

# West Virginia Bioscience Association



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# Biotechnology Industry Organization

- **Biotechnology companies**
- **Academic institutions**
- **State biotechnology centers**
- **Related organizations**

1100 Members across US and more than 30 other nations involved in research and development of technologies in:

- **Healthcare**
- **Agriculture**
- **Industry and Environment**

# **“The Good, the Bad, and the Ugly”**

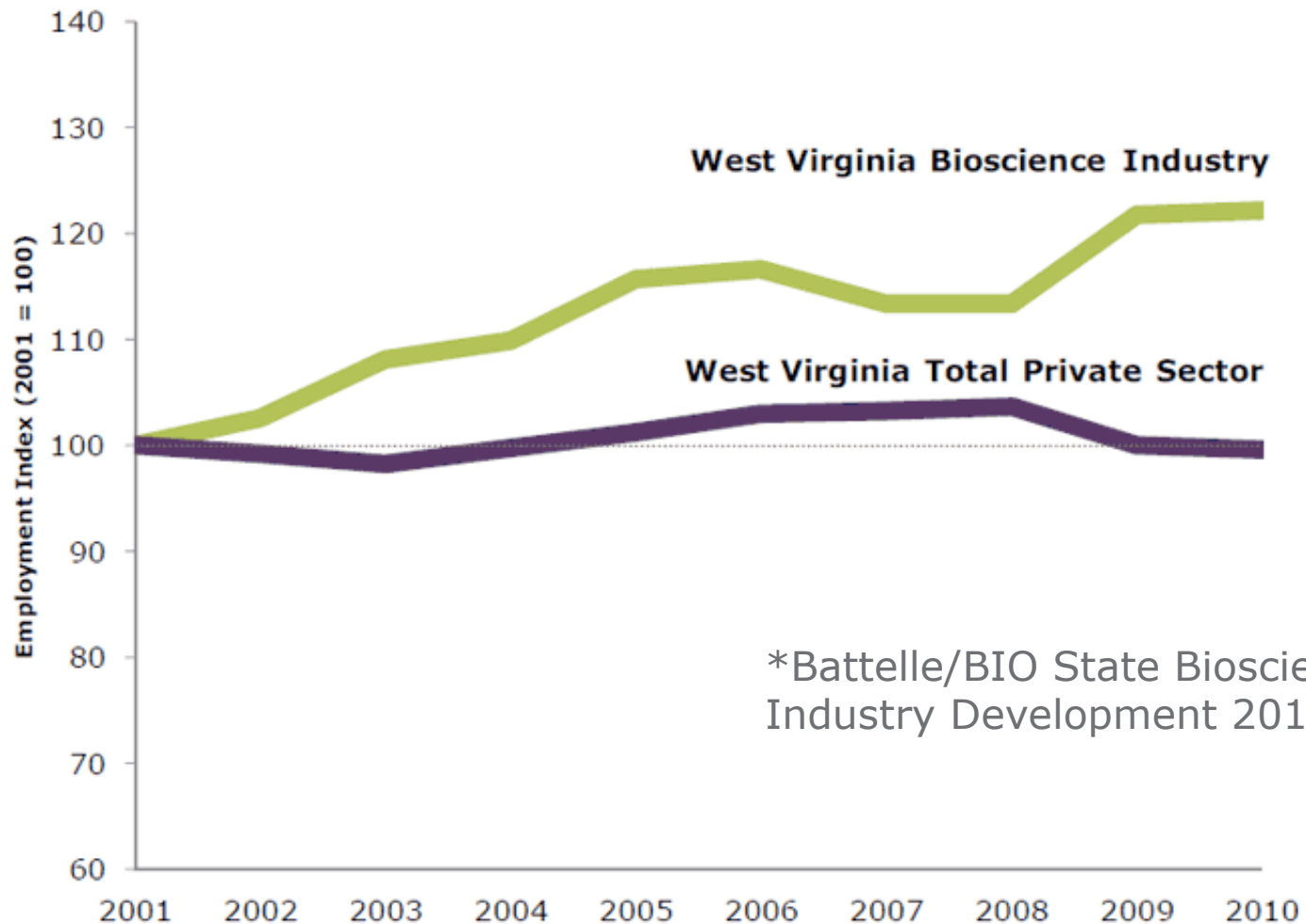
- **Bioscience employment is steady and perceptions of the industry are very positive.**
- **Fiscal situation for public and private sector is ominous—Sequestration Looms**
- **Divided electorate, status quo election, no consensus around a sustainable path forward**

# **“The Good...”**

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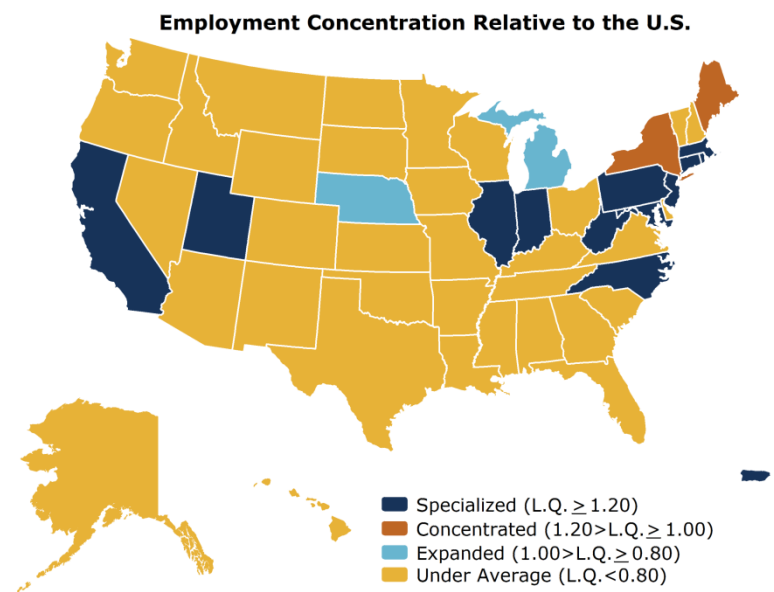
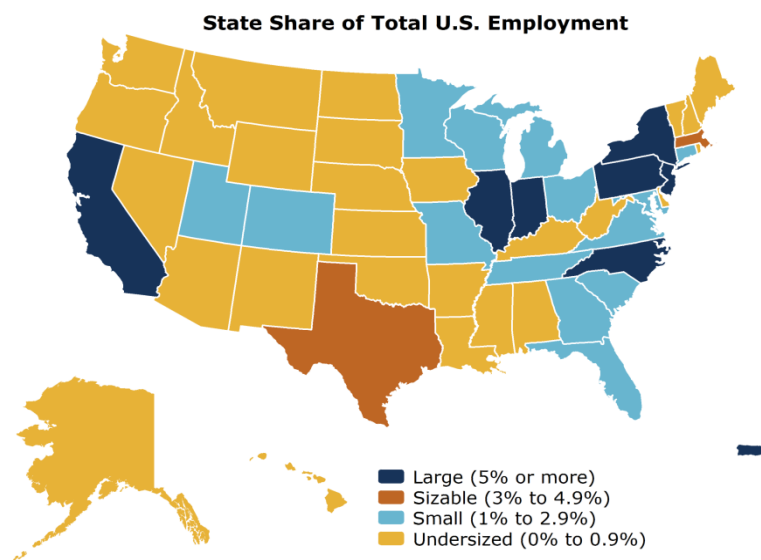
# **Bioscience Employment Growth Outperforms National Private Sector From 2001–2010**

# West Virginia's Bioscience Industry Continues to Expand



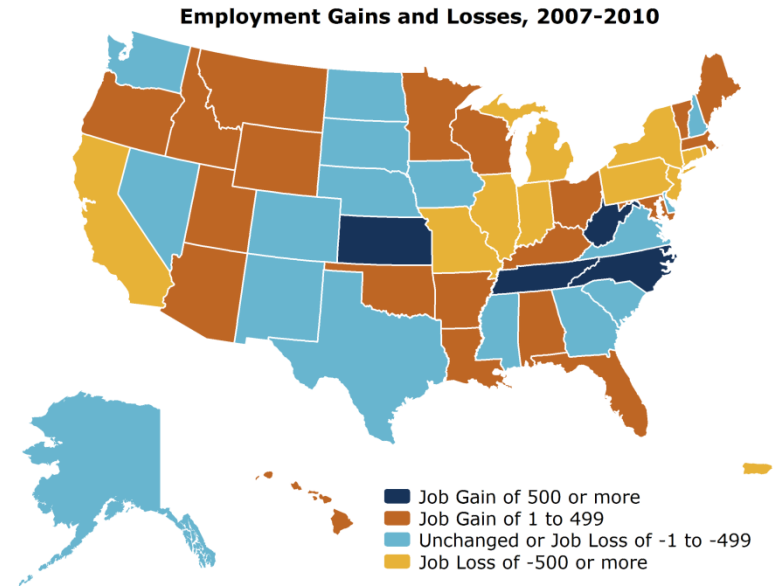
# The drugs & pharmaceuticals subsector is more concentrated with 10 states accounting for 71% of national subsector employment

States that are both large and specialized:  
California, New Jersey, Pennsylvania, North Carolina, Illinois,  
Puerto Rico, and Indiana



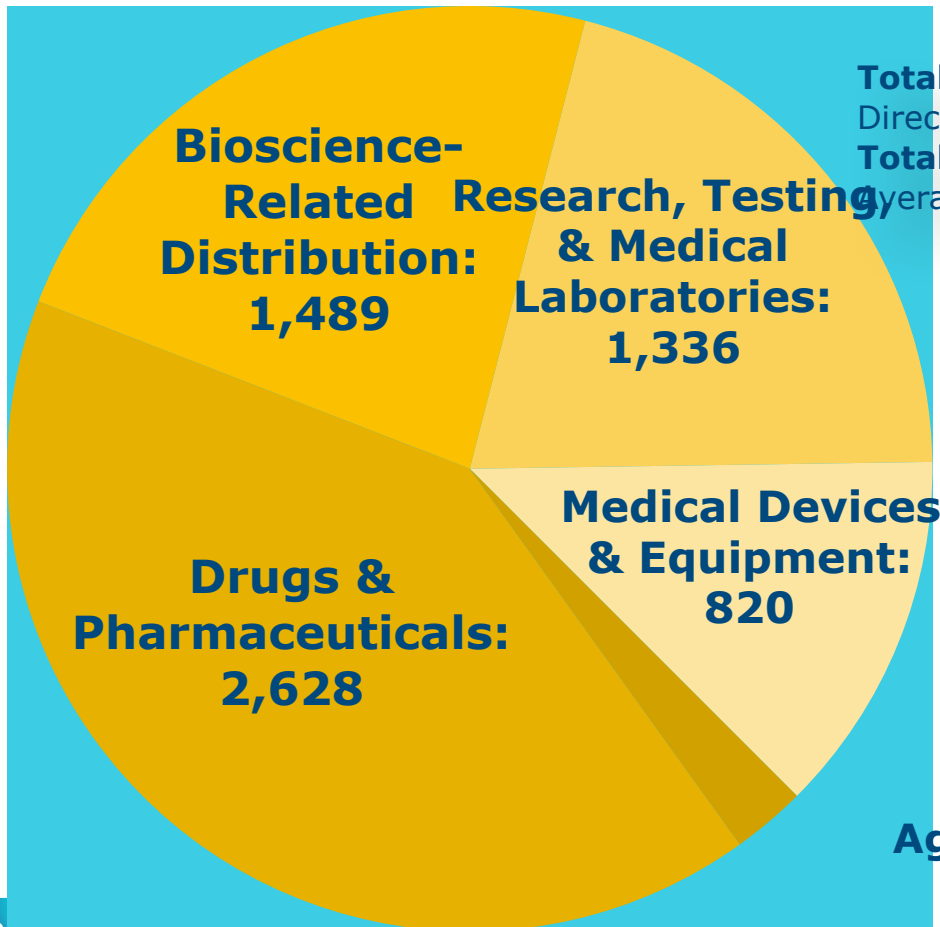
**Drugs & pharmaceuticals shed 7% of its employment base from 2007-2010, matching the decline for the overall private sector**

- Employment increased in 24 states from 2007-10
- West Virginia, North Carolina, Kansas, and Tennessee had gains of more than 500 jobs





# West Virginia's Bioscience Employment



**Total Bioscience Industry Employment: 6,439**

Direct-Effect Employment Multiplier: 2.4

**Total Employment Impact: 15,596**

Average Annual Wage (2010 dollars) \$67,008

**Agricultural Feedstock &  
Chemicals:  
166**

# Heal, Fuel, Feed the World



**Health &  
Medical**



**Industrial &  
Environmental**



**Food &  
Agriculture**

# Biomedicines Save Lives

**260+ approved  
biomedicines**

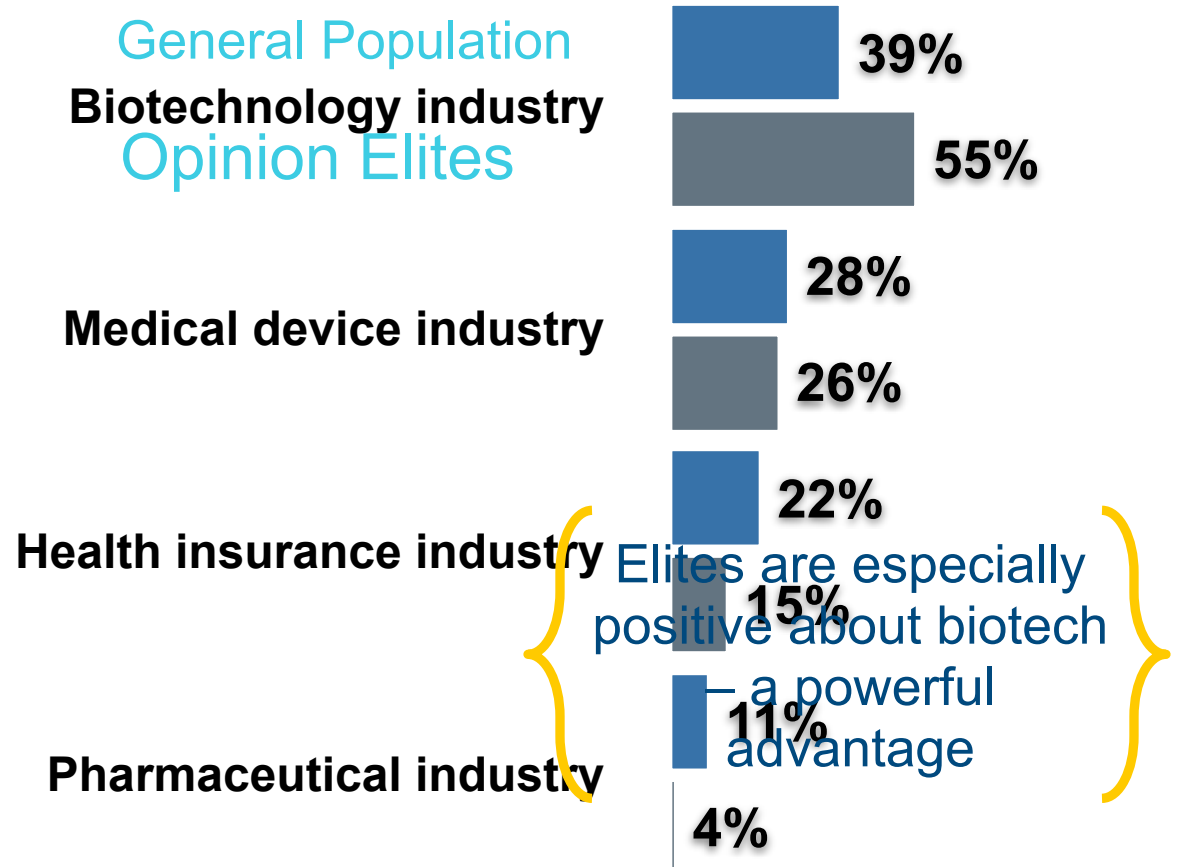
**800+ Biotech  
Medicines in  
Development**

**160+  
medicines  
developed for  
rare diseases**

	DRUG	INDICATION
1	Enbrel	rheumatoid arthritis
2	Rituxan	Hodgkin's lymphoma
3	Humira	rheumatoid arthritis
4	Avastin	colorectal cancer
5	Herceptin	breast cancer
6	Remicade	Crohn's disease
7	Gleevec	chronic myeloid leukemia
8	Neulasta	neutropenia
9	Lantus	Diabetes
10	Aranesp	Anemia in end-stage renal disease

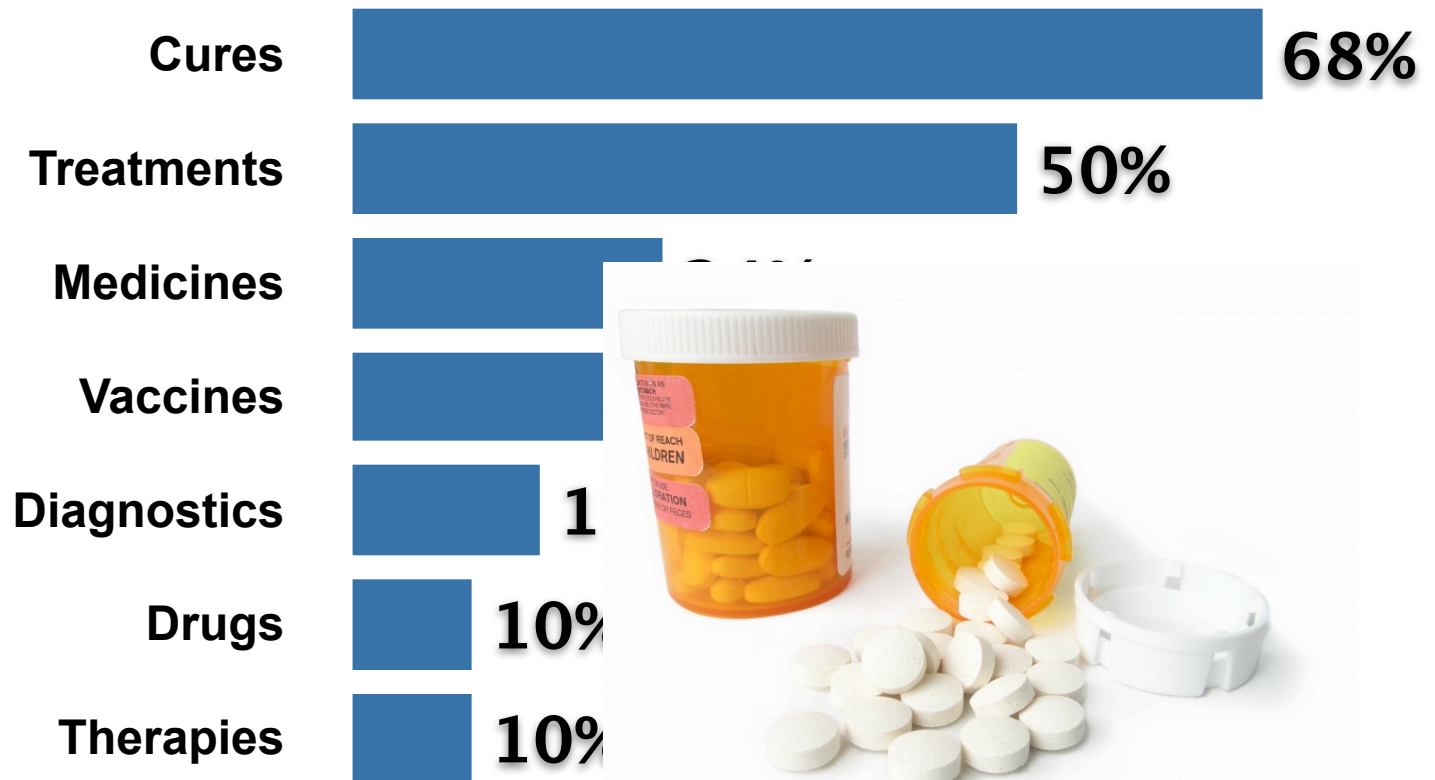
# Biotech is popular – use it or lose it

Which one of the following industries do you feel MOST favorable towards?



# Curing Diseases Rises To The Top

Which of the following is the greatest health care benefit of biotech companies? That they develop new (top 3 choices)...





# It's ALL about curing disease

- **Opinion elites and the general population need to hear about one thing and one thing only: curing diseases.**
  - Curing diseases means saving lives, it means reducing health care costs, it mean global competitiveness. It should be tied to everything we talk about.
- **Biotech offers innovative and lifesaving scientific breakthroughs through the development of new cures and treatment for disease.**
  - DON'T talk about biotech as a business ('entrepreneurship' or 'leading America into the 21st Century' sound hollow) and DON'T talk about developing drugs, therapies or vaccines (give the benefits of our work – cures and treatments – not the products).

# **“The Bio Century”**

- From Alabama to South Dakota policymakers around the country are trying to capture a piece of Bio Century for the good of their states.**
  - High paying jobs**
  - High multiplier effect. Capital Intensive. Even companies losing money plow significant resources back into the economy.**
  - Well educated and stable workforce**

# Growing a Bioscience Cluster

## ■ Education

- Research Trust Fund– “Bucks for Brains”

## ■ Entrepreneurship

## ■ Equity

## ■ Enlightened Elected Officials

- Supportive Public Policy Environment is critical to all facets of the cluster



# State Capital Formation Priorities

- Research and Development Tax Credits (Transferability)
- NOL Carry-forwards
- 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
- SBIR Matching Funds
-  Brain Gain– Incentives to attract Researchers and Entrepreneurs

# West Virginia Bioscience Association

# Near Term Policy Focus in Current Environment

- PDUFA V (Sequestration-- 8% cut in FDA and sequesters User Fees)
- Accelerated Approval, Breakthrough Therapies, Conflicts of Interest, Earlier and more streamline communication between FDA and companies
- Sequestration and budget cuts—Possible Pay Fors to Watch
- Government pricing in Medicare Part D
- ASP+6
- Changes to Dual Eligible
- Significant cuts to NIH
- ACA Implementation in the states
- Essential health benefits– innovative medicines covered
- Biosimilars Implementation in the States

# **“The Bad...”**

- Fiscal situation for public and private sector is ominous**
- Congress will be looking to industry for “pay fors”**
- Ongoing Mandatory GMO Labeling Concerns**
- Generic Pharmaceuticals Opposing State Biosimilars Bills**

# Mandatory Labeling Landscape

- Coordinated anti-biotech campaign
- Calls for labeling, low hanging fruit
  - Misinformation and scare tactics
  - Little public awareness about agriculture
- 2011-2012 three dozen bills introduced and defeated in state legislatures
- 2012 ballot initiatives proposed, CA, OR, WA

# Labeling Landscape— Federal level

- 2012 “Just Label It” petition to FDA claims 1M supporters
- Congressional Letter to FDA asking for a change in labeling policy (55 signatures)
- FDA continues to stand by current policy
- FDA response to petition: “...no decision made...we need more time...”

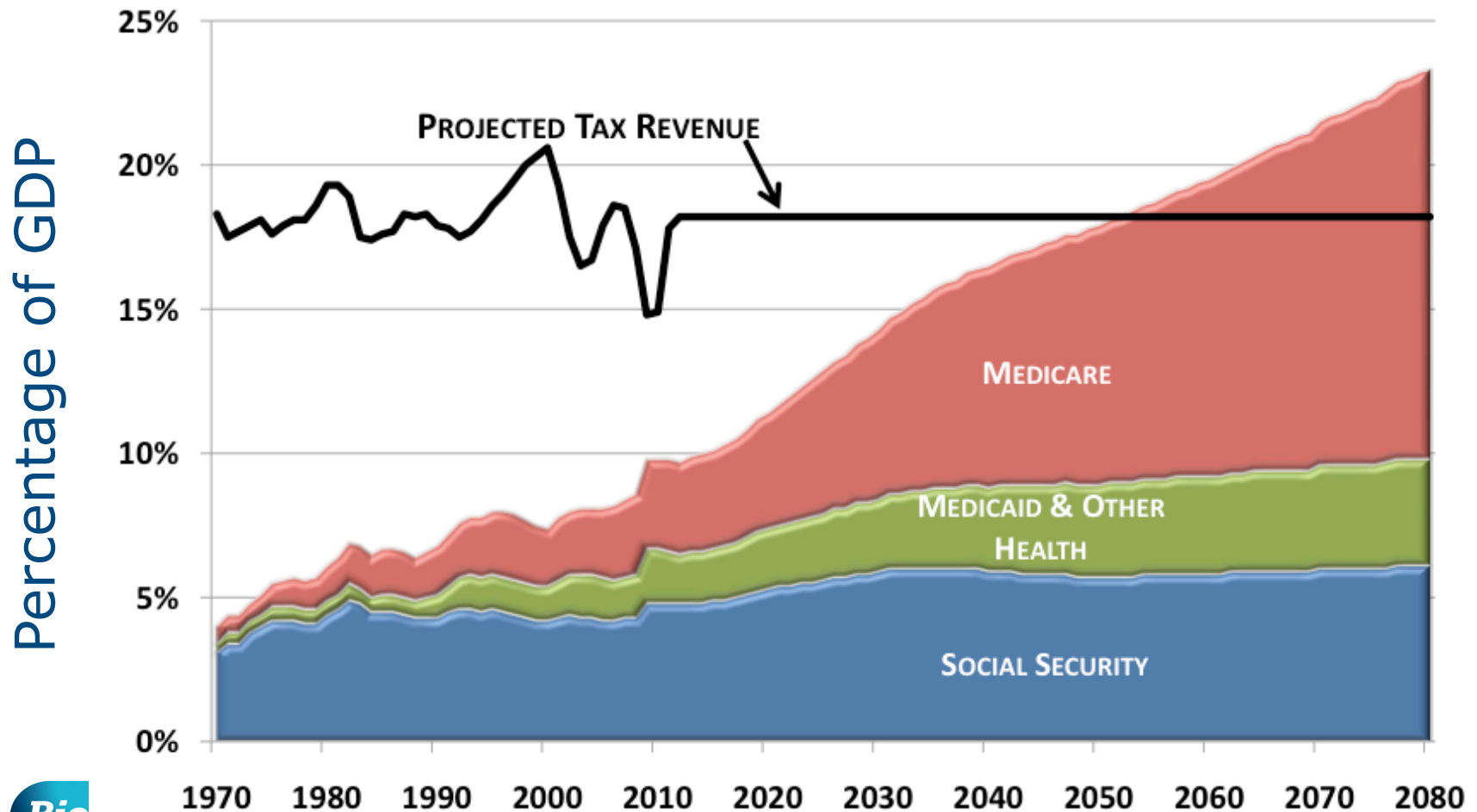
# Federal spending is growing faster than federal revenue

**WE HAVE MET  
THE ENEMY  
AND HE IS US.**





# Healthcare Entitlements Drive The Deficit



# The Fiscal Cliff

- Partial expiration of Bush tax cuts
- Expiration of the payroll tax cut
- Expiration of unemployment insurance benefits
- Expiration of the doc fix
- Expiration of expected Fiscal Year 2013 continuing resolution to fund the government beyond the end of 2012
- Sequestration of \$1.2 trillion in government spending (\$984 billion in reductions evenly split between defense and non-defense plus \$216 billion in debt services savings)
- Likely need to increase the current debt ceiling of \$16.4 trillion in late 2012 or early 2013

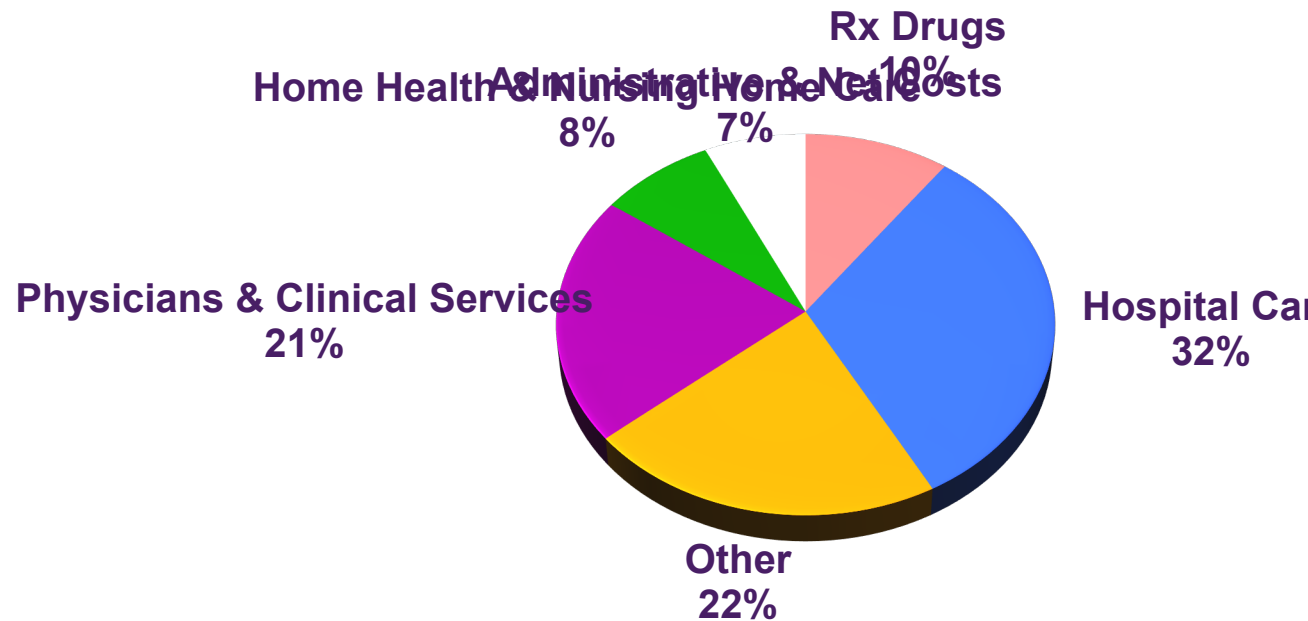
# Impact of the U.S. “Fiscal Cliff”

- The CBO estimates that the overall economic impact of the pending year end “fiscal cliff” will be in excess of \$600 billion in 2013 alone unless Congress acts to stave off these myriad tax increases and automatic spending cuts.
- Physician payment rates in the Medicare program alone will suffer a 27% across-the-board cut unless Congress intervenes to stop the application of the Sustainable Growth Rate formula.
- Other spending issues in 2013 include:
  - \$221 billion worth of expiring income and estate tax provisions;
  - \$65 billion in automatic spending cuts associated with last year’s budget deal (the “sequestration” measures);
  - \$95 billion from the expiration of a temporary payroll tax cut; and
  - \$18 billion in new taxes associated with the Affordable Care Act.

# How each healthcare dollar is spent



**Branded  
drugs  
6.5%**



# “The Ugly...”

 **Divided electorate, no consensus  
around a sustainable path forward**