

The Promise of Biotechnology and Idaho's Role



Growing Interest in Biosciences

The potential of bioscience technologies to improve human health, agriculture and nutrition as well as preserving and improving our environment has gained significant recognition world wide.

Many states and countries have put in place initiatives to improve the economic and regulatory climate in order to facilitate bioscience industry development.



Why the Interest?

- Public attention to human genomics
- \$ Billions allocated to life science and biotechnology research & development
- Investors more patient with capital in post dot.com bust
- Increase in citizen interest in human health and disease prevention
- And unfortunately, headlines like:

“Building a Raelian Nation Clone by Clone”

The Times (London) April 17, 2002

Industry Focal Points

There are numerous issues that can effect the development of the biotechnology industry.

- I.P. Protection
- Technology Transfer
- Capital Formation
- Bioethics
- Drug Safety
- Reimbursement
- Agricultural Biotech
- Industrial Biotech
- BioSecurity



Evolution Dictates Focus

Concern about public policy issues in the bioscience industry varies widely depending on the stage of evolution

- Early stage companies tend to focus issues like IP protection and access to capital
- Later stage companies are more concerned with issues like regulatory burden, tax policy and reimbursement



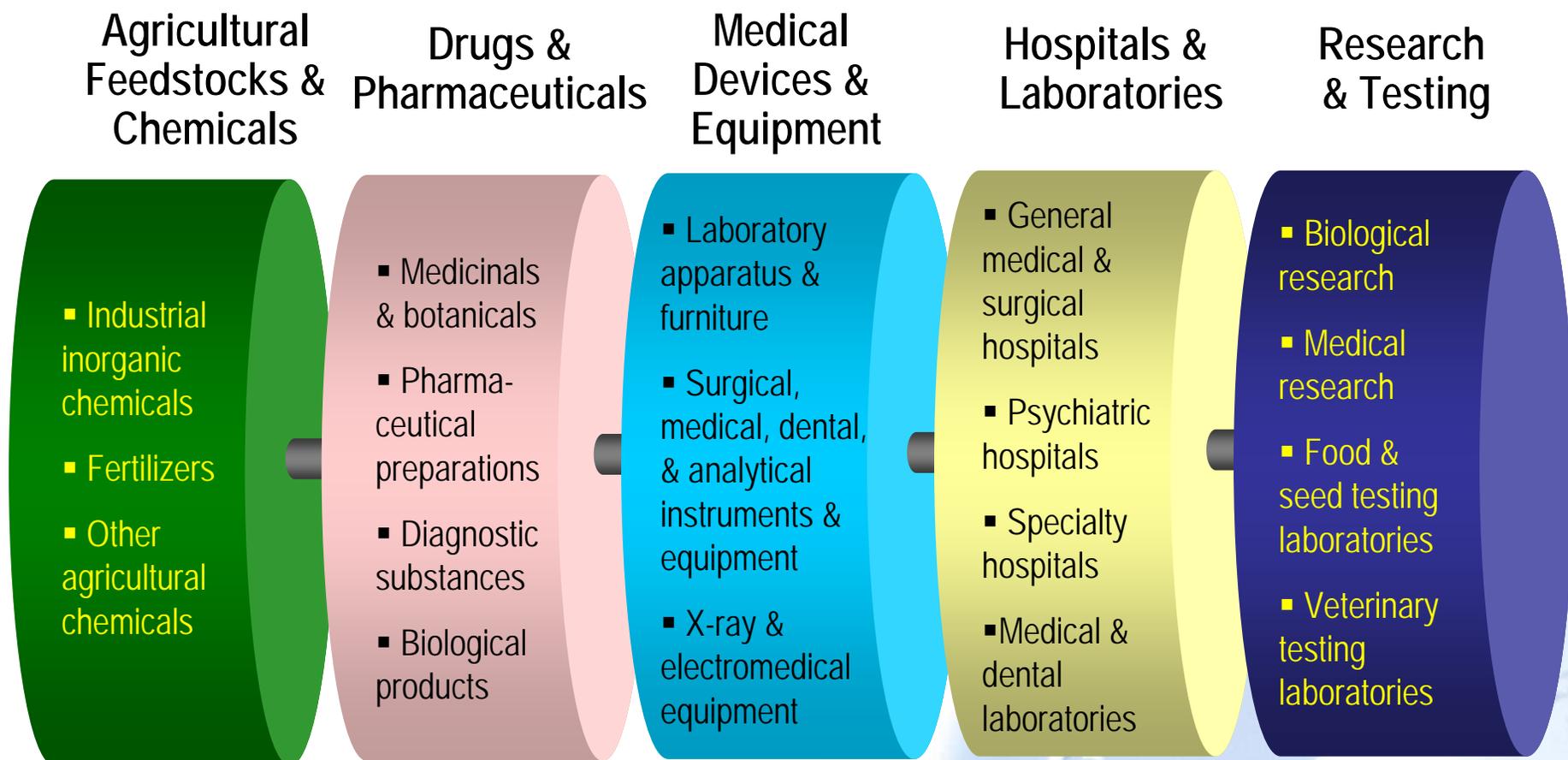
Laboratories of Innovation: State Bioscience Initiatives 2004



A PDF version of the report is available on the BIO website at www.bio.org under the “State Government” section



Defining the Biosciences



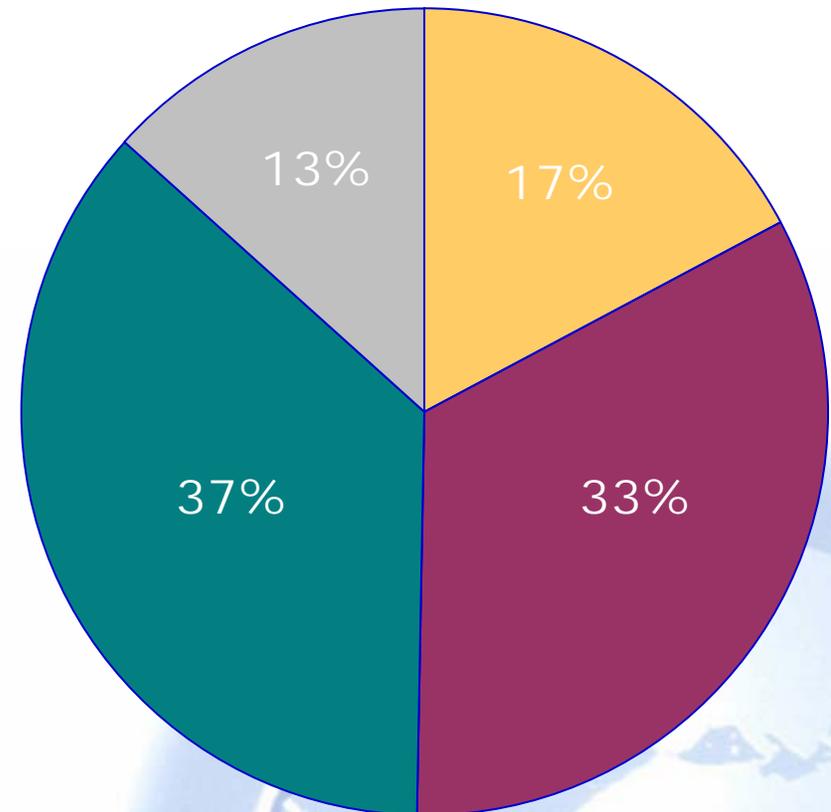
Findings and Summary

- **885,000 people**, located in over **17,000 companies** across all 50 states, are employed in the biosciences – a figure significantly surpassing previous efforts to track the industry.
- **Forty states** are now targeting biosciences today compared to 14 states in 2001; many are strategically targeting specific niches, based on their research and industry strengths, (e.g., biomanufacturing)



The Bioscience Subsectors

- Agricultural Feedstock & Chemicals
- Drugs & Pharmaceuticals
- Medical Devices & Equipment
- Research & Testing



The Bioscience Subsectors

Subsector	# Co.s	# Emp.s	Avg. Salary	% Growth*
Agriculture	3,337	153,581	\$55,261	- 7.5%
Drugs & Pharmaceuticals	2,511	291,268	<u>\$73,731</u>	<u>+ 4%</u>
Medical Devices	<u>6,175</u>	<u>322,881</u>	\$52,000	- 2%
Research & Testing	5,000	117,638	\$73,500	+ 1%

Rationale for State Interest

- Investment in the biosciences can lead to improving health care, a cleaner environment and healthier foods
- Biosciences are expected to grow at faster rate, in the next decade, than any other industry sector – **13% greater than average growth rate for overall U.S. employment**
- Biosciences provide a wide breadth of opportunities in the various subsectors
- Biosciences offer high-skill, high-wage jobs across a range of occupations - **\$26,000 (US) more than the national average for the entire private sector**



High Paying Jobs

U.S. Average Annual Wages per Employee 2003*

Drugs & Pharmaceuticals	\$73,731
Research & Testing	\$73,553
TOTAL BIOSCIENCES	\$62,555
Finance & Insurance	\$58,324
Information	\$55,588
Agricultural Feedstock & Chemicals	\$55,261
Medical Devices & Equipment	\$51,936
Manufacturing	\$44,277
Construction	\$38,097
Transportation & Warehousing	\$36,695
US Total Private Sector	\$35,925
Real Estate	\$33,238

* Wages are based on the second quarter of 2003 ES-202 data from the Department of Labor, Bureau of Labor Statistics. The data from BLS is considered preliminary according to the Department of Labor.

Why focus on the biosciences?

- Bioscience industries provide stability because demand for medical-related and food products remains fairly constant year after year
- Employment opportunities across the spectrum of experience and responsibility

medical doctor

nurse

healthcare technician

chemical technician

research scientist

lab tech

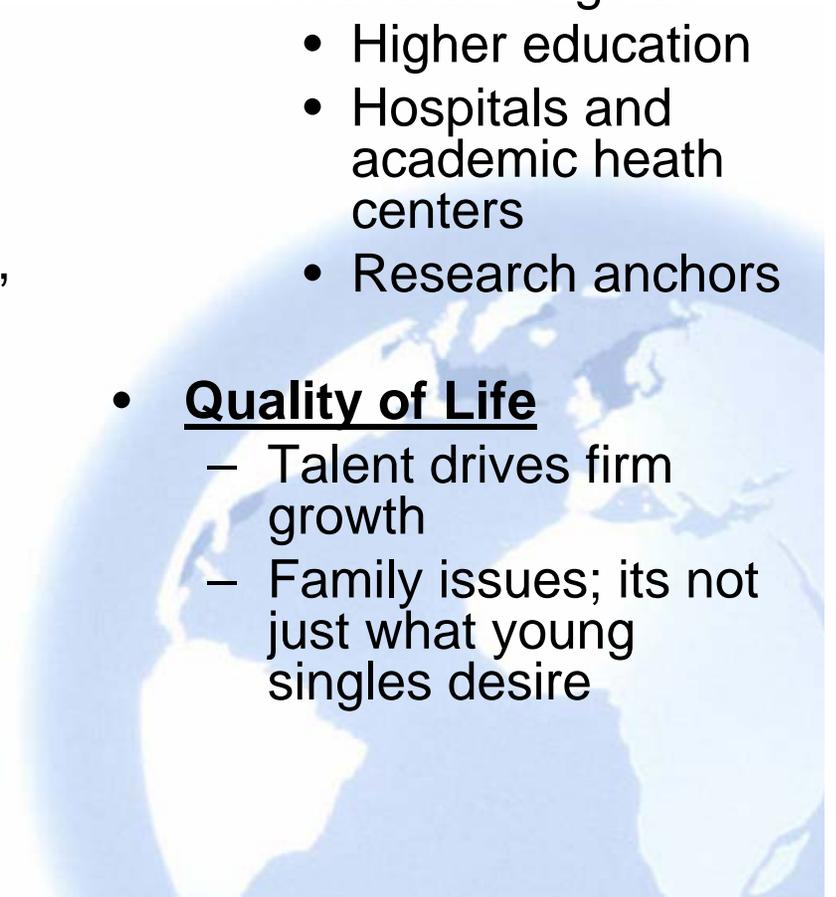
production technician

engineer

Multiplier Effect: Thousands of jobs are created to support bioscience companies e.g., construction, maintenance and service related jobs

Industry Drivers

- **Talent**
 - Chief Scientists and Technologists
 - Bench Scientists and Engineers
 - Technicians
 - Serial Entrepreneurial Managers (Regulatory, Sales and Marketing, Quality Control)
- **Capital**
 - Angel Investors
 - Pre-Seed/Seed
 - Venture Capital
 - Working Capital
- **Technology**
 - Infrastructure
 - Research Engines
 - Higher education
 - Hospitals and academic health centers
 - Research anchors
- **Quality of Life**
 - Talent drives firm growth
 - Family issues; its not just what young singles desire



Capital Financing Needs

<u>Company Stage</u>	<u>Private investment per company</u>
Proof of Concept	\$25,000 – \$100,000
Pre-seed	\$50,000 – \$500,000
Seed	\$150,000 – \$2 million
Early-stage	\$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>



Public Policy Issues

Federal

Medicare Reimbursement

Tax Policy

SBIR Eligibility

Stem Cell Research

Intellectual Property

Drug Safety Issues

Agricultural Issues



State

Medicaid Reimbursement

Importation

Stem Cell Research

Agricultural Issues

Capital Formation



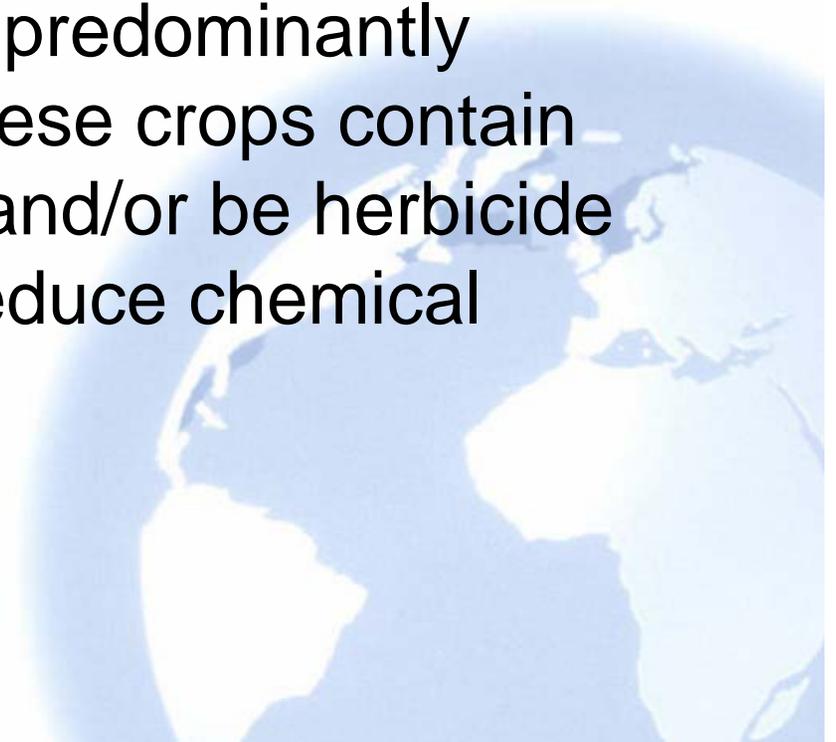
Beyond Economic Development

Although many states are working diligently to accommodate bioscience industry needs, there are numerous public policy issues being considered that could seriously impact industry development in the U.S.



Ag Biotechnology

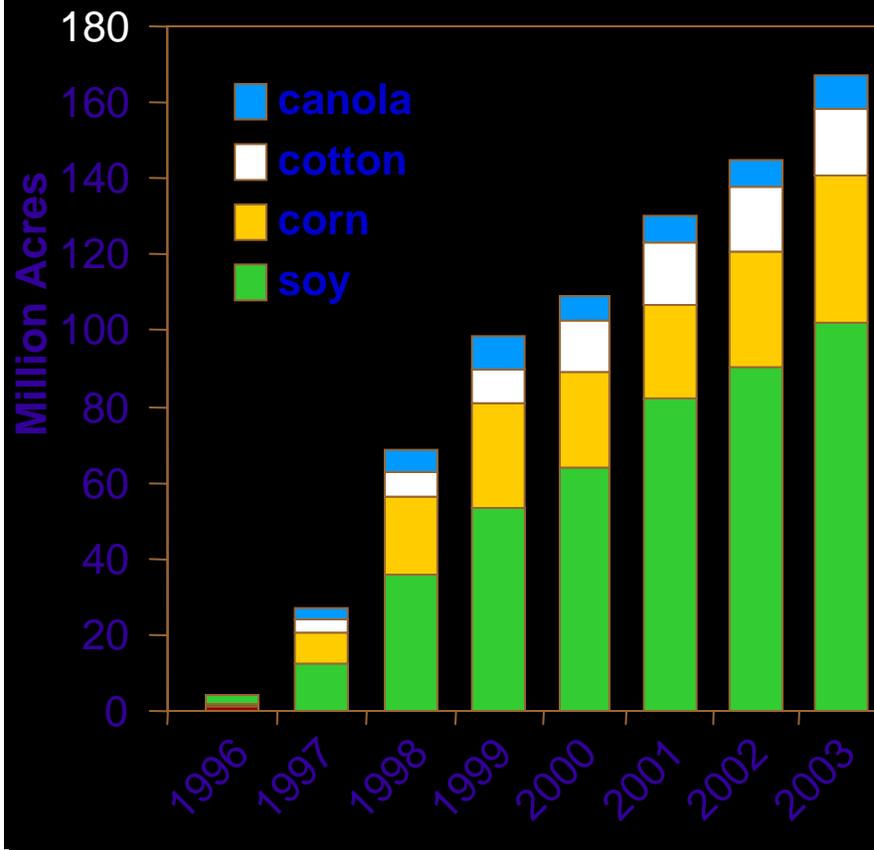
Biotechnology has revolutionized production agriculture. Worldwide, there are now 1 billion acres of biotechnology crops in production. Major commodity crops, including corn, soy, canola and cotton are now predominantly biotechnology varieties. These crops contain traits to either resist pests and/or be herbicide tolerant with the intent to reduce chemical inputs and increase yield.



A World of Biotechnology Benefits

More and Better Food for a Growing Population

Biotech Crops - Planted by 7 million Farmers in 18 countries



US Agriculture Impact:

- - **46 Million pounds less pesticide per yr**
- - **Food Security**
 - **4 Billion pound increase in food and fiber per yr**
- - **Economic Returns**
 - **Over \$1.5 Billion in increased income**

BIOTECHNOLOGY

INDUSTRY

Source: C. James, 2003. ISAAA

ORGANIZATION (International Service for the Acquisition of Agri-Biotech Applications)

Source: Gianessi et al., 2002. NCFAP
(National Center of Food and Agricultural Policy)

Products with Quality Attributes

- Better flavor, color, texture and extended freshness
- Improved processing characteristics
- Enhanced nutritional profiles – vitamins, nutrients, proteins and fats
- Decreased allergenicity of food



Ag meets Pharma

Significant progress in developing plant-made proteins and chemicals. Opportunities for diversifying production agriculture in areas of human therapeutics and industrial proteins and chemicals.

Again, concerns from commodity groups/food manufacturers about potential co-mingling with food supply.



Biotechnology PMP Committee

BIO PMP Industry Companies

- Chlorogen
- Planet Biotech
- SemBioSys
- Medicago
- Ventria BioScience
- Dow/Dow Agro Sciences
- Epicyte
- Meristem Therapeutics
- ProdiGene
- Syngenta
- Biolex
- Dupont
- Bayer CropScience

Accomplishments to date:

- Industry reference document for confinement and development of PMP in the US (May, 02)
- Outreach to stakeholders (medical health, agri /food/feed/fiber chain, academics)
- Education: fact sheets, Q&As
- Pew Public Forum (July, 02)
- Industry reference document on contingency plans, e.g., sentinel testing, validated detection assays
- CACCP* approaches for PMPs

Bio

BIOTECHNOLOGY

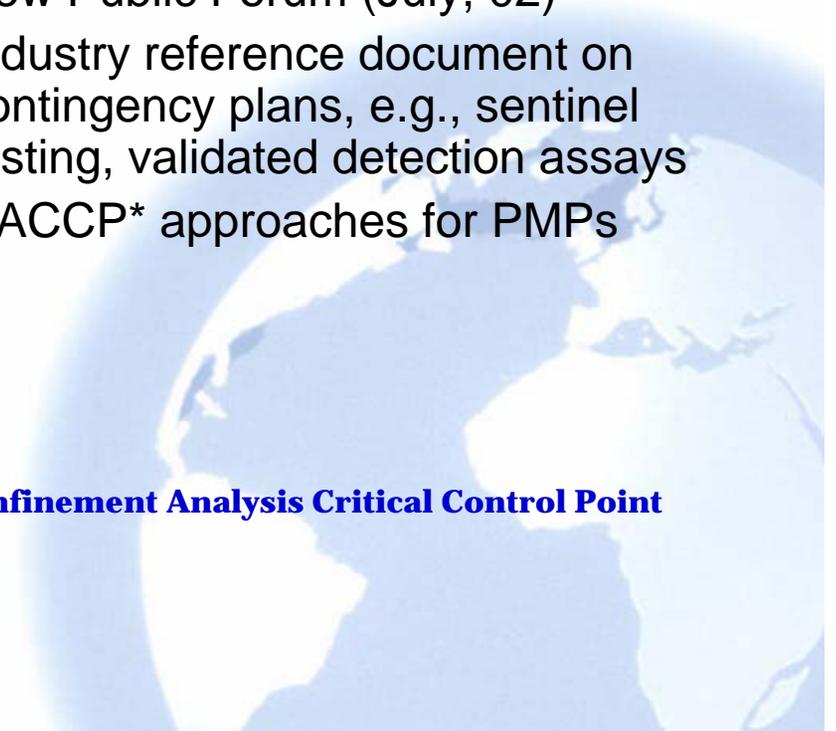
INDUSTRY
ORGANIZATION

Tobacco
Safflower
Duckweed



Alfalfa
Rice
Corn

* **Confinement Analysis Critical Control Point**



Industrial Biotechnology

Employ the techniques of biotechnology improve, and reduce the environmental impact of, industrial manufacturing.

- Novel Polymers
- Bio-based fuels
- Biocatalysts – Industrial Enzymes
- Nanotechnology



Key Issues Going Forward

- Adventitious Presence
- BioSafety Protocol
- USDA/APHIS Regulatory Reform
- Animal Biotechnology Regulatory Policy
- Coexistence/Liability
- State Issues



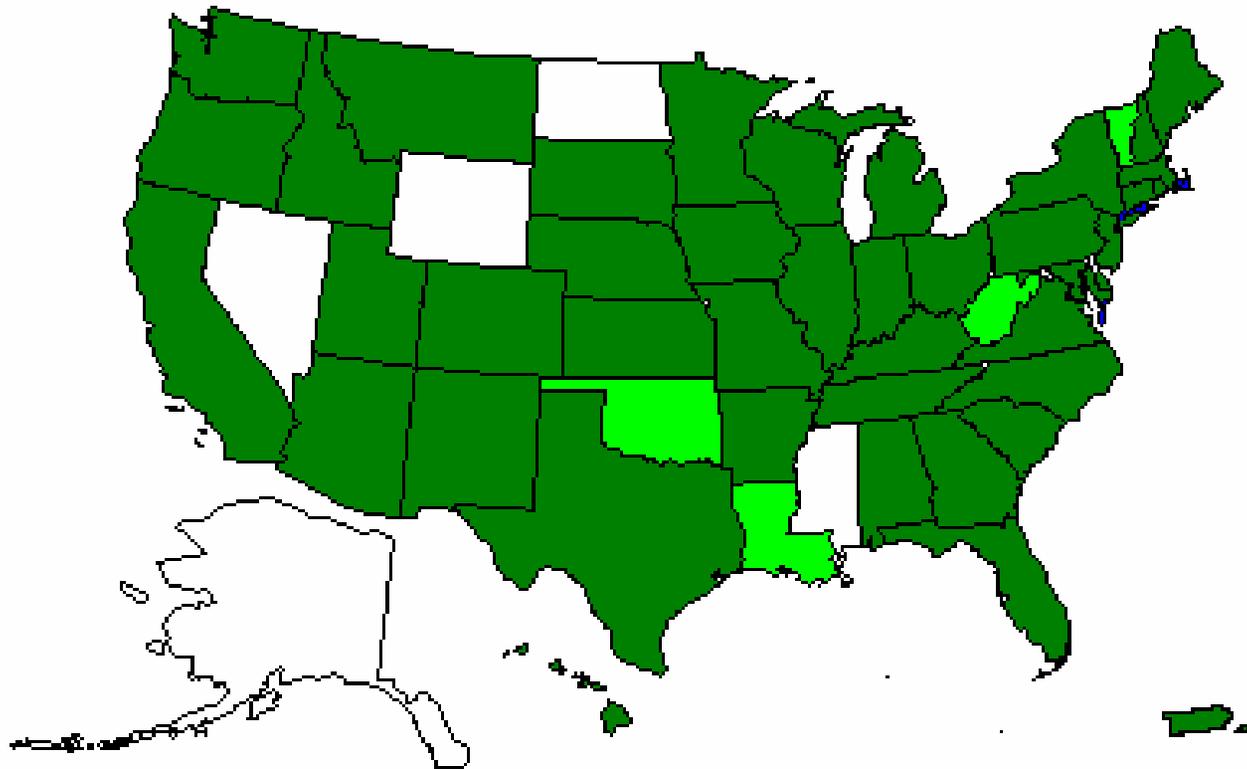
Challenges to Ag Biotech

The biotechnology industry faces significant challenges in the states

- Moratoria on GM crops
- Increasing liability standards for GM mfrs/growers
- Labeling of foods with GM ingredients
- Restriction on animal biotechnology products
- Animal Cloning restrictions



BIO State Affiliate Organizations



42 states (including Puerto Rico) have dedicated bioscience associations

Capital, Capital, Capital!

In the past several years, numerous states have put in place strategies and incentives to grow vibrant life science clusters. These programs run the gamut from building facilities for early stage company development to establishing capital access funds



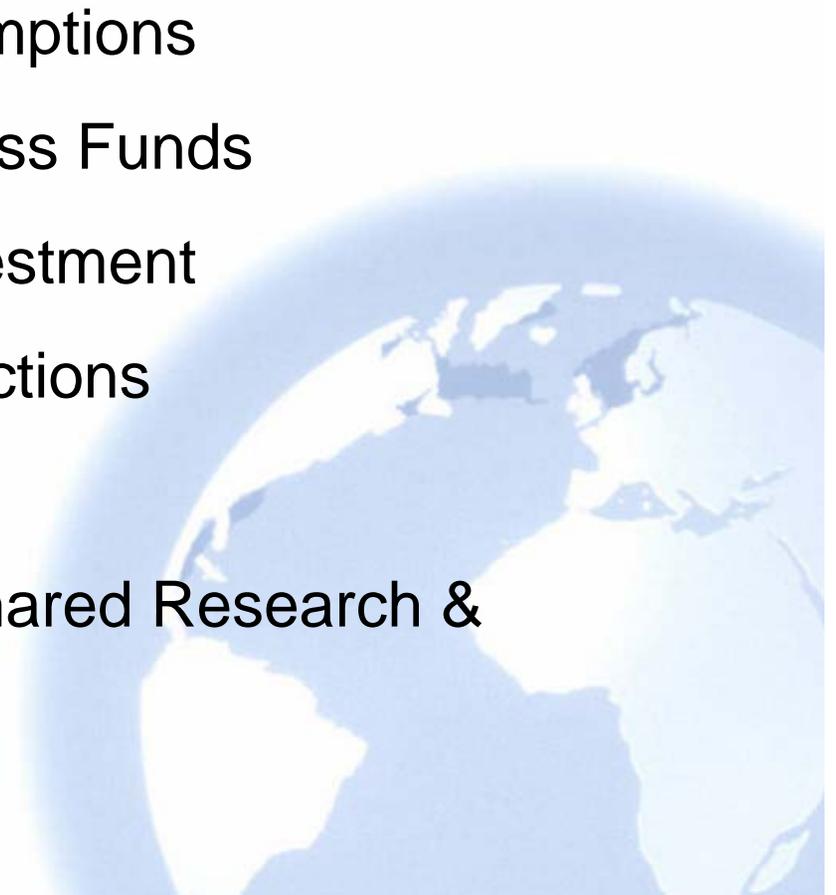
State Approaches to Addressing Risk Capital

- Use state general and pension funds to invest in privately managed venture funds
- Offer state assistance to firms to leverage Federal SBIR funds
- Provide technical assistance to companies to better access private financing sources
- Offer R&D tax credits
- Form pre-seed/seed or later stage funds



State Capital Formation Priorities

- Research and Development Tax Credits
- Tax Credit Transferability
- Sales and Use Tax Exemptions
- Creation of Capital Access Funds
- State Pension Fund Investment
- Capital Gains Tax Reductions
- Investment Tax Credit
- Developing Incubator/Shared Research & Manufacturing Facilities



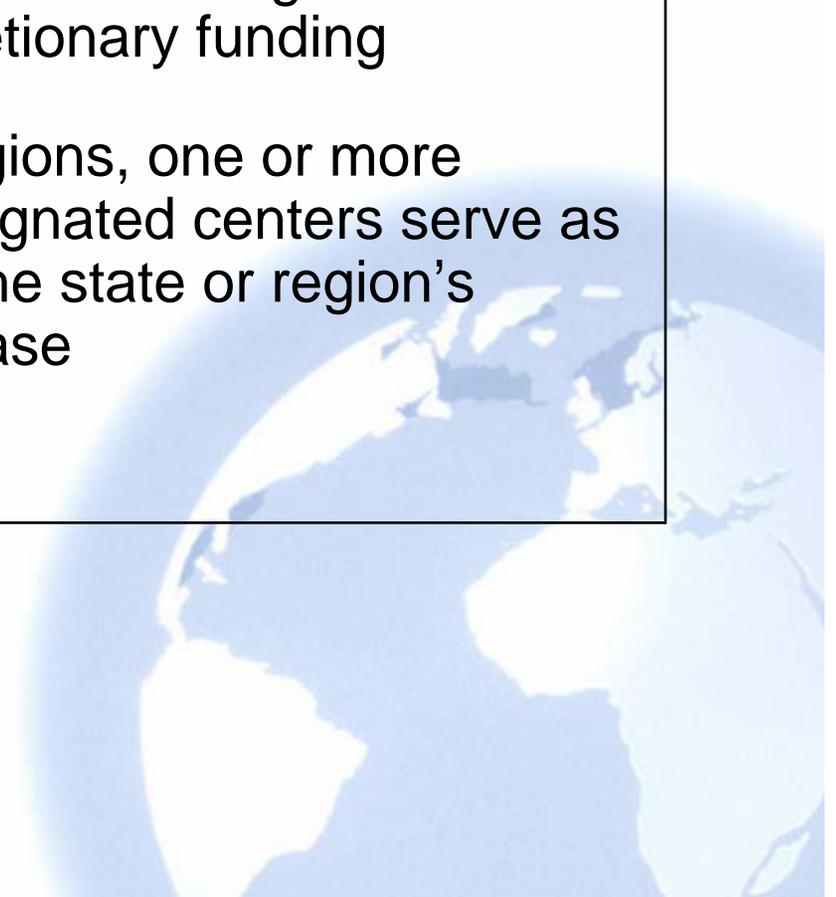
Best Practices for States

Factors of Success	Best Practice States/Regions
Engaged Universities with Active Leadership	<ul style="list-style-type: none">✓ Universities are engaged in economic development and committed to technology transfer✓ Have created vehicles for technology commercialization



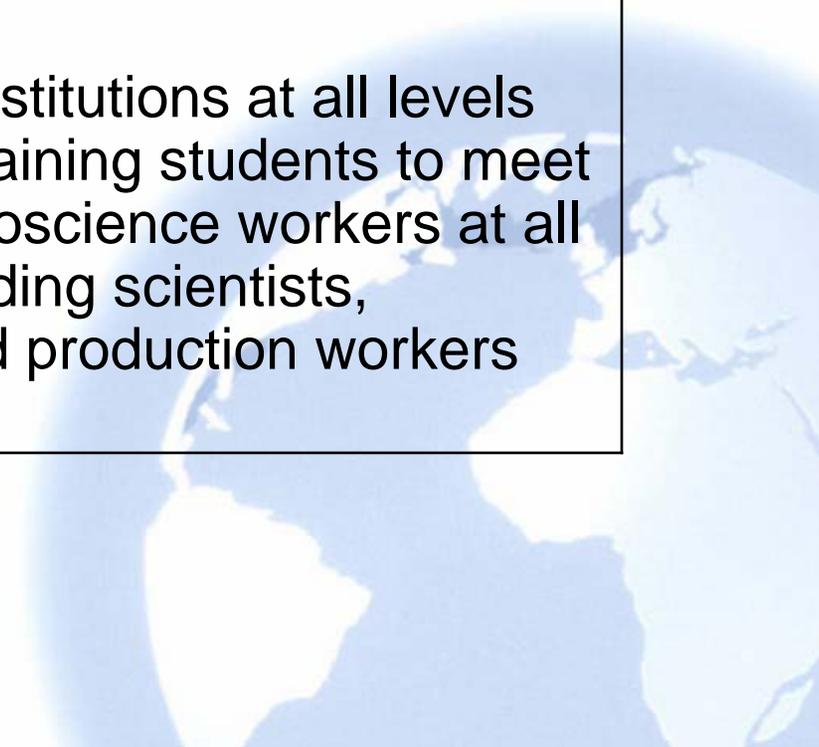
Best Practices for States

Factors of Success	Best Practice States/Regions
Discretionary R&D Funding	<ul style="list-style-type: none">✓ Every major technology region in the U.S. has received significant federal discretionary funding✓ In these regions, one or more federally designated centers serve as anchors for the state or region's bioscience base



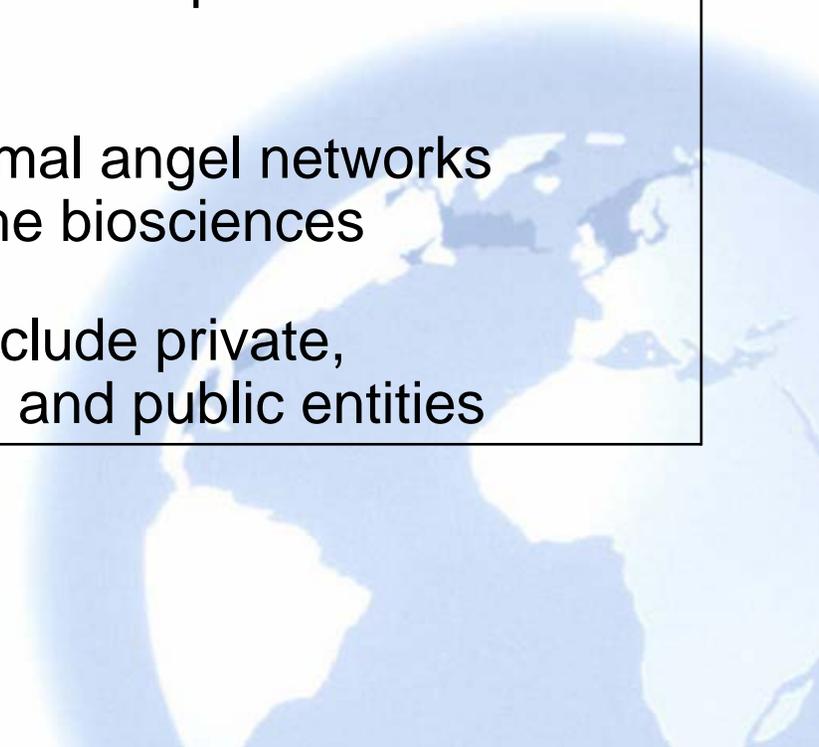
Best Practices for States

Factors of Success	Best Practice States/Regions
Talent Pool	<ul style="list-style-type: none">✓ Talent increasingly provides the discriminating variable for states and regions to build comparative advantage✓ Educational institutions at all levels responsive to training students to meet the needs for bioscience workers at all skill levels including scientists, technicians, and production workers



Best Practices for States

Factors of Success	Best Practice States/Regions
Available Capital	<ul style="list-style-type: none">✓ Some states and regions have created programs to address the commercialization, pre-seed, and seed financing gaps to help establish and build firms ✓ Active informal angel networks investing in the biosciences ✓ Investors include private, philanthropic, and public entities



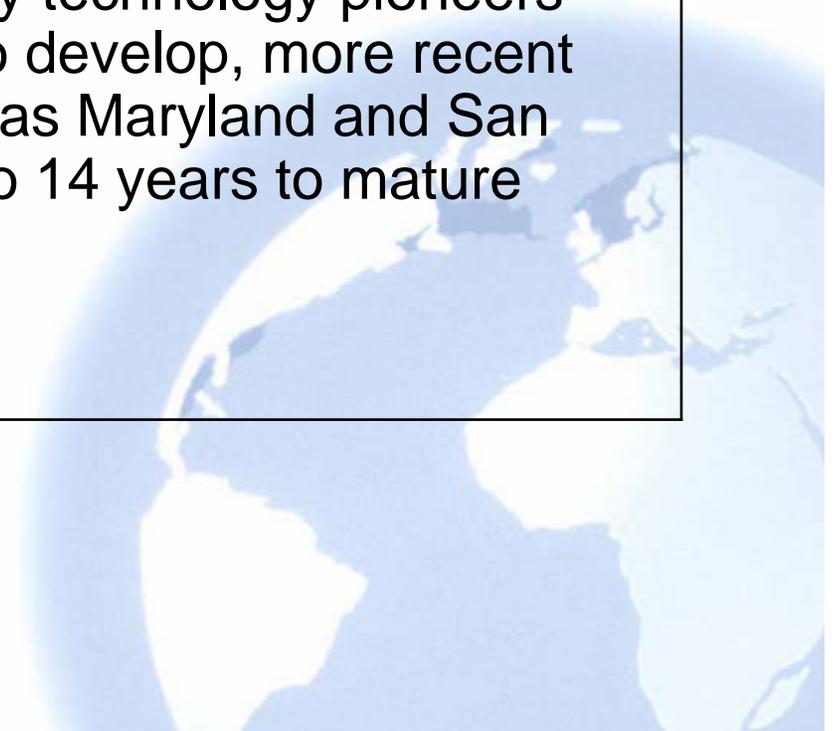
Best Practices for States

Factors of Success	Best Practice States/Regions
Specialized Facilities and Equipment	<ul style="list-style-type: none">✓ Leading bioscience regions have private markets that provide facilities offering space for bioscience companies✓ Specialized bioscience incubators and research parks are a growing trend✓ Access to specialized facilities and equipment, such as core labs and animal facilities, is readily available



Best Practices for States

Factors of Success	Best Practice States/Regions
Patience and Long-term Perspective	<ul style="list-style-type: none">✓ Building a critical mass of bioscience firms takes many years or even decades✓ While the early technology pioneers took 25 years to develop, more recent examples such as Maryland and San Diego took 12 to 14 years to mature



Recent State Economic Development Activity



California

California voters approved a bond measure to allocate **\$3 billion** (over 10 years) for a stem cell research initiative in the state. Most of these funds would go to academic research institutions.



Florida

Florida lands the Scripps Research Institute. The Florida legislature approved a \$310 million grant coupled with a \$200 million commitment from Palm Beach County to build a new 100 acre facility for Scripps. This is one of the largest financial commitments of state and local funds for a single entity.



South Carolina

In 2004 the South Carolina Legislature approved a \$500 million technology-based economic development package that targets life sciences, commits state funds to venture capital, and facility infrastructure improvements at the state's three research universities.



Maryland

Legislation (HB 664) approved to implement the Maryland Biotechnology Investment Incentive Act: A 50% income tax credit for qualified investment in biotechnology companies with fewer than 50 employees

Eligibility:

- Individuals investing more than \$25,000
- Corporations and VC firms investing more than \$250,000
- Value of credit capped at \$50,000 and \$250,000 respectively



New Jersey

In 1998, New Jersey became the first state to specifically allow small high-tech companies to trade their earned tax credits to supplement their R&D budgets.

In addition, last year the state funded the creation of a Stem Cell Research Institute and has since pledged \$150m in state resources to build-out the facility and voters will be asked to consider a \$230m bond measure this November.



Rhode Island

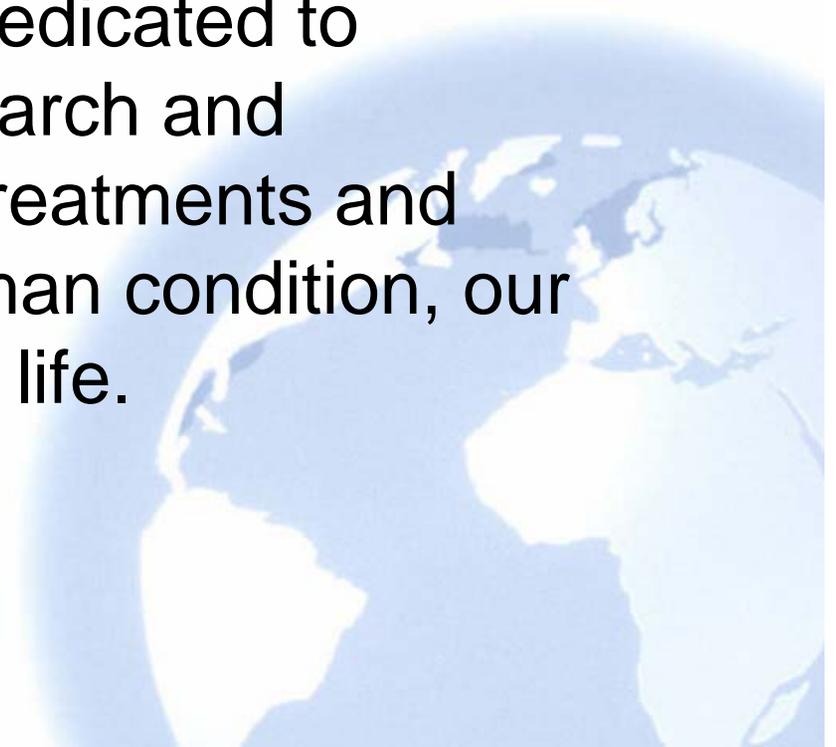
And, not to be outdone, the smallest state in the union approved a bond measure in 2004 to allocate \$50 million for the construction of the University of Rhode Island (URI) Center for Biotechnology and Life Sciences.



Conclusion

Biotechnology has the potential to be the most transformational technology in human history. It is currently revolutionizing healthcare, agriculture and industrial manufacturing.

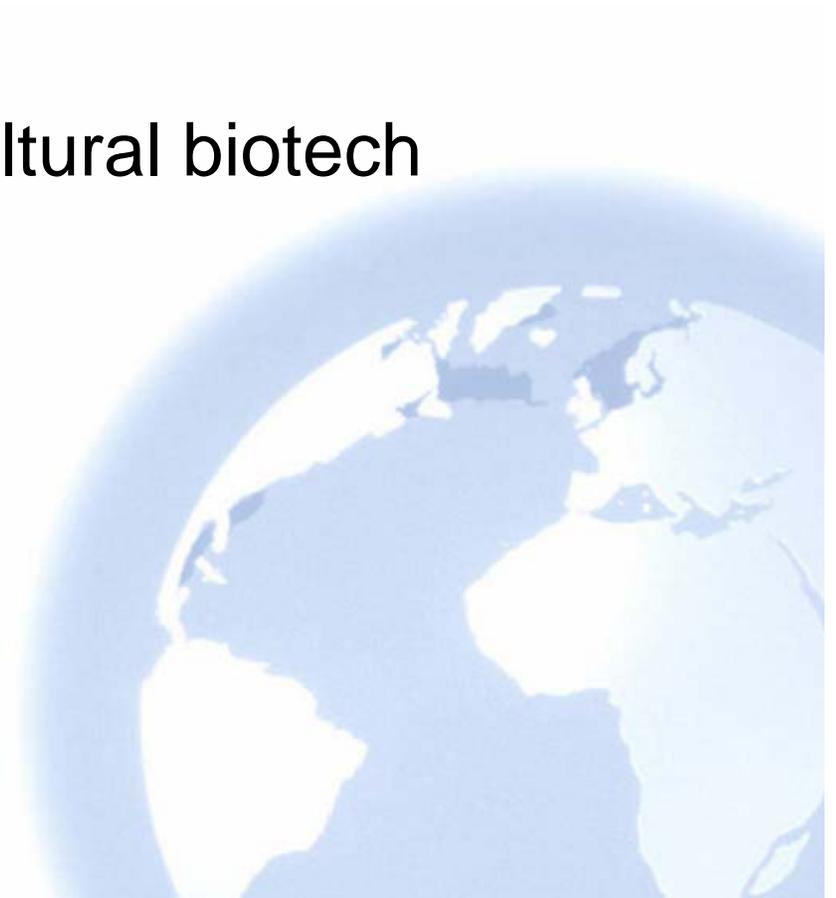
The bioscience industry is dedicated to encouraging continued research and development of innovative treatments and products to improve the human condition, our environment and our way of life.



What can Idaho Do?

Play to your Strengths

- High quality/sophisticated agricultural industry
- Diversified agriculture
- Can easily adapt to agricultural biotech specialty market needs
- Pro industry track record



What Can Idaho Do? Play to your Strengths

- Engaged universities with active leadership
- Available capital
- Talent pool
- Specialized facilities and equipment
- Patience and a long-term perspective



Possible Strategy Going Forward

- Develop economic incentives to attract industry
 - R&D tax credits
 - Sales and use tax exemptions
 - Investment tax credit
 - State pension fund investment
- Develop incubator/shared research & manufacturing facilities
- Develop a center of excellence in agricultural biotechnology



Thank You

Michael J. Phillips

Vice-President, Food and Agriculture

Ab Basu

Director, State Government Relations

Biotechnology Industry Organization

1225 Eye Street, NW, Suite 400

Washington, DC 20005