail & Distribution	$ 223,657,100
Electronics & Instrumentation	$ 189,158,000
Media & Entertainment	$ 146,199,100
Business Products	$ 129,581,000
Industrial & Energy	$ 128,282,300
Consumer Products	$ 100,178,900
Computers & Peripherals	$ 69,749,800
Semiconductors	$ 67,952,000
Telecommunications	$ 12,250,000
Healthcare Services	$ 3,000,000
Other	$ 1,484,000

MassTech 2014

State sponsored agencies

- Massachusetts Life Sciences Center
- supports life sciences innovation, research, development and commercialization.
- Mass Technology Collaborative
- fosters growth of dynamic, innovative industry clusters.
- MassDevelopment
- economic development and finance agency stimulating business growth.

Cluster Organizations

- Massachusetts Biotechnology Council
- represents and provides support for biotech community.
- Massachusetts Medical Device Industry Council
- medical device manufacturers and suppliers group.
- Mass Technology Leadership Council
- network for technology executives, investors and entrepreneurs.

Issues and Programs

- Evolution of issues
- Responses at the national level
- Program responses at the state level
- Impact on local innovation ecosystem
- Bioeconomy and medical technology
- Interdisciplinary challenges

US Industry Issues for Biotech 1990 - 2000

1990

- Animal patents
- State Activity
- Science literacy / training
- Health care costs
- Biotech in Europe
- Food Safety
- Liability Insurance
- Regulatory resources
- Public relations / perceptions

Industrial Biotech. Assn.

2000

- Medicare
- Stem Cell Research
- Genetic Discrimination
- Intellectual Property
- Technology Transfer
- Capital Formation
- Agricultural Biotech
- Energy Legislation
- Farm Legislation

Biotech. Indus. Org.

US Industry Issues for Biotech 2010

BIO

- Stem cell research
- Expansion of pediatric health services
- General healthcare reform
- Regulation of follow-on biologics
- Patent protection
- Bioenergy
- [Comparative effectiveness research]

MassBio

- Healthcare reform
- Drug importation
- SBIR eligibility
- R&D credits
- Stem cell research
- Increased NIH funding,
- Follow-on biologics
- FDA funding
- Protection of biotech patents
- Gift disclosures
- [Public perception]

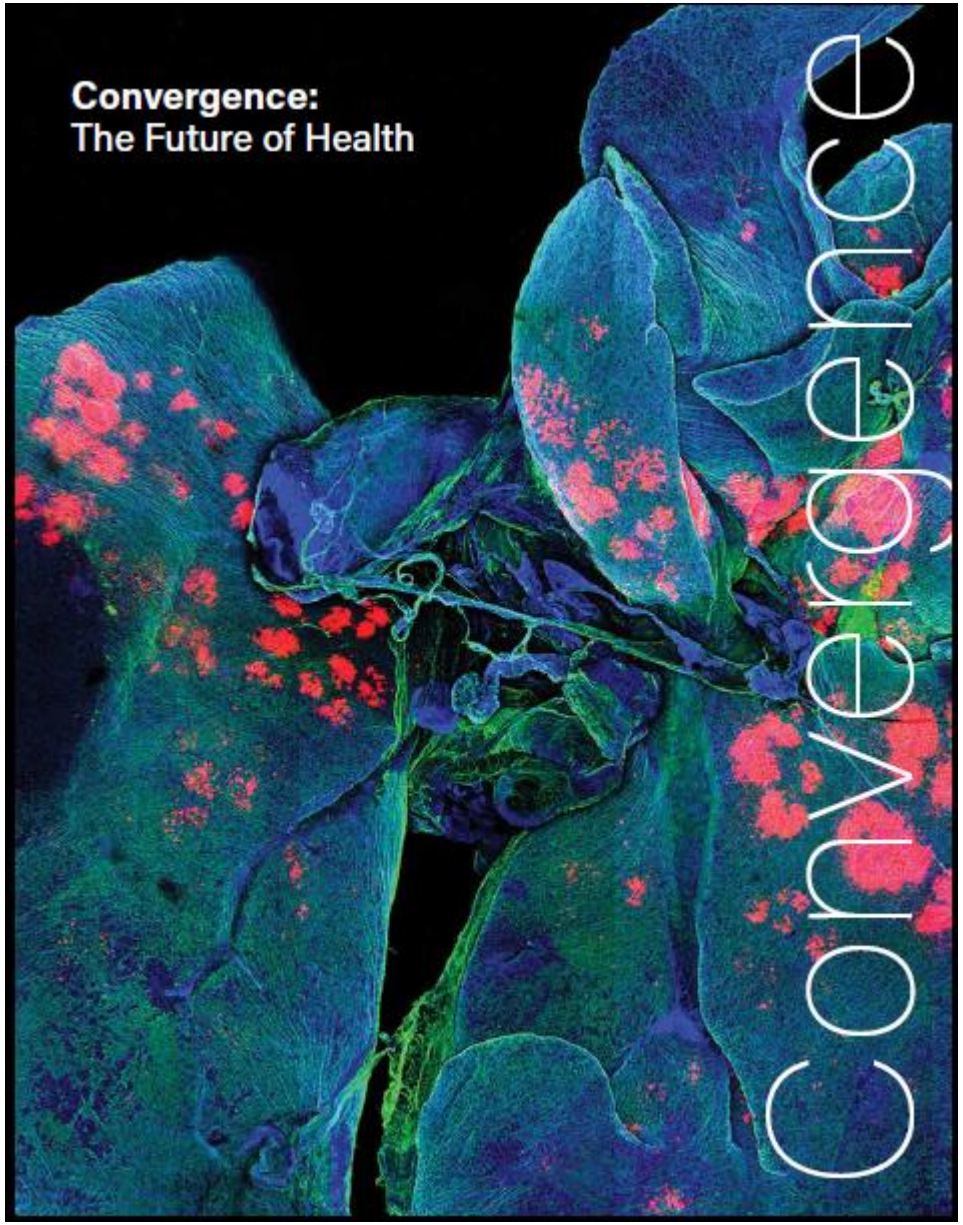
Biotechnology Industry Organization

Massachusetts Biotechnology Council

Continuing industry issues 2016

- Medicaid, Medicare, Affordable Care Act
- Drug prices and reimbursement
- Cost effectiveness
- Electronic medical records; big data interface
- Non-compete contracts
- Precision Medicine and companion diagnostics
- Digital health
- Open innovation and local innovation climate
- Technological convergence

Convergence: The Future of Health



Phillip Sharp
Institute Professor, MIT

Susan Hockfield
President Emerita, MIT

Tyler Jacks
Director, Koch Institute, MIT

MIT 2016

Convergence timeline

Timeline: The three revolutions

1953: Discovery of DNA Structure

1976: Biotech sector emerges with founding of Genentech

mid-2000s: Academic sectors start exploring convergence

2009: NAS releases *A New Biology* report

Molecular Biology Revolution

Genomics Revolution

Convergence Revolution

1950 1960 1970 1980 1990 2000 2010

1969: Salvador Luria, theorist of molecular biology, awarded Nobel Prize

2001: Human Genome Project, Celera publish working draft of human genome

Image and info credits (clockwise from top-left): DNAmazing.com, Gene.com, BioX.stanford.edu, qb3.org, mit.edu/ki, nap.edu, sciencemag.org, nature.com, nlm.nih.gov

Sharp, P., R. Langer, The Convergence of Engineering and the Life Sciences , *The Bridge, Fall 2013*

Selected US Convergence Initiatives

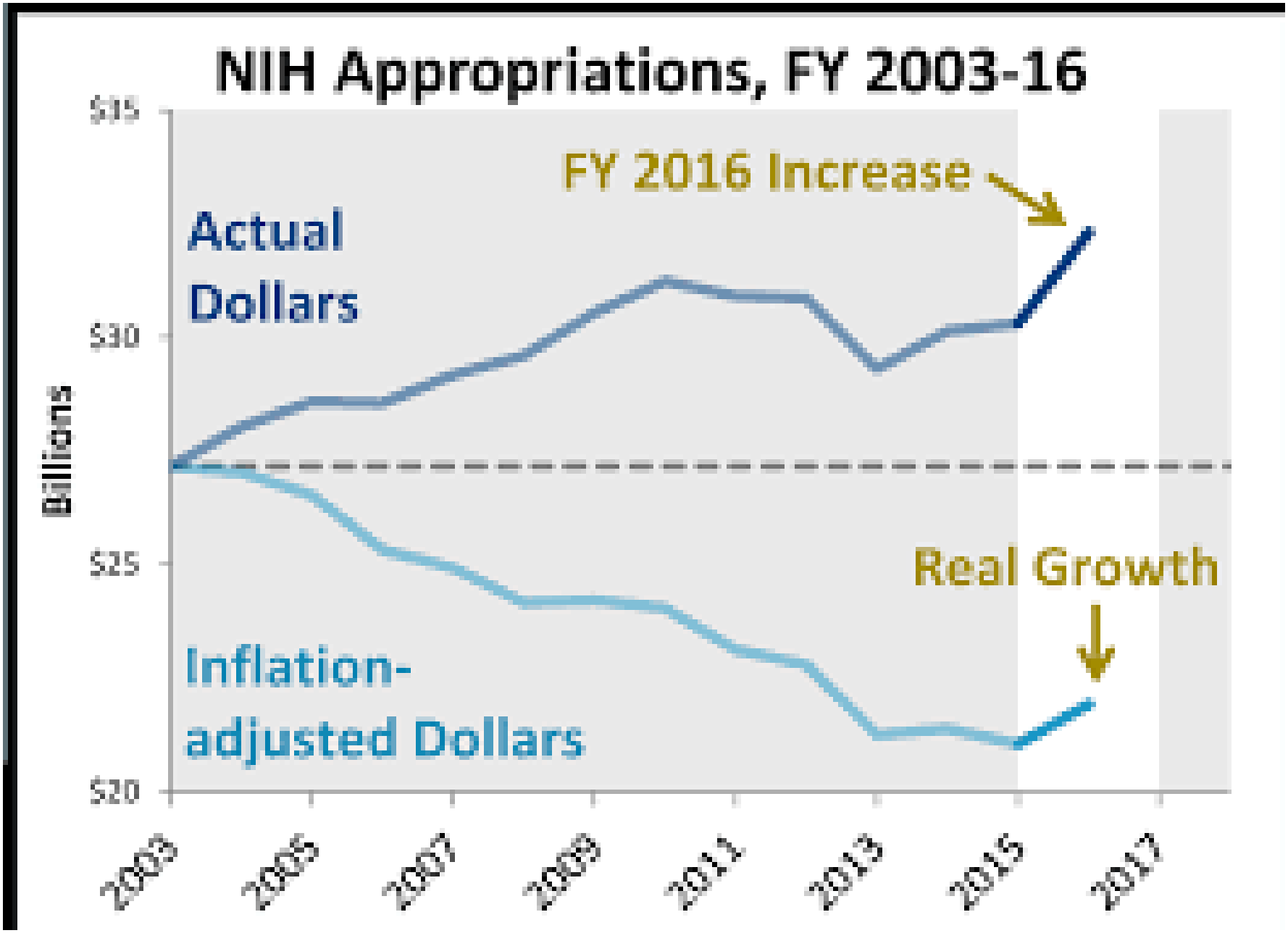
- Transformational Convergence Technology Office
- Biological Technologies Office
- Brain Initiative
- Precision Medicine Initiative
- Nanotechnology Initiative
- Cancer Moonshot Initiative

National Nanotechnology Initiative

- Central coordination science, engineering and technology R&D for nanoscale projects.
  - advance a world-class nanotechnology research and development ;
  - foster the transfer of new technologies into products for commercial and public benefit;
  - develop educational resources, a skilled workforce, and the supporting infrastructure;
  - support responsible development of nanotechnology.
- $1.4 billion

Cancer Moonshot Initiative

- Announced by President Obama January 2016
- Led by Vice President Biden
- $1 billion for jumpstart
- Collaboration across disciplines
- Goals:
  - accelerate cancer research.
  - make more therapies available to more patients,
  - Improve ability to prevent cancer and detect it at an early stage.


NIH Appropriations, FY 2003-16
Billions
$35
$30
$25
$20
FY 2016 Increase
Actual Dollars
Real Growth
Inflation-adjusted Dollars
2003
2005
2007
2009
2011
2013
2015
2017

Source: NIH

Observations and Forward Perspective

- Sequential dynamics of medtech and biotech initiatives .
- Bioeconomy impact on:
  - public sector programs
  - private sector financing
  - cluster organizations
  - real estate and quality of life
  - workforce
  - political dialogue
  - innovation climate
- Minimal coordination

Structural/Functional Adaptations

- Adaptations at Universities
  - Technology licensing offices
  - Patent policies
  - Conflict of interest provisions
  - Industrial liaison offices
- Adaptations in Government
  - Dedicated offices
  - Special instruments
  - Locational incentives
- Adaptations in Private Sector
  - Creation of associations
  - Collaboration of associations
  - Industry consolidation
  - Big pharma partnerships
  - Professional services

Ongoing challenges

- Projected demographic trends
- Affordable Care Act (Obamacare)
  - Emphasis on cost effectiveness
  - Value-based business model
- Regulatory reform
- Multi-centered decision making
- Increased stakeholder involvement
- Expansion of international value chain

Thank you

www.BioAmericas.org