

Fee-for-Service is Dead!
Long Live Value-Added Reimbursement!

*Why Innovative Labs Are Poised to Succeed
as Public Demands Higher Standards
for Quality and Patient Care*

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Premise:

**Healthcare's need for value
that improves patient outcomes
and reduces cost of care...**

**...intersects with use by clinical labs
of Lean, process improvement,
quality management systems.**

Today's' Broad Themes

- **THEME ONE:**

Understand what is unfolding within U.S. healthcare system.

- **THEME TWO:**

Explain how transparency and regulation are linked to broader healthcare trends.

- **THEME THREE:**

Examples of what early-adopter laboratories are doing to deliver value in support of new models of clinical care.

Assumptions You Know...

Shift in Clinical Emphasis

- Away from reactive/acute care and toward proactive care.
(early detection/active intervention.)
- Different demographics:
 - ◆ Growing incidence of chronic disease.
 - ◆ Increase in proportion of older folks.
- Personalized Medicine and Genetic Medicine
- ...Don't forget integration of clinical care!

Assumptions You Know...

New Health Delivery Models

■ **Medicare:**

- ◆ Accountable Care Organizations (ACO).
- ◆ Value-Based Reimbursement.
- ◆ Bundled Reimbursement.
- ◆ Pay incentive for provider use of electronic health record (EHR) systems.
- ◆ Pre-authorization of expensive molecular and genetic tests.

BECKER'S

Hospital CFO



HHS hits goal of shifting 30% of Medicare payments to alternative models

Written by Ayla Ellison (Twitter | Google+)

March 03, 2016

Print | Email

A Word on MACRA...

Understanding MIPS & APMs

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).
- Replaces SGR formula.
- New payment model for physician professional fees; data baseline is 2017.
- Merit-Based Incentive Payment System (MIPS).
- Advanced Alternative Payment Models (APMs).
- Speeds transition away from Fee-for-Service.

Payment Under MACRA

MIPS OR APM

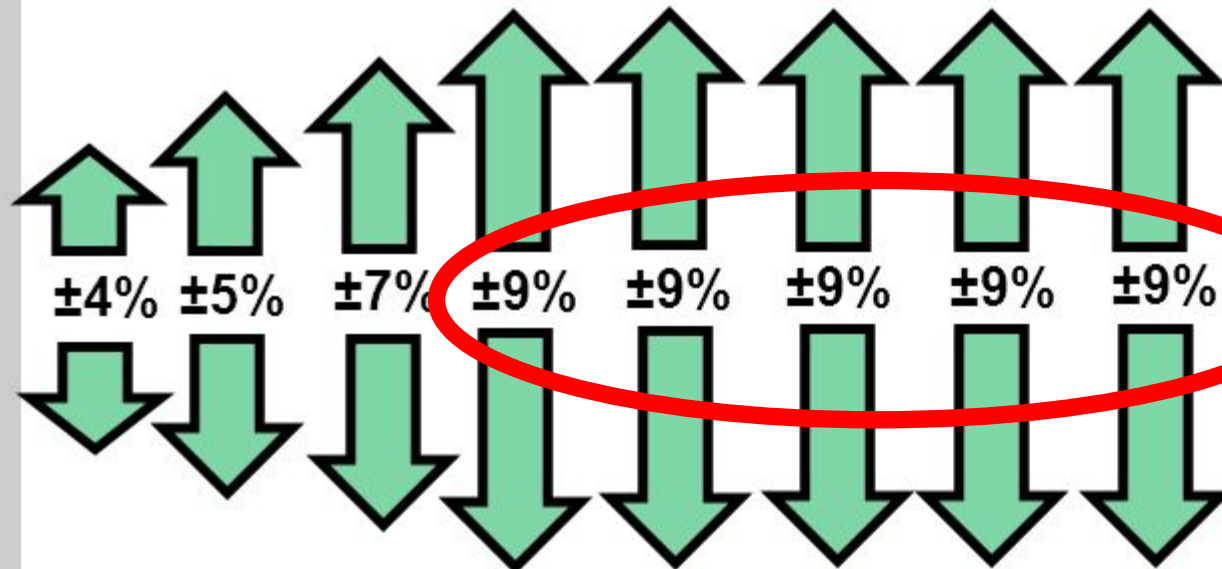
APM: Bonus of 5% of PFS payments annually

APM
0.75% annually;
no bonus payments

0.0% annual update

2019 2020 2021 2022 2023 2024 2025 2026

MIPS
0.25% annually, PLUS
penalties/bonus up to
 $\pm 9\%$



American Hospital
Association

A Word on PAMA

Lab Market Price Reporting

- Protecting Access to Medicare Act of 2014 (PAMA).
- Six Sections address clinical lab testing.
- Effective Jan. 1, 2017, certain labs must report market price data: every payer, every price for every test.
- Effective Jan. 1, 2018, CMS to use market data to set prices for Part B clinical laboratory tests.
- Prices cannot decline more than 15% in 2018, 2019, 2020 and 10% in 2021, 2022, 2023.

Impact on Labs Is Huge

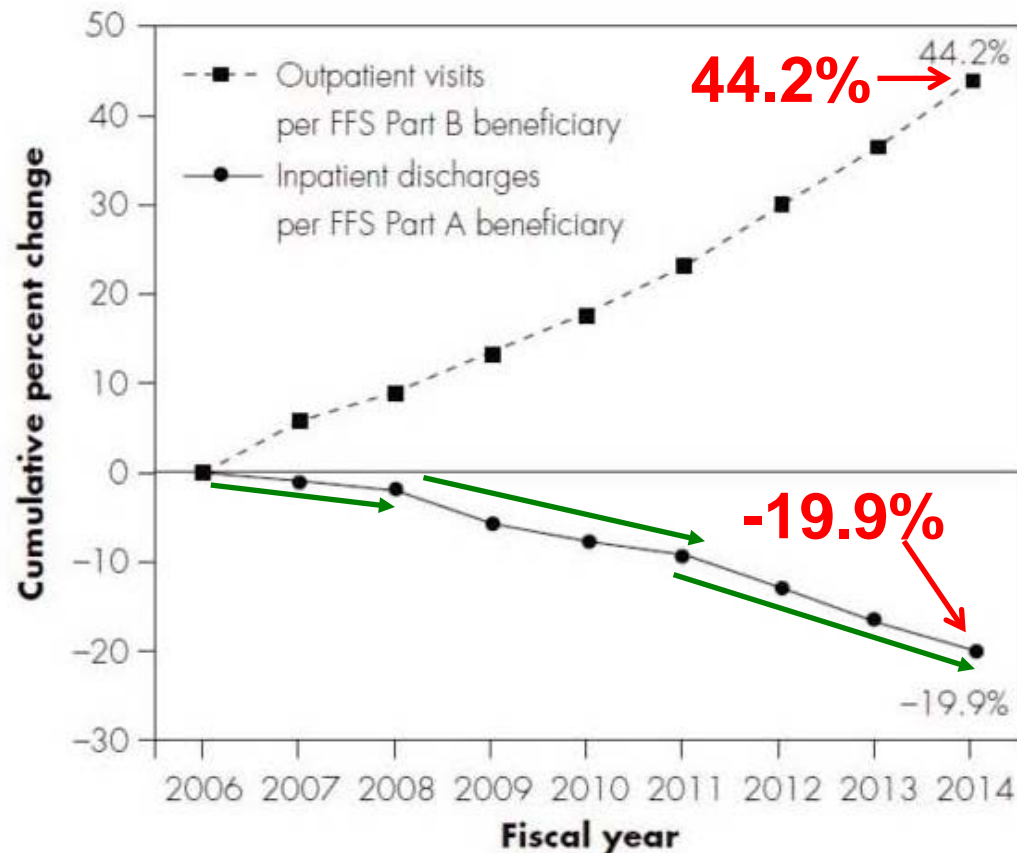
- Lab economics recognizes value of economies of scale when payment is fee-for-service.
- As fee-for-service disappears, labs will be paid according to how they add value to physicians and help improve patient outcomes.
- Big change for clinical labs, since high volume no longer guarantees success.

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
3-1**

Medicare inpatient discharges per beneficiary continued to decline as outpatient visits per beneficiary continued to increase



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

Source: MedPAC analysis of CMS's inpatient and outpatient claims and enrollment data.

Key Point

Inpatient procedures shrinking by single digits each year.

Outpatient procedures growing at double-digit rates annually.

Labs must have access to outpatient and outreach specimens!

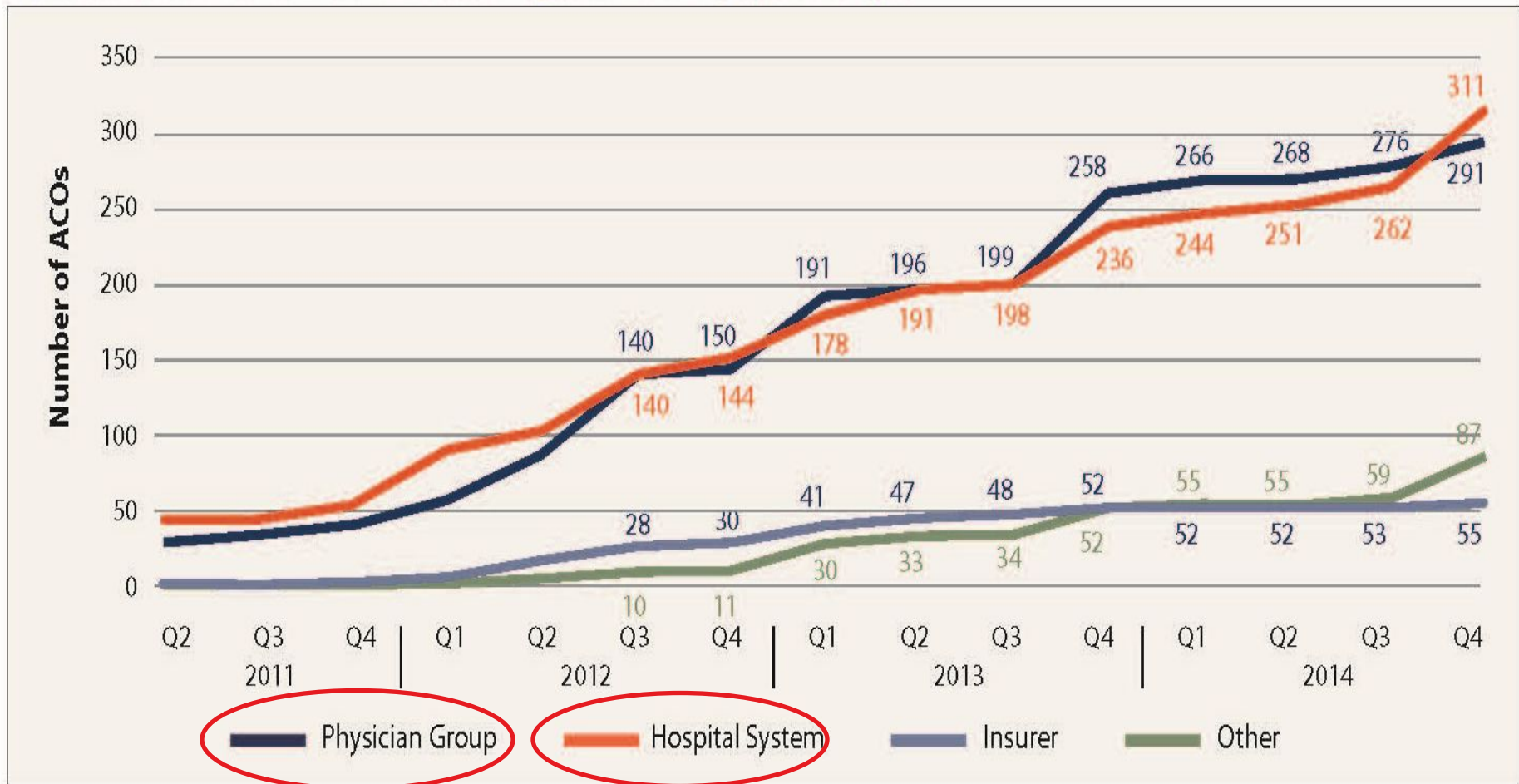
Source:

*MedPac Report to Congress:
Medicare Payment Policy,
March 2016*

ACOs Continue to Grow

Hospital Systems and Physicians jockeying to control care via their own ACO.

Figure 1. Growth in Accountable Care Organizations by Sponsor Type*

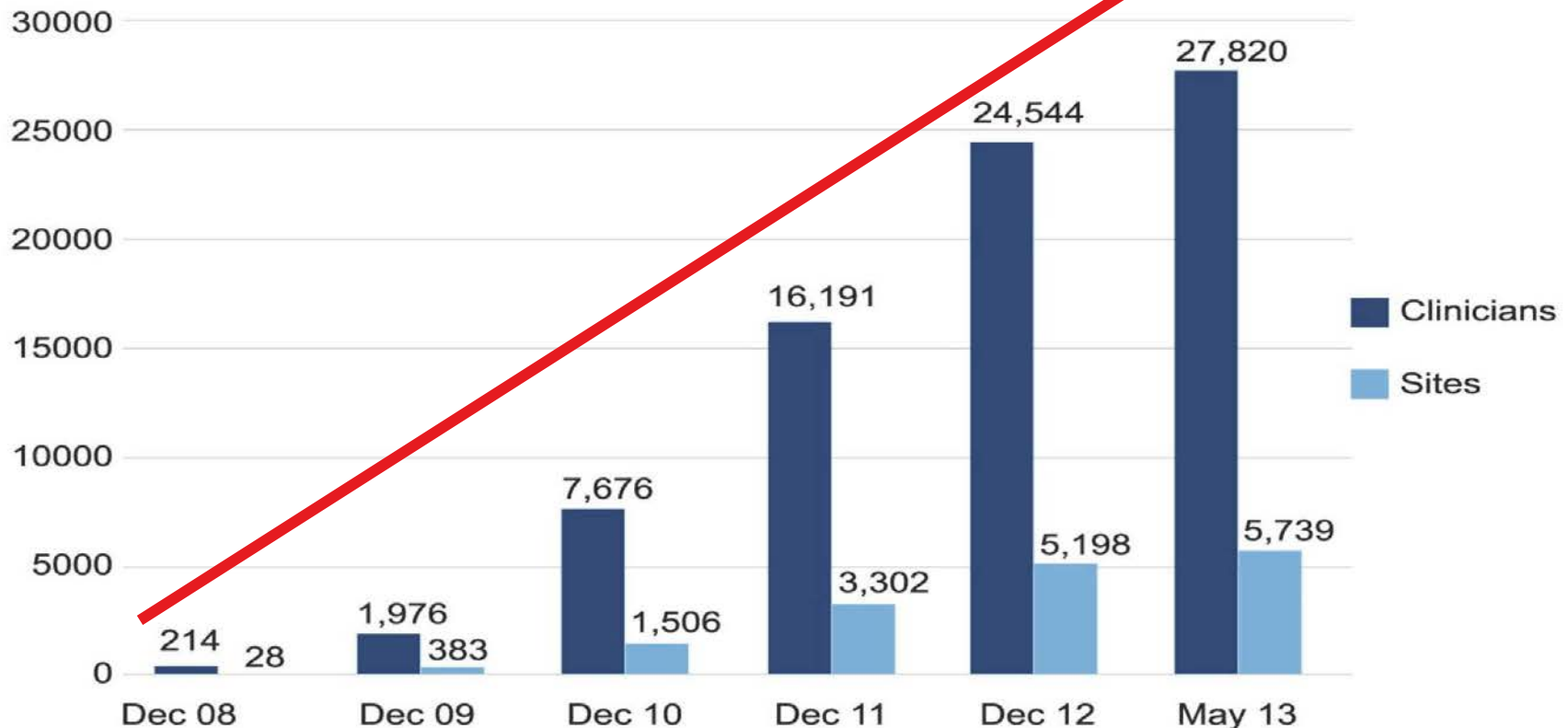


* Includes ACOs with both government and commercial contracts. Source: Leavitt Partners, 2015.

Patient-Centered Medical Homes Also Growing

Figure #1

NCQA PCMH Growth 2008-2013



Source: National Committee for Quality Assurance, 2013

Force for Change

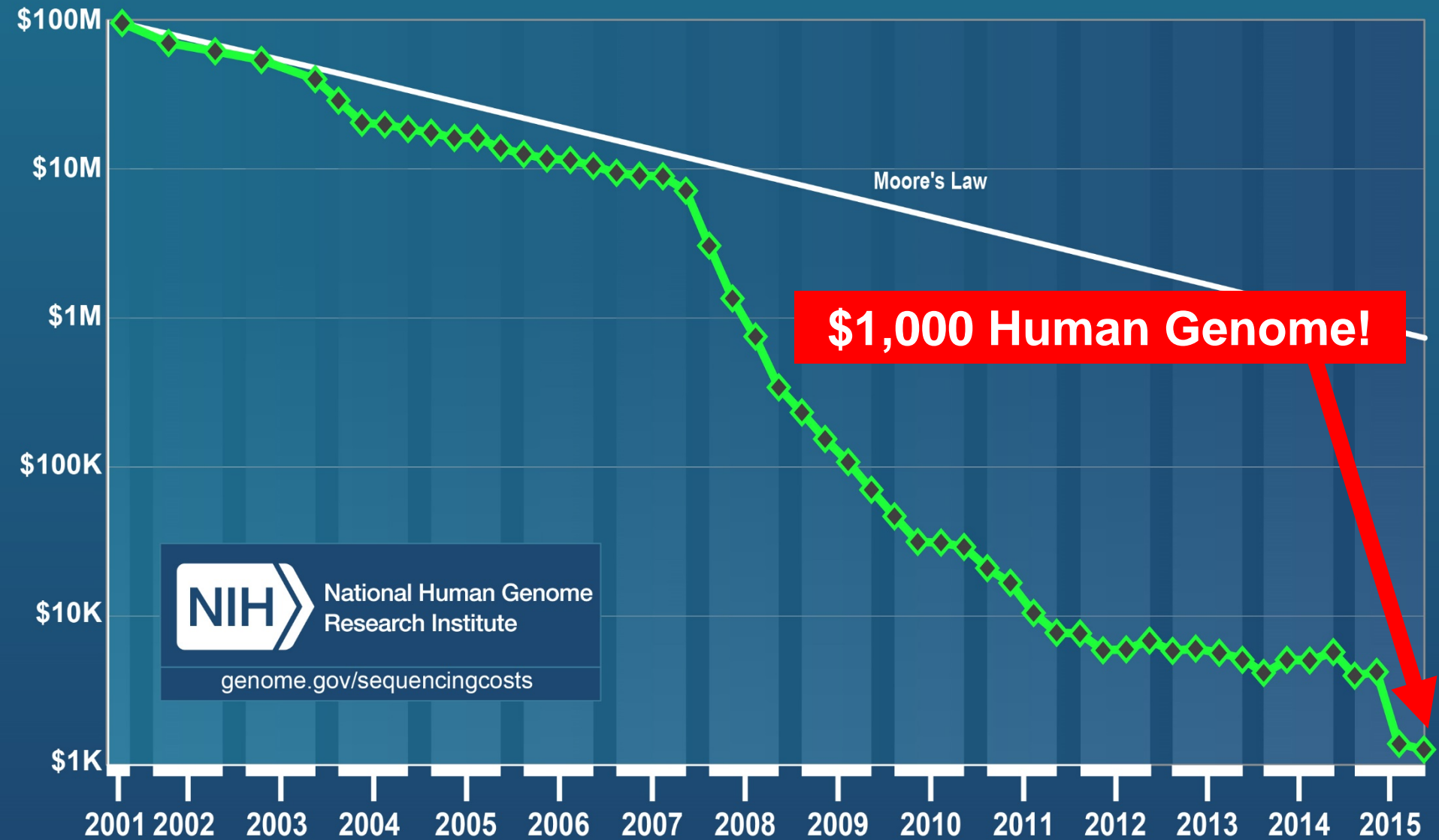
Personalized, Proactive Medicine Informed by Genetics

- During your career: reactive medicine and acute care.
- Coming soon to a provider near you:
 - ◆ Proactive Medicine.
 - ◆ Personalized Medicine (Precision Medicine).
 - ◆ Genetic analysis; whole human genome sequencing.

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 Genome



Informatics, Big Data, & Labs

- Healthcare big data will address two ends of the care spectrum:
 - ◆ Analysis in support of population health management.
 - ◆ Analysis in support of personalized medicine; diagnosis/treatment of individuals.
- Lab test data is essential in support of both activities.
- Every clinical lab and pathology group needs an informatics strategy.

Transparency Has Several Dimensions

- ✓ **Price transparency**
- ✓ **Outcomes transparency**
- ✓ **Errors transparency**

Price Transparency

- Employers, Medicare, payers want consumers to have more skin in the game.
- High-deductible health plans (HDPs) and ACA insurance exchange products.
- Individual/family deductibles as much as \$5,000 to \$10,000 per year.
- 24% of employees enrolled in employer-sponsored high-deductible plans in 2015.
- Up from just 4% of employees in 2006, according to Kaiser Family Foundation.

Outcomes Transparency

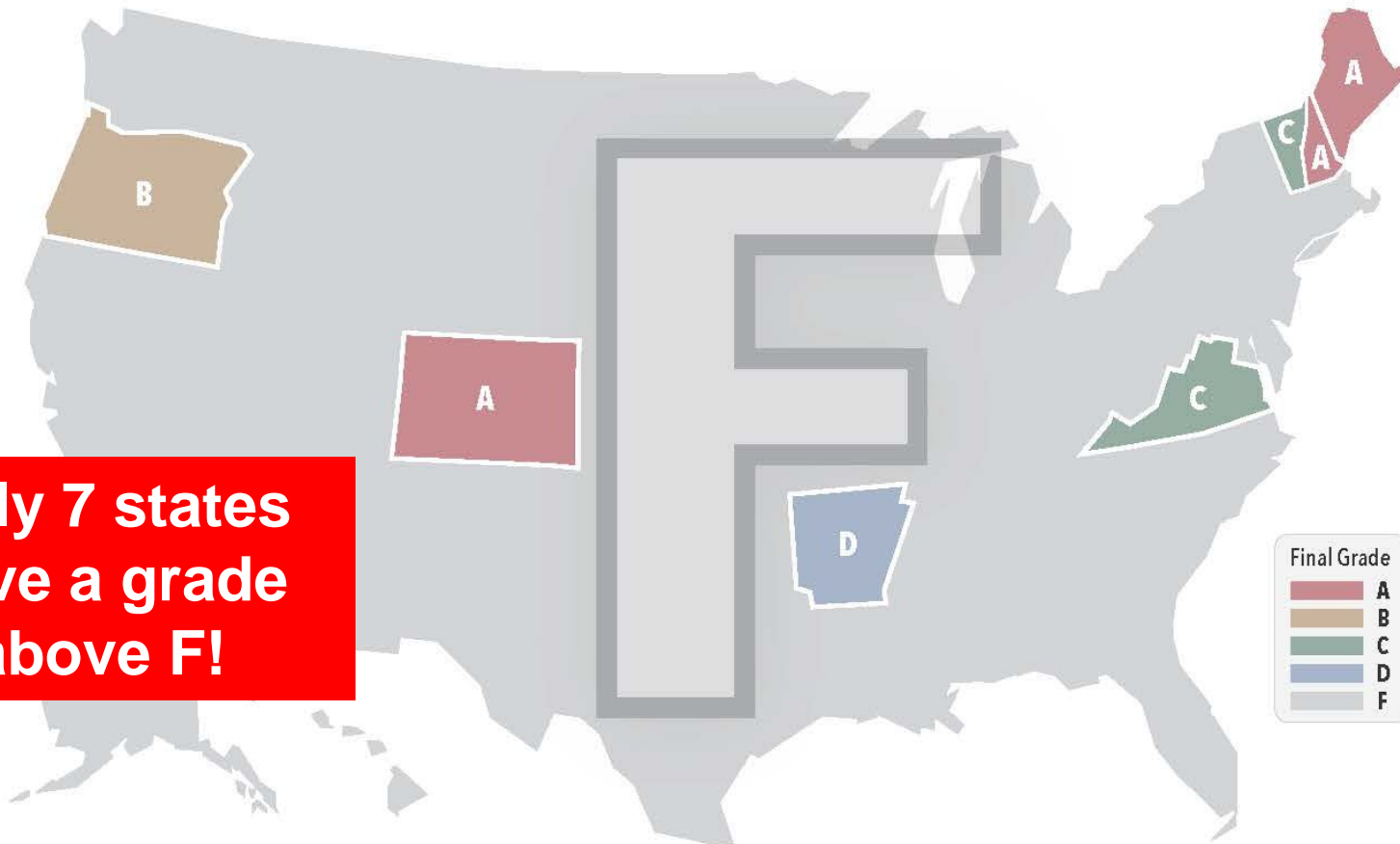
- “41% decrease in central-line blood infections between 2008 and 2011 because public reporting programs that spurred action among senior-level hospital management.” *
- “Public Reporting Measures Fail to Describe the True Safety of Hospitals”
 - ◆ Johns Hopkins study of May 10, 2016.
 - ◆ Study finds only one measure out of 21 to be valid.

** Improving Health Care Through Transparency & Performance Measurement, Consumer-Purchaser Alliance. December 2014*

Report Card on State Transparency Laws—July 2016

8 | Report Card on State Price Transparency Laws — July 2016

Report Card



**Only 7 states
have a grade
above F!**

Why Price Transparency...

- For example, the pricing of a heart imaging perfusion procedure in San Jose, California is all over the board. It can cost as little as \$1,000 or as much as \$3,000, according to Healthcare Bluebook.
- That would be the automotive equivalent of a Honda Accord available for sale at one dealership for \$24,000, and one in another part of town for \$72,000, although you wouldn't actually know the deal you received until the payment book arrived in the mail.
- Healthcare Blue Book's fair price is in the middle: \$1,518.

***If you were a patient,
would this help you?***

INTERPRET THE DATA: CALL OUT VALUE KNEE REPLACEMENT

HOSPITAL	IMPROVED FUNCTIONING	PREVENTION OF COMPLICATIONS	AVERAGE COSTS	HIGH VALUE (high quality and low cost)
EVERGREEN HOSPITAL	Average	Below	\$32,685	
LAKEVIEW HOSPITAL	Better	Better	\$23,815	✓
WOODLAND HOSPITAL	Below	Below	\$44,686	
SIERRA VISTA HOSPITAL	Better	Better	\$25,652	✓
PARKDALE HOSPITAL	Average	Average	\$38,789	

Outcomes Transparency

- Consumers incentivized to buy healthcare based on price and quality.
- Healthcare 'big data' to give consumers access to provider outcomes, quality.
- Patient price-shopping tools multiplying.

Price Transparency Tools

- Aetna's Member Payment Estimator
- Geisinger's MyEstimate®
- Maine HealthCost
- Maricopa Integrated Health System's Copa Care estimate
- Spectrum Health and Priority Health price transparency tools
- UnitedHealthcare's Price Transparency Tool
- Wisconsin PricePoint

Errors Transparency

- Consumers and media have increased expectations for quality.
- Medical errors regularly reported by local and national media.
- Expect more federal regulations and state laws that require medical errors to be reported to public.

AmeriPath Lab In Shelton Fined \$152,000 For Safety Violations



a woman working in a medical lab User Upload Caption: A Shelton laboratory that performs diagnostic services for doctors and hospitals has been fined \$152,000 for worker-safety violations, including failing to provide appropriate medical exams to employees who had symptoms of exposure to hazardous chemicals, federal regulators said Thursday. Getty Images/iStockphoto (Achim Prill / HANDOUT)



By **Josh Kovner**

Hartford Courant
Sept. 1, 2016

OSHA Made Violations Public

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Home Business

Shelton diagnostic lab cited by OSHA

By **Luther Turmelle**, *New Haven Register*

POSTED: 09/01/16, 8:50 PM EDT | UPDATED: ON 09/01/2016 0 COMMENTS

SHELTON >> Federal workplace health and safety officials have cited a city-based subsidiary of Quest Diagnostics Corp. for failing to take the proper precautions to protect workers from hazardous chemicals.

The U.S. Department of Labor's Occupational Safety and Health Administration wants to fine Quest Diagnostics \$152,000 for 17 health and safety violations at the company's Ameripath diagnostic laboratory in Shelton. The announcement of OSHA's proposed penalties on Thursday came after the agency investigated complaints by Ameripath workers about sore throats, headaches and difficulty with breathing they were experiencing.

The Columbus Dispatch

777-4806



» Hot Links:

OSU lab in trouble over test samples; no one at risk

No one at risk; officials say federal issue will be cleared up

2012

The New York Times

BUSINESS DAY

Quest Acknowledges Errors in Vitamin D Tests

By ANDREW POLLACK JAN. 7, 2009

The nation's largest medical laboratory company provided possibly erroneous results to thousands of people who had their vitamin D levels tested in the last two years, the company has acknowledged.

2009

Sloppiness, lax oversight revealed at Cleveland Clinic's Marymount lab; overhaul includes firings



Investigators found that Cleveland Clinic's Marymount Hospital was violating dozens of federal rules meant to protect patients and ensure the accuracy of laboratory test results. (*Plain Dealer*)



[\[http://connect.cleveland.com/staff/caseyross/index.html\]](http://connect.cleveland.com/staff/caseyross/index.html) By **Casey Ross, The Plain Dealer**

[\[http://connect.cleveland.com/staff/caseyross/posts.html\]](http://connect.cleveland.com/staff/caseyross/posts.html)

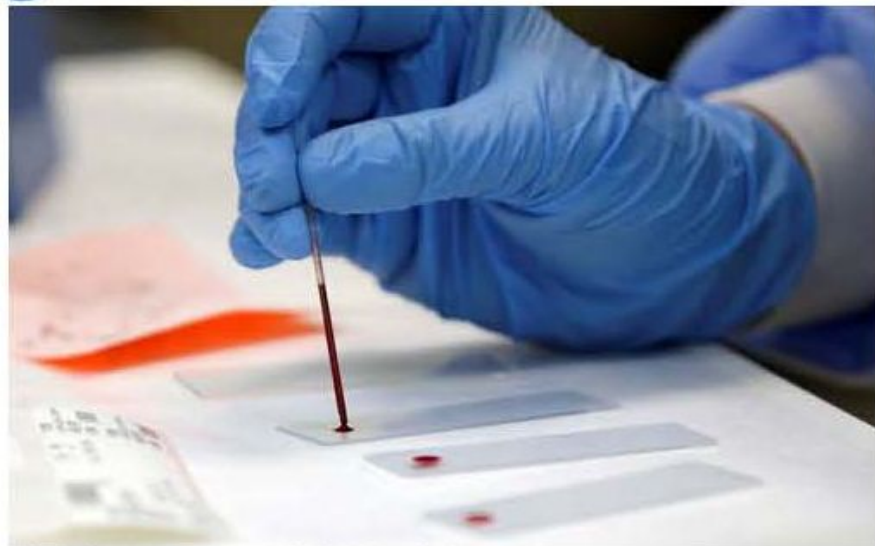
Follow on Twitter [\[https://twitter.com/byCaseyRoss\]](https://twitter.com/byCaseyRoss)

on September 25, 2015 at 8:00 PM, updated September 27, 2015 at 8:00 AM

CLEVELAND, Ohio -- The test results inside Marymount Hospital's clinical laboratory were a patchwork of scribbled notes and white-out.

In some instances, new results were written on top of the white-out. In others, the words "change" or "RERUN" were written and circled. The notations were evidence of a severe violation: the Cleveland Clinic-owned lab was improperly altering tests designed to verify the accuracy of its results, according to a report by federal investigators.

The report's findings meant not only that the lab was violating dozens of government rules, but also that the quality of its testing of patient blood and urine samples was in doubt.



Hidden Errors | A Watchdog Report

Weak oversight allows lab failures to put patients at risk

From drug screens to vital medical tests, secretive system hides lab problems from the public

By [Ellen Gabler](#) of the Journal Sentinel staff

May 17, 2015 12:00 p.m.

Everyone assumes lab results are correct.

For Kenneth Drew, the results showed he had HIV in 2011. By the time he found out the lab was wrong, his relationship with his wife was badly damaged. The Alabama couple separated, both distraught about the diagnosis.

Adding Value to Lab Testing with Lean and Quality Management

- ✓ **Eliminate systemic errors**
- ✓ **Identify opportunities to add value**
- ✓ **Continuous improvement to stay ahead of customer expectations.**

Explaining 'Volume to Value'

- Fee-for-service reimbursement rewarded hospitals, doctors, labs for providing more care.
- Shift to budgeted reimbursement will quickly make volume unprofitable.
- Thus, keen interest by providers to eliminate unnecessary procedures.
- Lab test utilization: cut duplicate and unnecessary tests.
- Help physicians order right test, then use test results to do right thing for patient.



**BIG BROTHER IS
WATCHING YOU**

Theranos Said It Could Deliver...

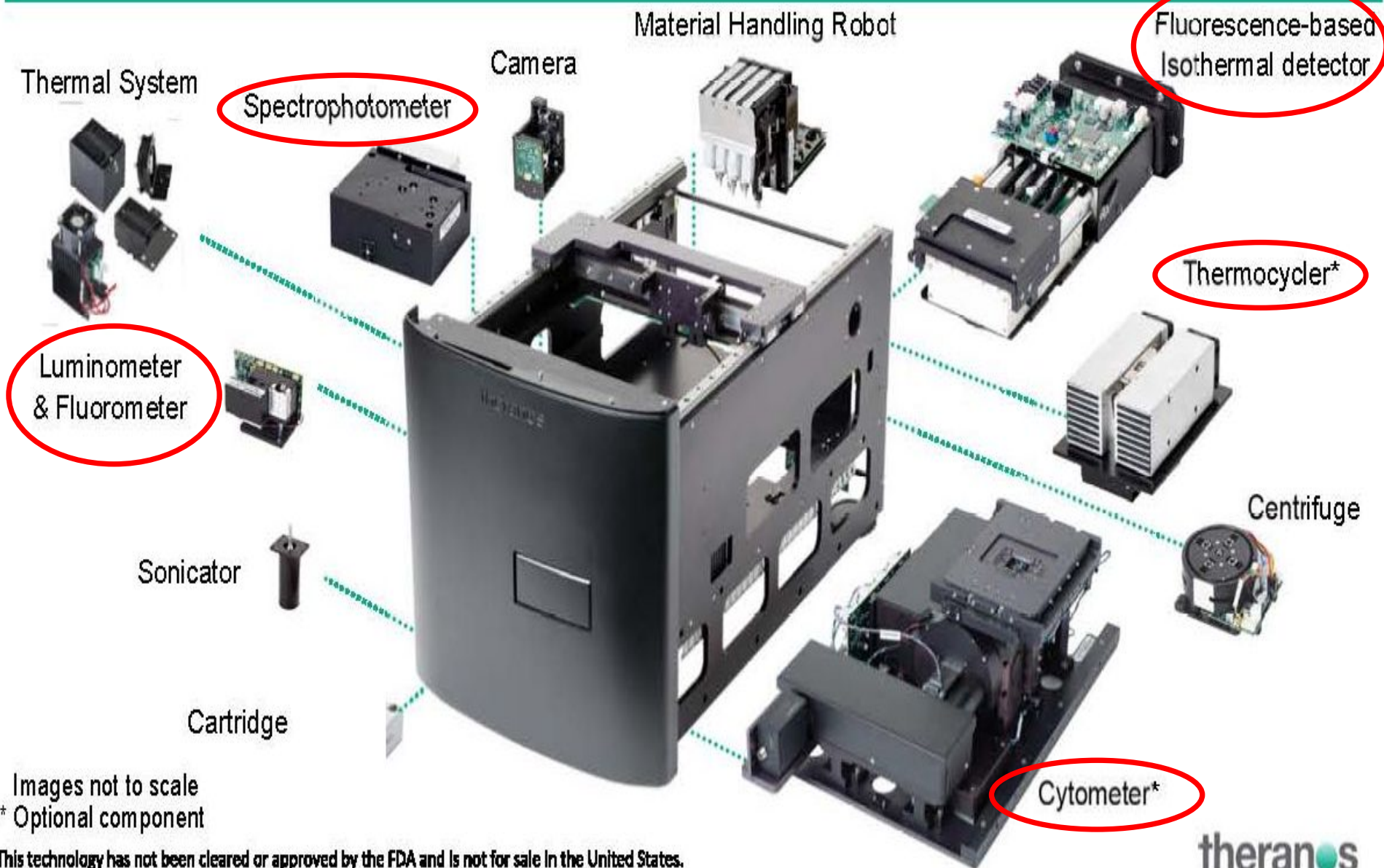
- Because people don't like needles, it can collect a specimen with a needle stick on the fingertip.
- Only requires a small amount of specimen, between 25 to 50 microliters. *(Can perform up to 30 tests on single drop of blood.)*
- Theranos can report results to physicians and patients in four hours.
- Will charge only 50% of Medicare Part B lab test prices.
- CBC: Medicare: \$10.50 / Theranos: \$5.25.

What Happened?

- *The Wall Street Journal* published a series of exposés about Theranos in Oct./Nov.
- Since 2013, Safeway spent \$350 million to remodel 800 grocery stores to have a patient service center and room for lab testing. Theranos did not deliver.
- Walgreens ended its agreement with Theranos.
- CLIA inspection of lab in Newark, California, identified serious deficiencies that could cause patient harm.
- CMS imposed sanctions, including banning Holmes from owning a lab; Theranos appealed.



Theranos Sample Processing Unit (miniLab)



Speakers Today

- **Jim Ellis** on:
How to use the Laboratory Value Pyramid
- **David Layton, Bonnie Messinger** on:
Pursuing Best-of-Class on a budget
- **Richard Zarbo, MD, PhD,** on:
Delivering Value to physicians, patients
- **James Crawford, MD, PhD,** on:
Supporting precision medicine today

Speakers Tomorrow

- **Hess, Driscoll, Nucifora, Olea, Querry** on:
Laboratory certification and accreditation
- **Denise Utweiller-Geiger, PhD** on:
Hospital-wide collaborations with the lab
- **Lucia Berte** on:
Recognizing and eliminating sources
of recurring bad quality in the lab

Final Thoughts on Opportunity...

“The aim of medicine is to prevent disease and prolong life...

...the ideal of medicine is to eliminate the need for a physician.”

—William James Mayo
1861-1939

