

Positioning Labs to Serve Patients
A Call to Arms!
A Call to Quality!
(Quality Management Systems, That Is)

ROBERT L. MICHEL

Editor In Chief

THE DARK REPORT

Spicewood, Texas

Lab Quality Confab

1 October 2013

New Orleans, Louisiana

rmichel@darkreport.com

ph: 512-264-7103

fax: 512-264-0969

My Premise Today:

- U.S. healthcare system is out of money.
- Lab industry in America is at a crossroads.
- Clinical labs and pathology groups face a financial crises.
- To manage/operate labs in traditional way is sure road to failure.

***But Labs Have a Safe Path
to Clinical and Financial Success!***

Why Old Ways Won't Work

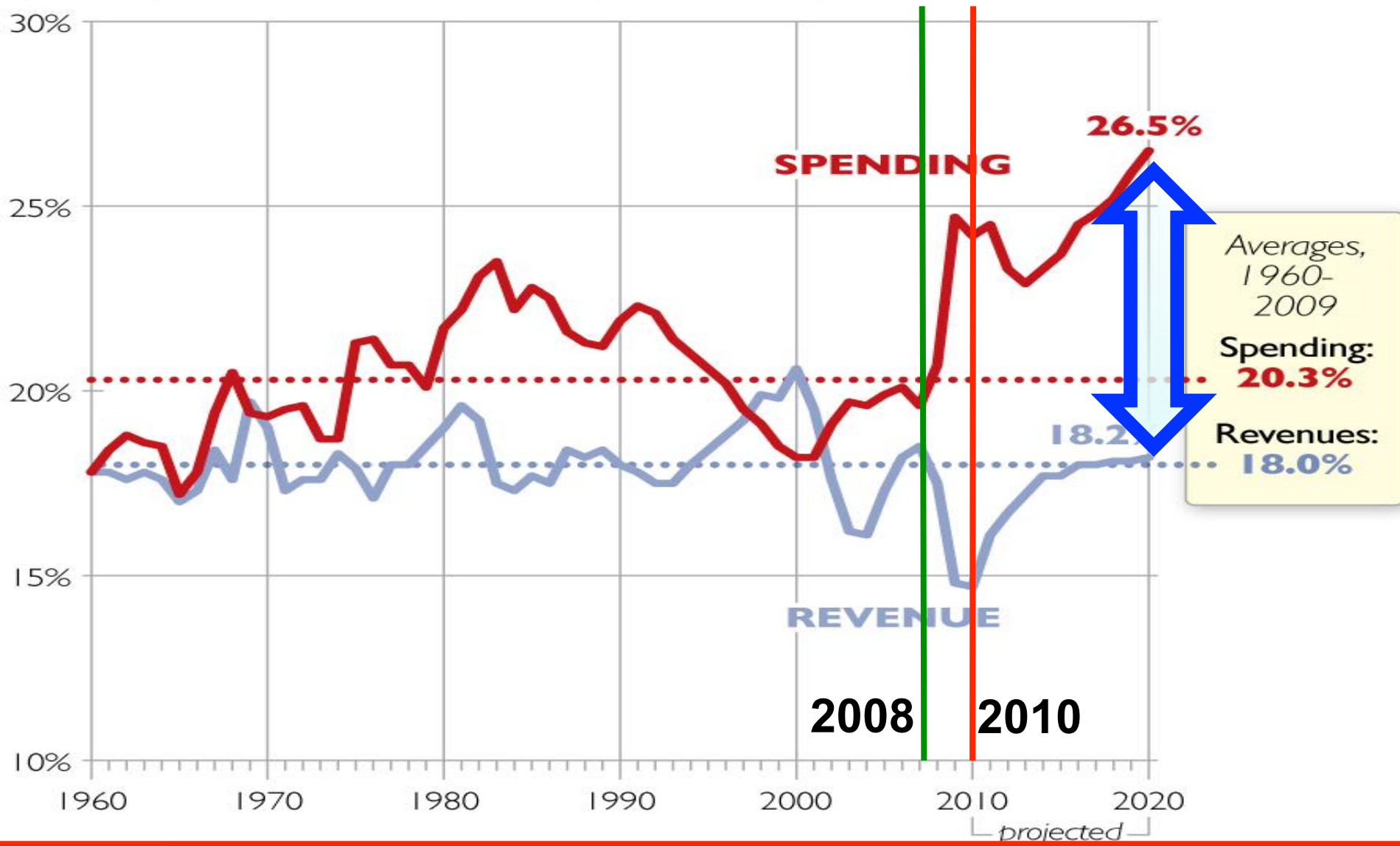
- Traditional lab management is “system of detection.”
- Managers can't unlock creativity and commitment of lab staff to fix problems, improve quality and service.
- Limitations to new technologies in diagnostics, automation, informatics.
- New management paradigm needed.

Why Is Crisis Coming?

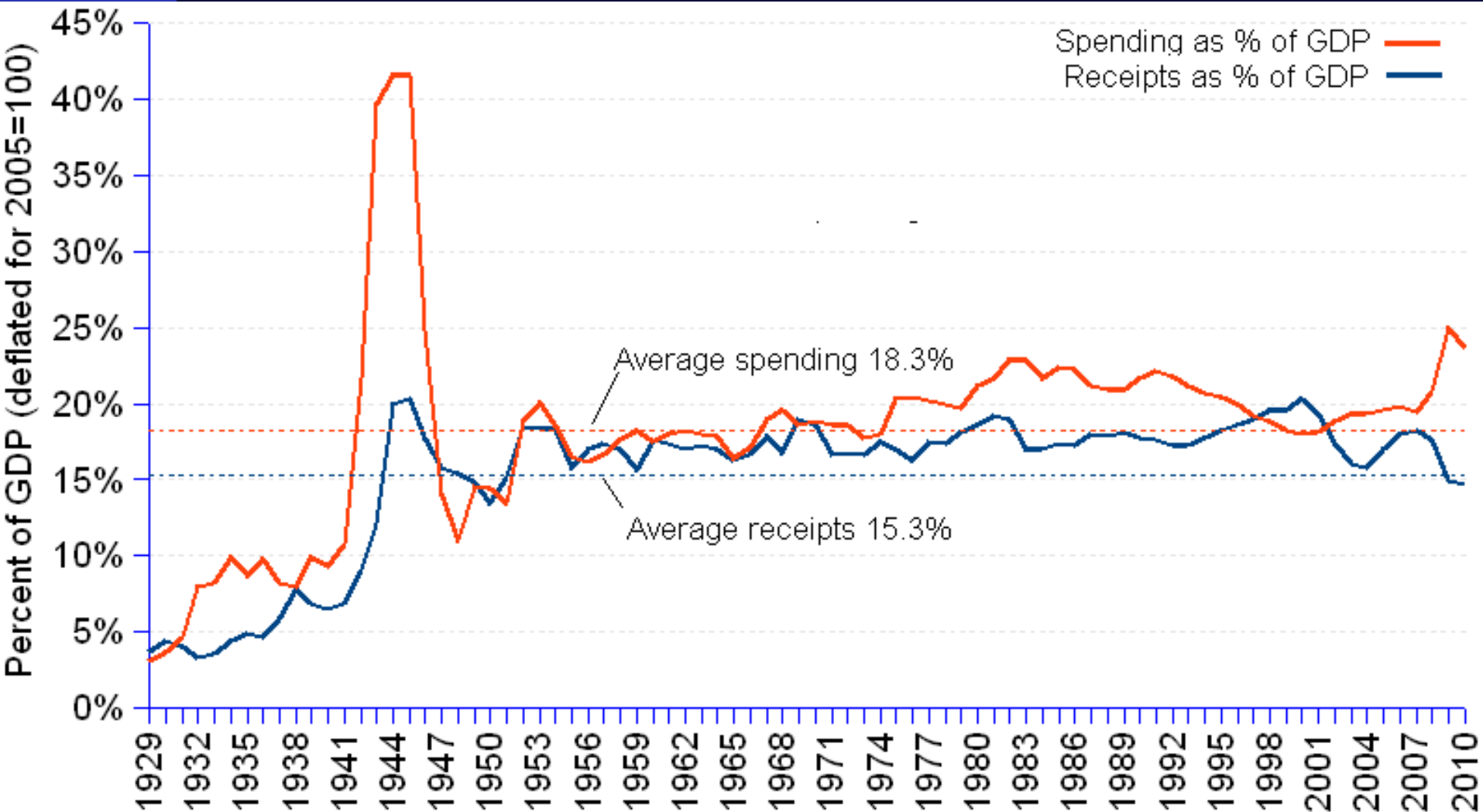
- Payers have no money!
- Doctors shifting from private practice to corporate medicine.
- Fee-for-service is going “**Bye Bye!**”
- New diagnostic technology is expensive.

Federal Spending-Circa 2011

Spending, Revenues as Percentage of GDP, by Fiscal Year



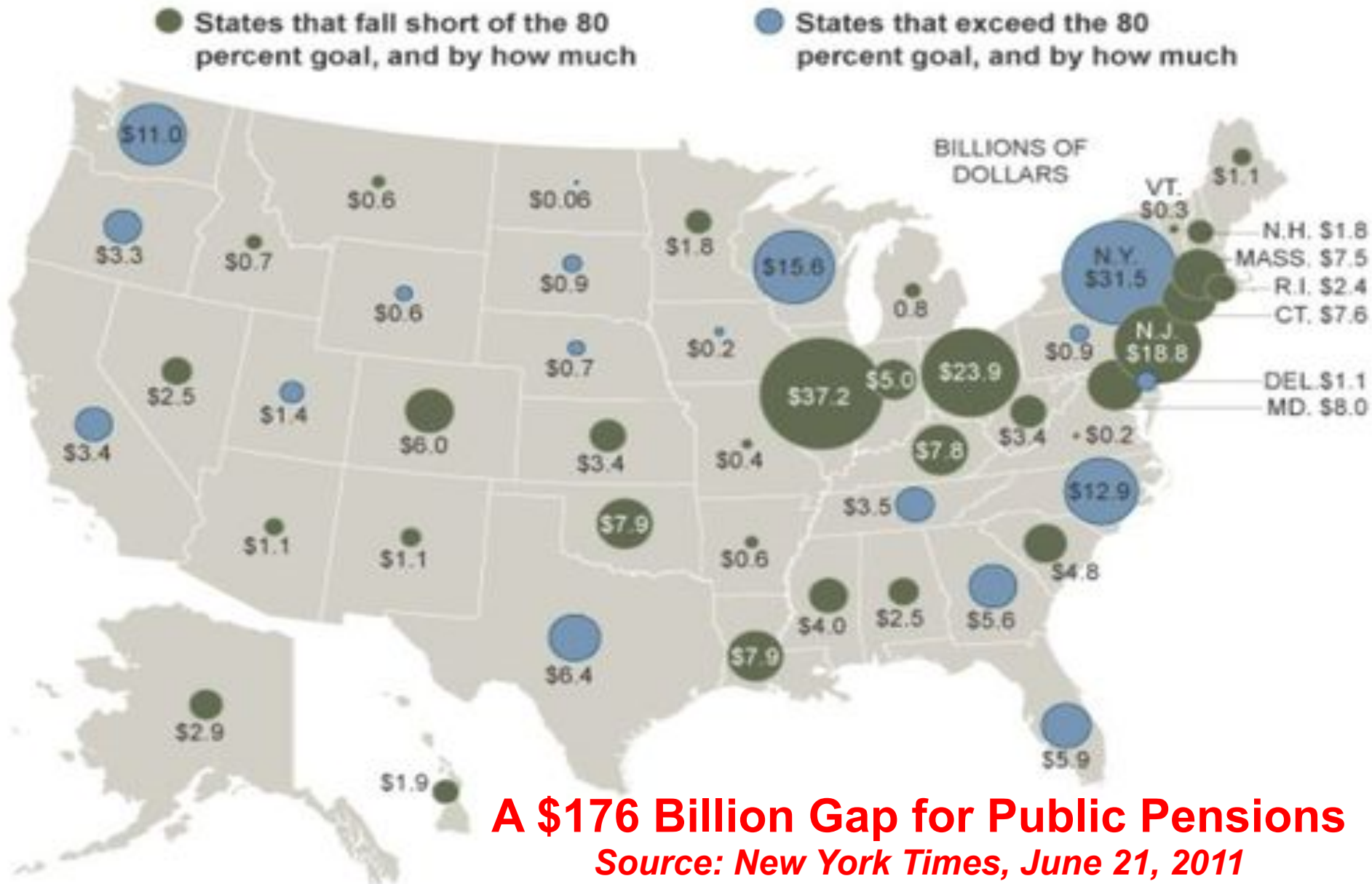
Current Federal Spending Compared: 1929 to Present... 83 Years!



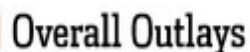
Impact of Fed's Finances

- Demand for spending exceeds federal capabilities across all categories.
- Healthcare competes for funding with education, defense, etc.
- Without reform, Medicare and Medicaid programs are budget-busters by themselves.
- States have their own budget crises.

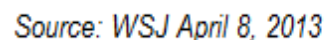
Shortfall in Funding for State Employee Pensions



A breakdown of health-care spending state by state



■ \$5,000-\$5,999 ■ \$6,000-\$6,999 ■ \$7,000-\$7,999 ■ \$8,000+



1/DGS10
Federal Government Debt: Total Public Debt (GFDEBTN)



Shaded areas indicate US recessions.
2012 research.stlouisfed.org

Government's Money Mess

- Federal budget problems lack a short-term solution.
- Providers should prepare for further cuts because of federal budget shortfalls.
- Don't forget impact of federal debt of \$17 trillion...
 - ◆ Interest of \$170 billion at 1% rate.
 - ◆ Interest of \$850 billion at 5% rate!

Force for Change

New Reimbursement Models

- Fee-for-Service is on the way out.
- In its place:
value-based reimbursement.
- Expect to see:
 - ◆ Bundled payments.
 - ◆ Capitation.
 - ◆ Pay for Performance (P4P).
- Transition is already underway
with Medicare and private payer ACOs.

Impact on Labs Is Huge

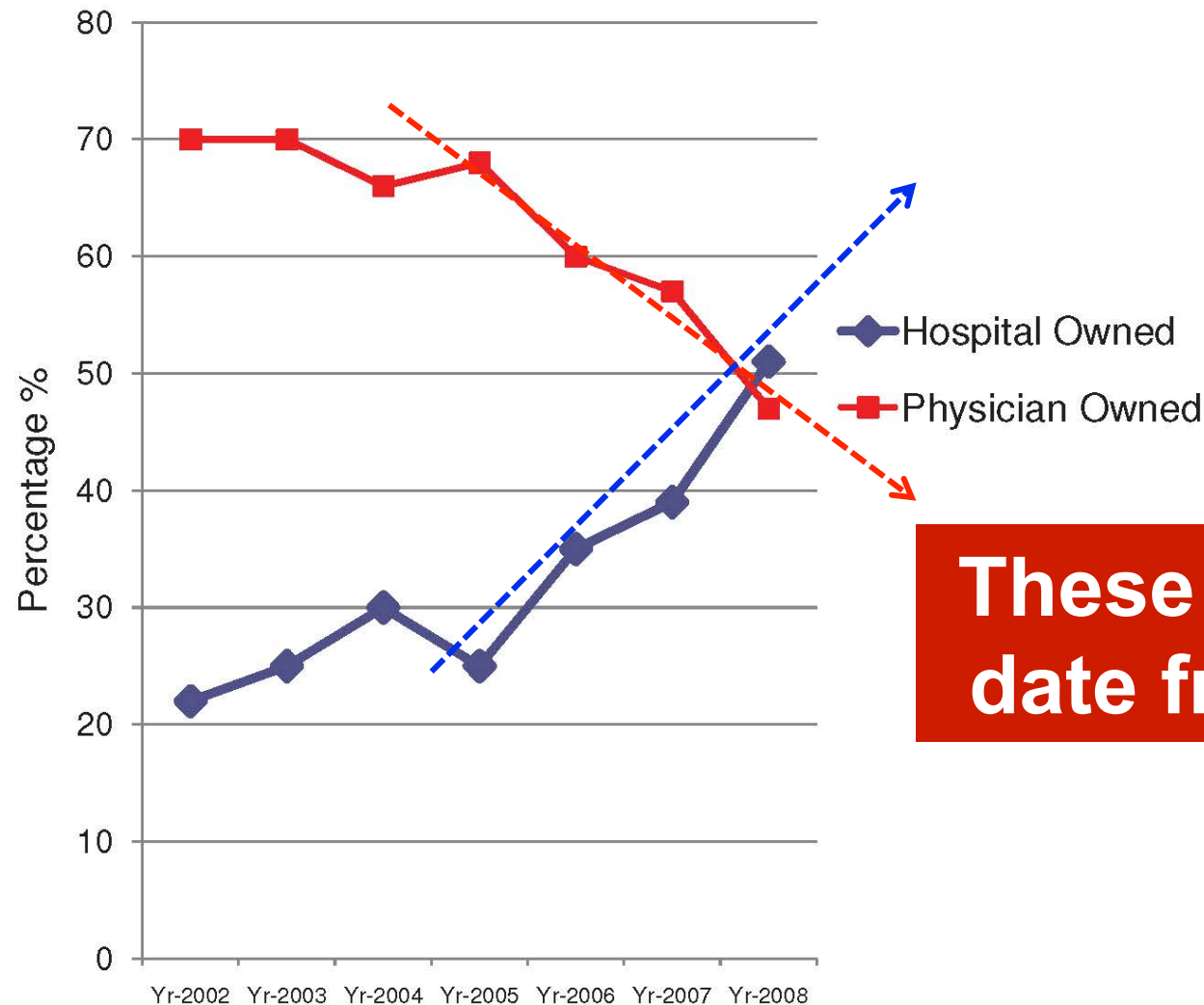
- Economics of clinical Labs recognizes value of economies of scale when payment is fee-for-service.
- As fee-for-service disappears, labs will be paid according to how they add value to physicians and help improve patient outcomes.
- Big change for the two blood brothers, who are the industry's "volume kings."

Era of Private Practice Medicine is Ending

- Large numbers of office-based physicians sold/are selling their medical practice.
- Doctors are no longer owners, but employees.
- Buyers of these medical practices are hospitals and managed care companies.
- Employers are opening corporate clinics.
- New owners of medical groups now decide their choice of a laboratory company to provide testing.

Medical Practice Ownership in the USA

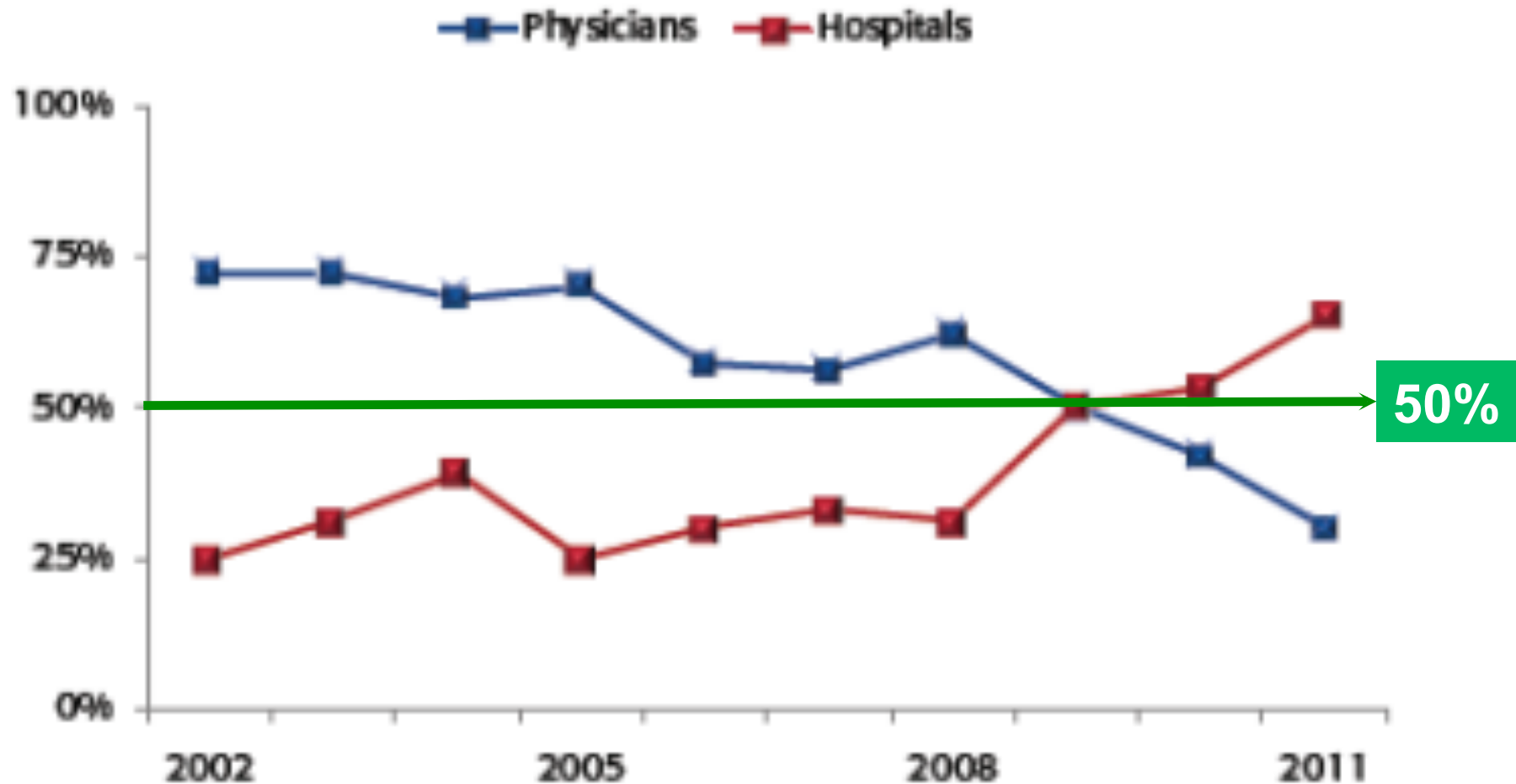
Trend in Hospital Ownership of Medical Practices is Compelling.....



**These numbers
date from 2008!**

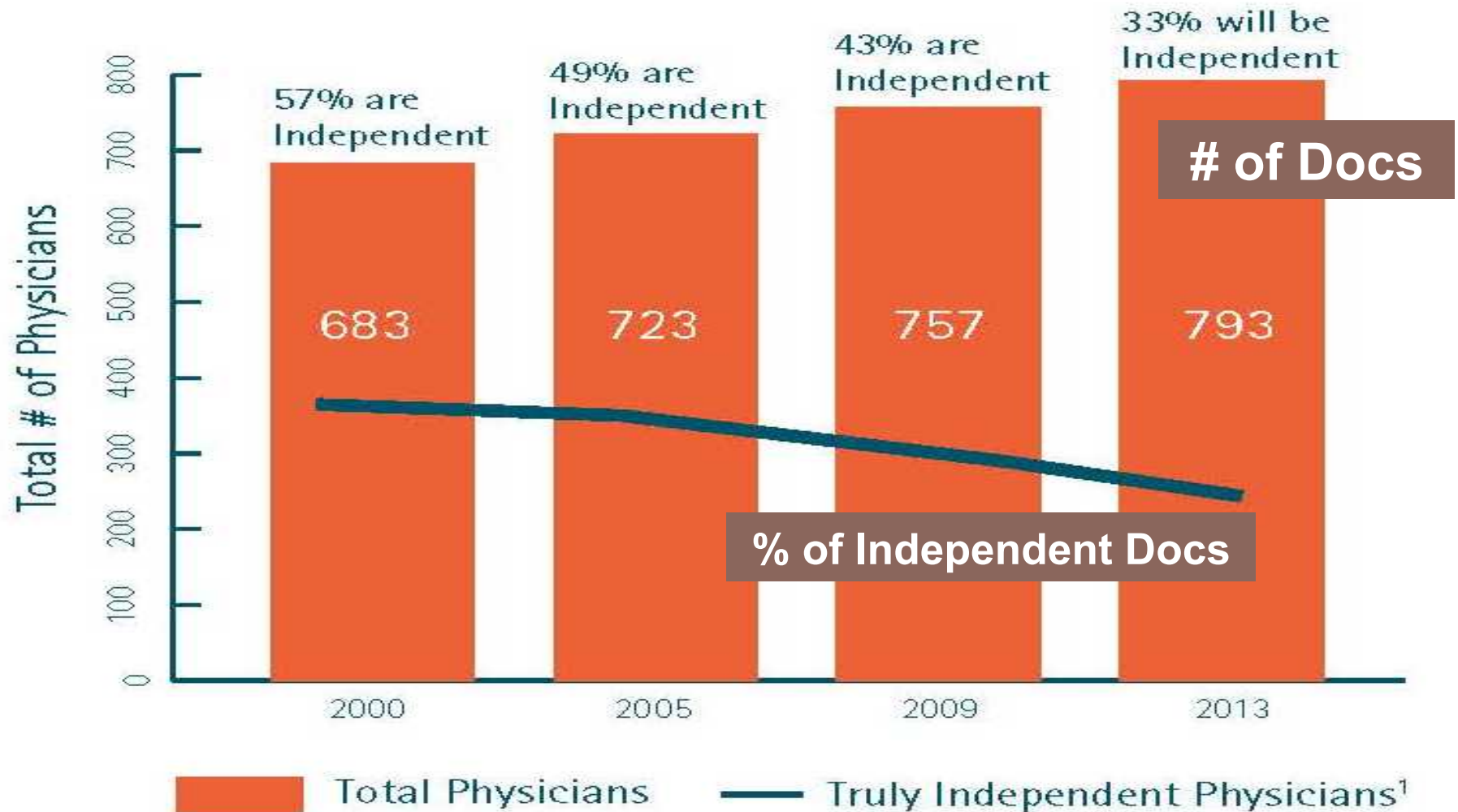
Source: MGMA Physician Compensation and Production Survey

Percentages of U.S. Physician Practices Owned by Physicians and Hospitals, 2011



Source: Physician Compensation and Production Survey, Medical Group Management Association, 2011 Survey

Total Physicians vs. Truly Independent¹ – Projected Change, 2000–2013 (000s)



1.Estimated

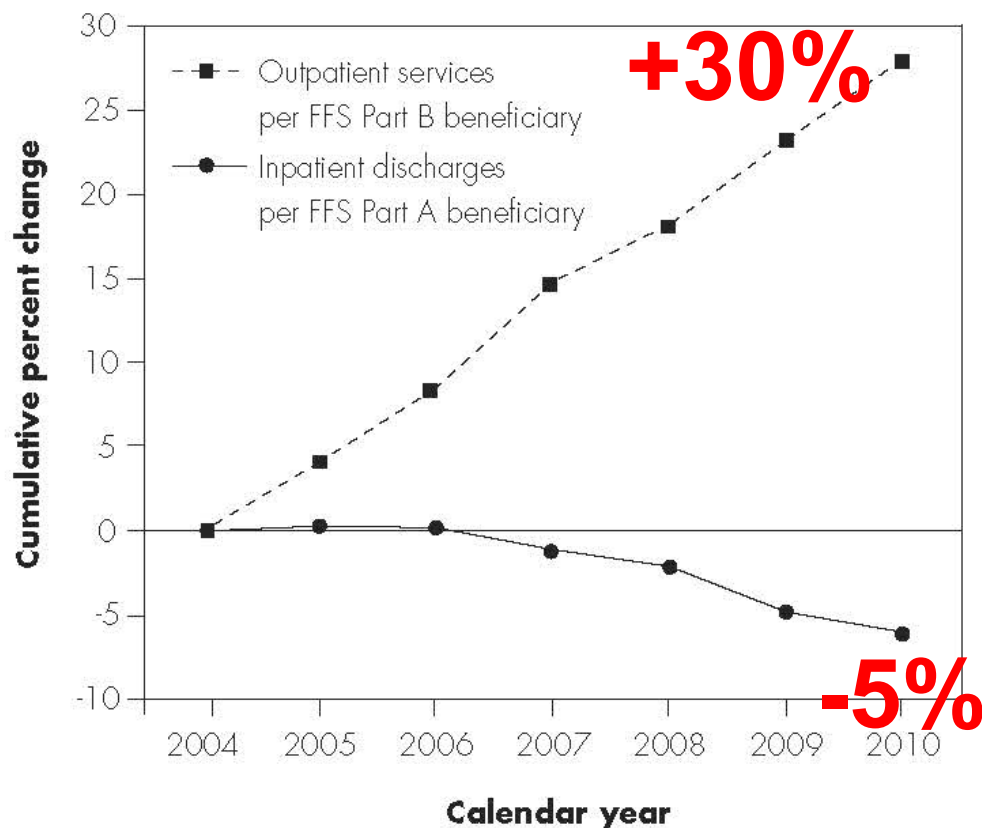
Sources: Accenture Analysis. MGMA. American Medical Association

Trend is Away from Inpatient Services

- Community hospital lab outreach programs have interesting dilemma.
- Emphasis now on keeping people out of hospitals.
- Growing proportion of lab specimens will be originate in outpatient and outreach settings.

**FIGURE
3-2**

**From 2004 to 2010, Medicare
outpatient services grew
while hospital inpatient discharges
per FFS beneficiary declined**



Note: FFS (fee-for-service). Data include general and surgical hospitals, critical access hospitals, and children's hospitals.

Source: MedPAC analysis of MedPAR and hospital outpatient claims data from CMS.

Key Point

**Inpatient procedures
growing by single digits
each year.**

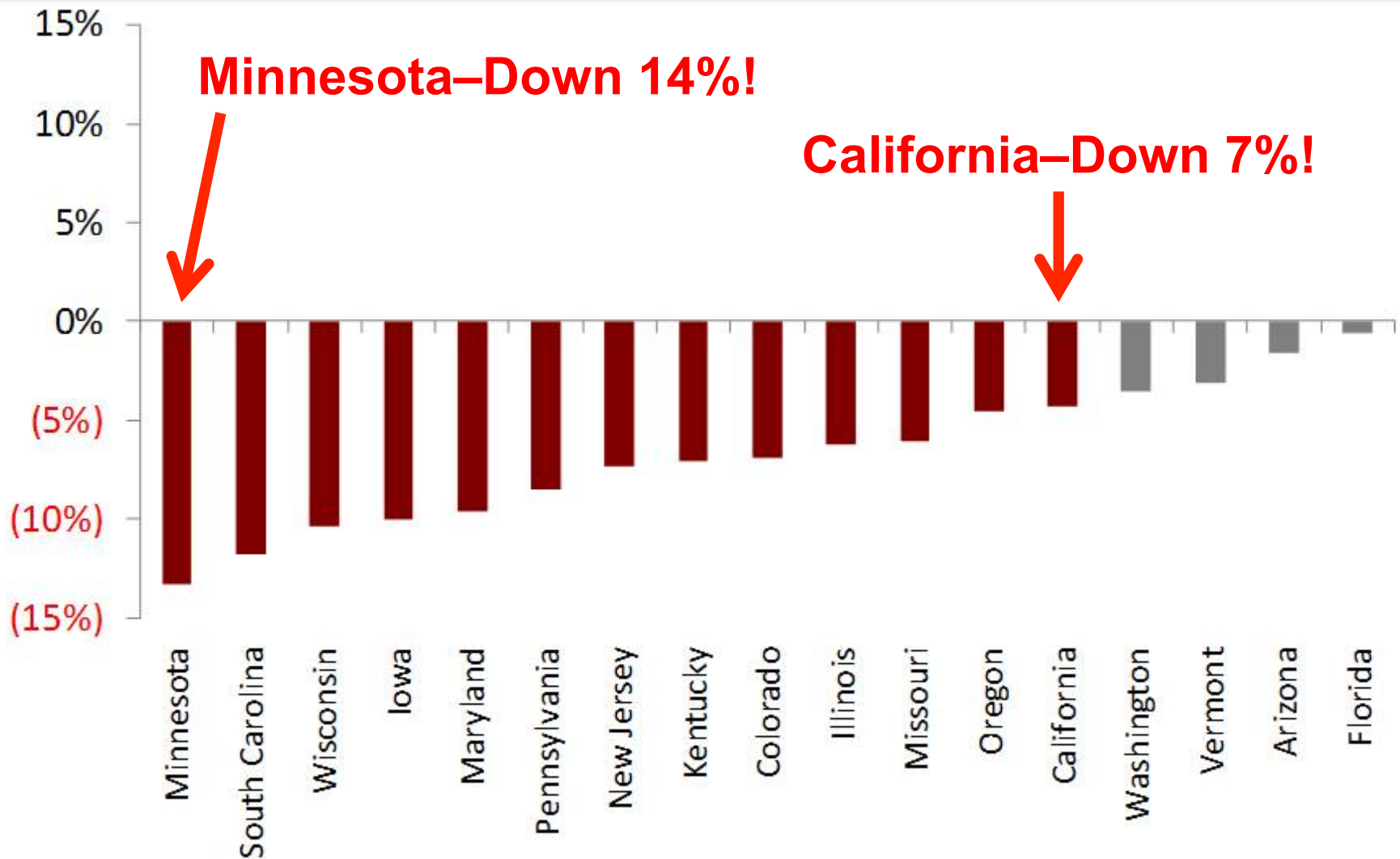
**Outpatient procedures
growing at double-digit
rates annually.**

**Labs must have access
to outpatient and outreach
specimens!**

Source:

**MedPac Report to Congress:
Medicare Payment Policy, March
2012**

**Figure 2. 2006-2011
Change in Inpatient Use Rates per 1,000**



Source: *Decline In Utilization Rates Signals A Change In The Inpatient Business Model*, Health Affairs Blog, March 18, 2103; Grube, Kaufman, and York

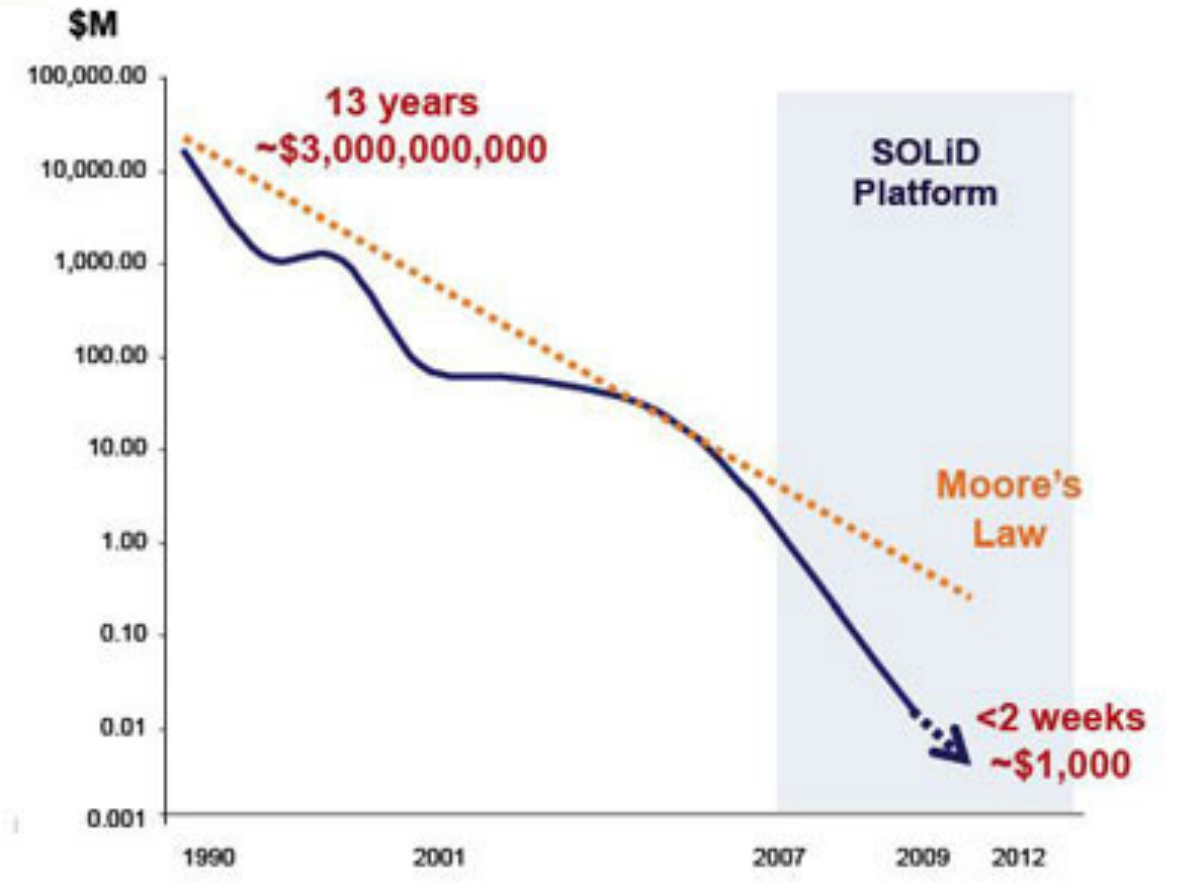
A Word on ACOs

- Did you know?
- Between 27 million and 33 million Americans involved in some fashion with an ACO in early 2013!
- 40% of Americans live in a primary care service area with at least one ACO.
- Report by Oliver Wyman in November 2012.

New Clinical Care Paradigms

- Keep patients out of hospitals!
- Detect disease early, when it is more easy to treat.
- Actively help patients manage their chronic diseases.
- Use incentives to encourage positive lifestyle choices and activities.
- Support these goals with genetic knowledge as it is developed.

Cost per Human Genome



**Trend predicts
that whole
human genome
sequence can
fall below \$100!**

**Moore's Law is seen in declining
cost of sequencing base pairs**

Now To Labs' Opportunity

- Adoption of QMS is essential.
- Quality Management System (QMS).
- ISO 9001 (*certification*)
- ISO 15189: Medical Laboratories (*accreditation*)
- ISO 17011: Accrediting Bodies (*accreditation*)
- CLSI Document GP-38

Why QMS?

- Quality Management System (QMS).
- Perfect complement to Lean, Six Sigma, process improvement methods.
- Enables labs to improve quality while cutting unnecessary costs.
- Decades of evidence that QMS works and improves value/cost equation.

Remember These?



Car Phone of the 1980s...



iPhone smartphone of the 2010s

And These?



Apple II of 1978

**Laptops, tablets,
smartphones in 2013**



IBM PC of 1980



Value of QMS

- Each functional area of an organization works from a consistent management model.
- Supports continuous improvement and system of prevention.
- Relevant metrics used to guide deliberate change and improvement.
- Customers (physicians) understand the quality basis of their supplier (laboratory).

Adding Value with Lab Tests

- Goal is to improve patient outcomes while reducing the cost per episode of care.
- Lab can spend a bit more money, but contribute to millions in cost savings.
- Example of John T. Mather Memorial Hospital in Port Jefferson, NY.
- 248 beds, lab runs 2.3 million tests annually.

Reduced cases of MRSA at Mather Mean Better Outcomes, Reduced Costs

Costs

- Screened high risk patients
- 2008: 88/mo = 1,050/yr
- 2009: 139/mo = 1,663/yr
- 2010: 176/mo = 2,107/yr
- 2011: 182/mo = 2,181/yr
- 2012: 164/mo = 1,967/yr
- PCR Assay ~ \$50 per test
- Total Screening Cost \$448,400
- NO ADDITIONAL FTES
- MRSA testing performed 24/7

Savings

248 bed hospital

82,373 patient days/91% occupancy

Rate of Infection/1000 Patient Days

- 0.90/1,000 = 74.0 infections (2007)
- 0.59/1,000 = 48.0 infections (2008)
- 0.29/1,000 = 23.0 infections (2009)
- 0.25/1,000 = 19.0 infections (2010)
- 0.17/1,000 = 13.0 infections (2011)
- 0.23/1,000 = 18.0 infections (2012)

(2007 vs 2012)

Difference = 56.0 fewer infections @ \$35,000

Decrease in 2008 hospital costs = \$910,000

Decrease in 2009 hospital costs = \$875,000

Decrease in 2010 hospital costs = \$140,000

Decrease in 2011 hospital costs = \$210,000

Increase in 2012 hospital costs = \$175,000

\$1,960,000 cost avoidance

Net Savings Due to Prevention

\$1,511,600

New Laboratory Algorithm Generates Substantial Benefits for *C. difficile* Testing

Costs

Total Testing Volume

- 2009: 275/mo = 3,107/yr
- 2010: 148/mo = 1,774/yr
- 2011: 160/mo = 1,919/yr
- 2012: 122/mo = 1,522/yr
- Simultaneous EIA- \$12 per test
- PCR Assay ~ \$40 per test
- Cost 2010: \$ 26,968
- Cost 2011: \$ 33,108
- Cost 2012: \$ 26,384

Total Testing Cost: \$86,460

NO ADDITIONAL FTES

C. diff testing performed 24/7

Savings

248 bed hospital

82,373 patient days/91% occupancy

Rate of Infection/1000 Patient Days

- 0.95/1,000 = 70.0 infections (2009)
- 0.57/1,000 = 46.0 infections (2010)
- 0.65/1,000 = 50.0 infections (2011)
- 0.34/1,000 = 26.0 infections (2012)

(2009 vs 2012)

Difference = 44.0 infections @ \$35,000

Decrease in 2010 hospital costs = \$840,000

Increase in 2011 hospital costs = \$140,000

Decrease in 2012 hospital costs = \$840,000

\$1,540,000 cost avoidance

Net Savings Due to Prevention

\$1,453,540

Labs Reeling from Price Cuts!

- July 1, 2012: Expiration of Grandfather TC clause. Painful for pathology labs.
- August 1, 2012: Palmetto GBA's policy caps prostate biopsies at five cores. Policy walked back last month.
- ACA mandates annual 2% cuts from 2011 to 2015 in Medicare Part B Lab Test Fees.
- SRG Fix in February 2012 cuts another 2% from Medicare lab fees.
- Sequester believed to trigger 2% lab fee cuts.

Survive?

- Can any lab survive if it continues to operate in the traditional way?
- System of Inspection is no longer good enough.
- “Traditional Labs” operate at 3-4 Sigma.
- That’s not good enough!
- Patients won’t tolerate these error rates.

Six Sigma for Lab Processes

Q-Probe QUALITY INDICATOR	% ERROR	DPM	SIGMA*
TDM timing errors	24.4	244,000	2.2
Cytology specimen adequacy	7.32	73,700	2.95
Surgical pathology specimen accessioning	3.4	34,000	3.3
PAP smear rescreening false negatives	2.4	24,000	3.45
Order accuracy	1.8	18,000	3.6
Surg path froz sect diagnostic discordance	1.7	17,000	3.6
Duplicate test orders	1.52	15,200	3.65
Laboratory proficiency testing	0.9	9,000	3.85
Wristband errors (not banded)	0.65	6,500	4
Hematology specimen acceptability	0.38	3,800	4.15
Chemistry specimen acceptability	0.3	3,000	4.25
Reporting errors	0.0477	477	4.8
*Conversion using table with allowance for 1.5s shift			

The following Sigma metrics are drawn from Nevalainen D, Berte L, Kraft C, Leigh E, Morgan T.: "Evaluating Laboratory Performance on Quality Indicators with the Six Sigma scale." *Arch Pathol Lab Med* 2000;124:516-519.

Or Prosper?

- “System of Prevention” is essential for labs.
- Continuous improvement, informed and guided by QMS.
- Lean, Six Sigma, work flow redesign necessary complements.
- This will be the new model for successful clinical labs and pathology groups.

You Are Change Agents

- Everyone in this room today are lab industry leaders.
- You have knowledge of how to apply “System of Prevention” principles to the benefit of patients.
- Positions you to be change agents in your labs, hospitals, communities.
- “Change means opportunity!”

Speakers Today

- **Luci Berte** on:
True Cost of Recurring Bad Quality
- **Charles Hawker, PhD.** on:
Achieving Six Sigma Performance
- **James Westgard. Ph.D.** on:
Elevating Analytical Quality

Speakers Tomorrow

- **Denise Geiger, Ph.D.** on:
Improving Patient Outcomes
- **Richard Zarbo, M.D., Ph.D.** on:
Benefits of CAP 15189 Accreditation
- **Leslie Wright** on:
United Kingdom's Quality Improvement Efforts

Conclusion: Trouble Ahead for Unwary Labs

- On multiple fronts, labs will see less payment and reduced budgets for lab testing services.
- Market poised for fundamental restructuring and much disruption to status quo.
- Innovative labs will rely on vendors for help across all aspects of lab management and operations.

But Don't Forget!

- There are 320 million Americans who continue to need clinical lab tests and anatomic pathology services.
- Someone will do this work.
- Message is for your lab to get out ahead of these trends.
- Be one of the labs that do this work...
...by delivering clinical value.

Updated September 8, 2013

Elizabeth Holmes: The Breakthrough of Instant Diagnosis

*A Stanford dropout is bidding to make tests more accurate, less painful—
and at a fraction of the current price.*

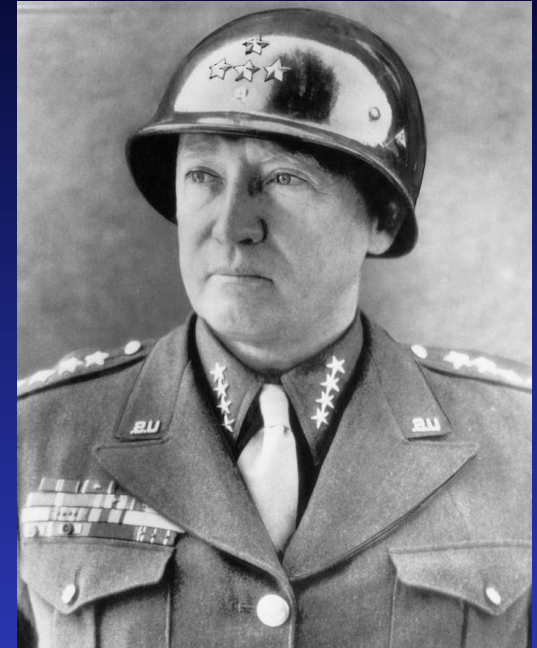
- Founder of Theranos, Silicon Valley
- Established 2003—secretive!
- \$100 million in venture funding
- CLIA lab in Palo Alto
- Finger stick specimen—Patented technology
- Priced at 50% of Medicare
- Will offer testing at 8,117 Walgreens' stores nationally!
- Bigwigs on Board of Directors



Thoughts on Leadership...

“Never tell people how to do things. Tell them what to do and they will surprise you with their ingenuity.”

—General George S. Patton



“As we look ahead into the next century, leaders will be those who empower others.”

—Bill Gates