

***Surviving & Thriving Past the “Regulatory Perfect Storm”***

**Thinking Strategically about What Happens  
Next after Labs Weather the “Perfect Storm”**

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***29<sup>th</sup> Annual Executive War College***  
***30 April 2024***  
***New Orleans, Louisiana***

A dramatic background image of a stormy sea with dark, turbulent waves and a bright lightning bolt striking down from a dark, cloudy sky. The overall tone is ominous and urgent.

## *Recap from This Morning: Perfect Storm Is Heading to Laboratory Profession!*

- Major developments unfolding that will touch most labs.
- Like 1991's Perfect Storm, three major factors are converging to create a once-in-a-lifetime event
- Most clinical lab and pathology leaders are aware of at least two of the three components.
- At this time, few laboratory organizations have a strategy that recognizes all three factors.

## Storm Force #1:

# FDA Issued Final LDT Rule Yesterday!

- FDA issued final rule to regulate laboratory developed tests (LDTs) yesterday, April 29.
- “Unpublished” final LDT rule was released to the public.
- Federal Register will publish final LDT rule on May 6, 2024.
- Unpublished version of LDT rule is a total of 538 pages.
- Here at *Executive War College* today, you were first to learn specifics about the final LDT rule.
- Expect litigation! Many group dispute FDA’s authority to regulate IVDs.

## *Storm Force #2:*

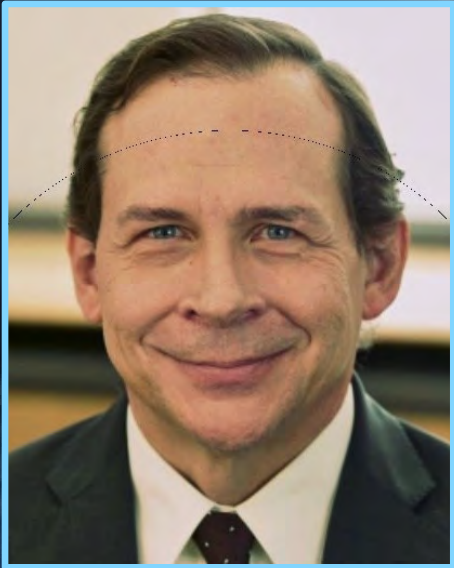
# ***Private Health Insurers Require Z-Codes for Genetic Tests Insurers***

- Problem for Medicare & private payers: 160,000 genetic tests in Concert Genetics' database.
- Last spring, UnitedHealthcare issued a policy requiring approx. 250 genetic test CPT codes to have a Z-Code when claim is submitted; now to become effective on June 1, 2024.
- UnitedHealthcare deferred implementing this policy several times, but labs are on notice that it will happen.
- All major health insurers watching to see if this policy succeeds after implementation by UnitedHealthcare.

# *Storm Force #3:* **Revisions and Updates to 1992 CLIA Regulations**

- Clinical Laboratory Improvement Amendments (CLIA) Act of 1988: Regulations were issued in 1992 and significant updates have not been put in place in past 32 years.
- Clinical laboratory testing in 2024 uses technologies, methods, and processes not invented in 1992.
- Effort ongoing with the CLIA Committee and CDC Division of Laboratory Services to develop updates and revisions.
- Expect these recommendations to be made public during next 12 to 24 months.

*Preparing Your Lab for the Storm:*  
**Trifecta of Policy-Makers Spoke Today!**  
*Executive War College, April 30-May 1, 2024*



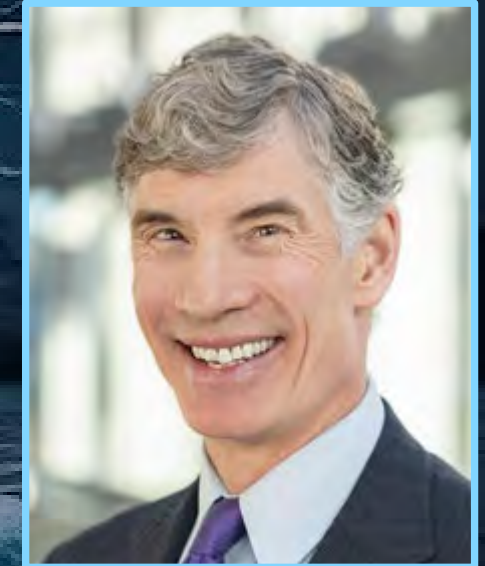
**Tim Stenzel, MD, PhD**

Former Director  
FDA Office of In Vitro  
Diagnostics



**Gabriel Bien-Willner, MD, PhD**

Medical Director, MoIDX, Z-Code  
programs Palmetto GBA,



**Reynolds Salerno, PhD**

Director, Division of Laboratory  
Systems, CDC

# *Three Themes Today*

- Snapshot of macroeconomic trends in the United States to inform every lab's strategic planning.
- Examples of major financial stress already happening in major sectors of U.S. healthcare system.
- Profitable paths forward for clinical labs and pathology groups.

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## **Major Lab Trend: Staff Shortage, Higher Salaries**

- Chronic shortage of labor across all skills and all positions.
- Demand for pathologists outstrips capacity of pathology residency programs.
- Cost of labor skyrocketing.
  - Strong demand causes labs to raise wages to attract workers
  - Inflation is separate factor driving up wages
  - California's Senate Bill 525 (passed Oct. 2023) raises minimum wage to \$25 for healthcare workers.



## *Major Lab Trend: Rising Costs, Tight Supply Chain*

- Steady rise in prices for automation, analyzers, test kits, consumables.
- Unpredictable supply chain continues, creating need to pay more for alternative sources of needed lab products.
- Ongoing **inflation** in U.S. economy adds **rocket fuel** to the continuing rise in prices for everything a lab purchases.



# **Major Lab Trend: Payers Not Paying Lab Test Claims**

- Increasingly common for health insurers to simply not pay lab test claims.
- Since 2010, explosion in number of molecular and genetic tests overwhelmed both Medicare and private payers.  
*(Concert Genomics tracks 160,000 genetic tests.)*
- MoIDx with Z-Codes launched by Palmetto GBA in 2011 as a response to code stacking and similar issues with claims.
- In 2017, UnitedHealthCare and Anthem (now Elevance) instituted prior-authorization programs for many genetic tests; other payers followed with similar requirements.
  - *In recent years, some health insurers scaled back their prior-authorization requirements.*



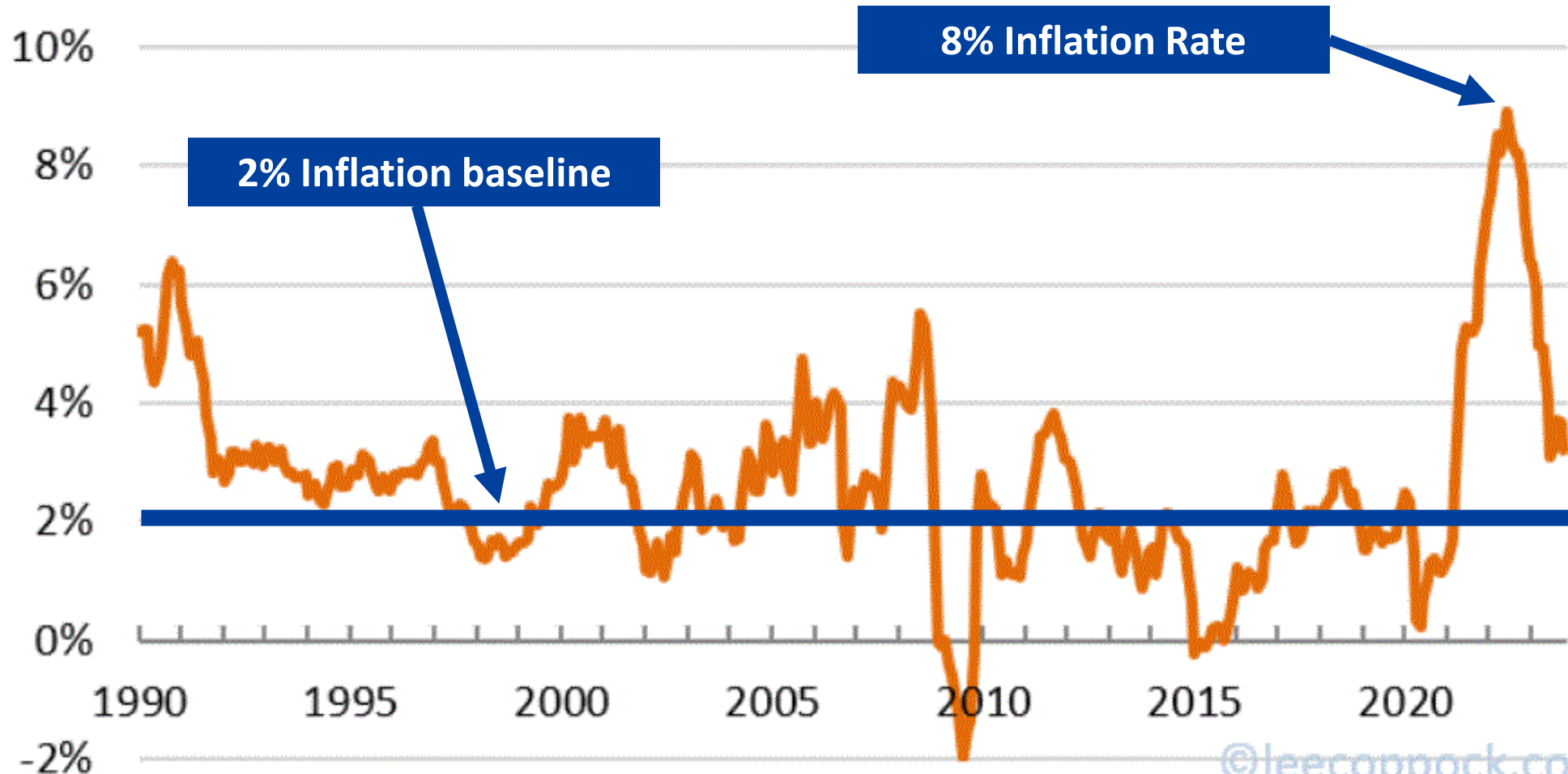
## *Next: Should Inflation Inform Your Lab's Strategic Planning?*

- You always hear:  
***“U.S healthcare costs are on an unsustainable path!”***
- Let's look at the macro financial forces that support that statement.
- Here's a quick lesson in macroeconomics in 12 slides!

# 1. Inflation Rate Increased after 2020

## U.S. Inflation

Year-over-year pct. growth in monthly CPI, 1990 - 2023



@leecoppock.com

# ***Definition of Inflation...***

“Inflation is always and everywhere, a monetary phenomenon. It's always and everywhere, a result of too much money, of a more rapid increase in the quantity of money than of an increase of output.”

**“Inflation is taxation without legislation.”**

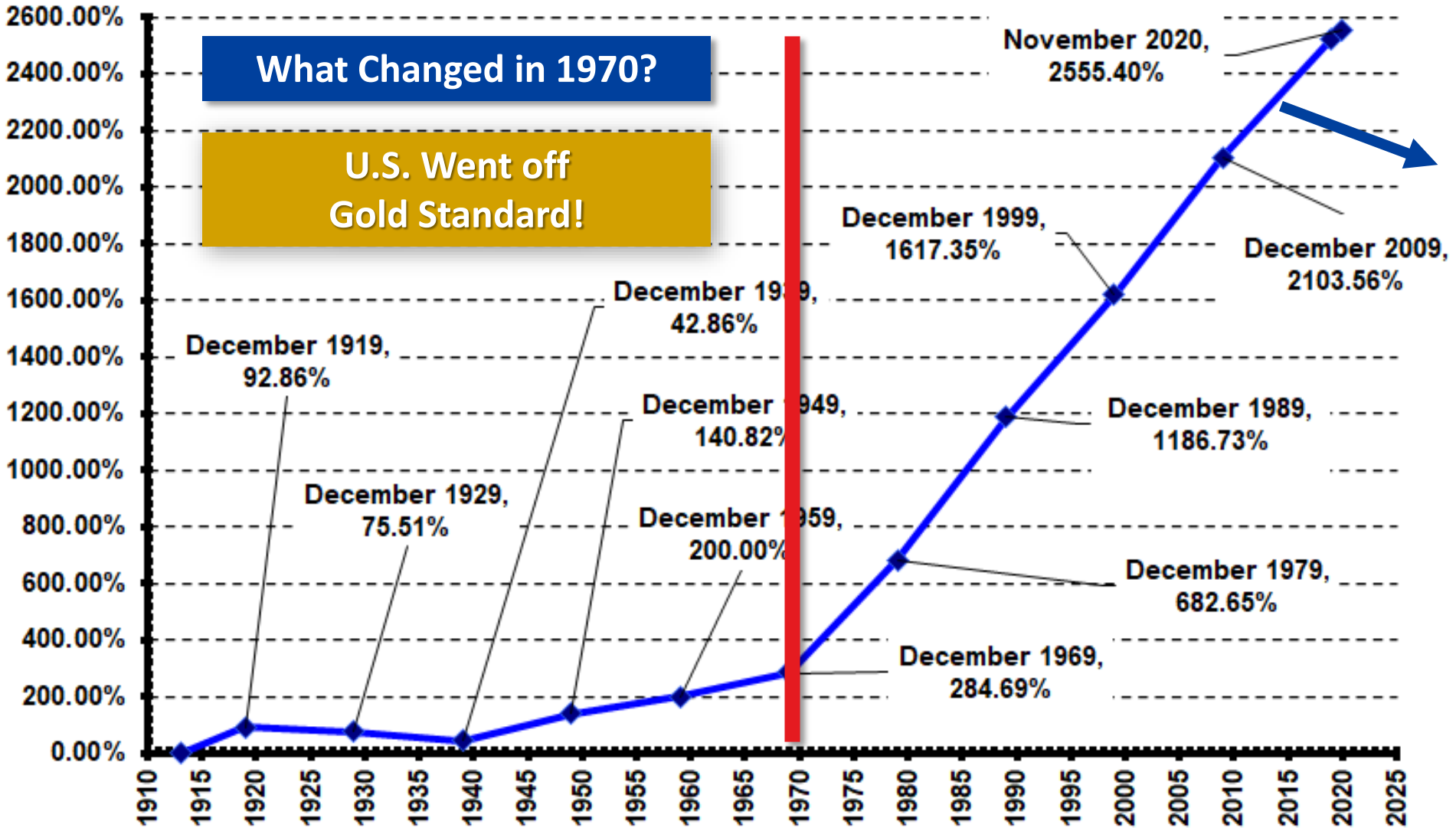


**–Milton Friedman**  
*Nobel-Prize Winning Economist*

# 2.

## Cumulative Inflation 1913 - 2020

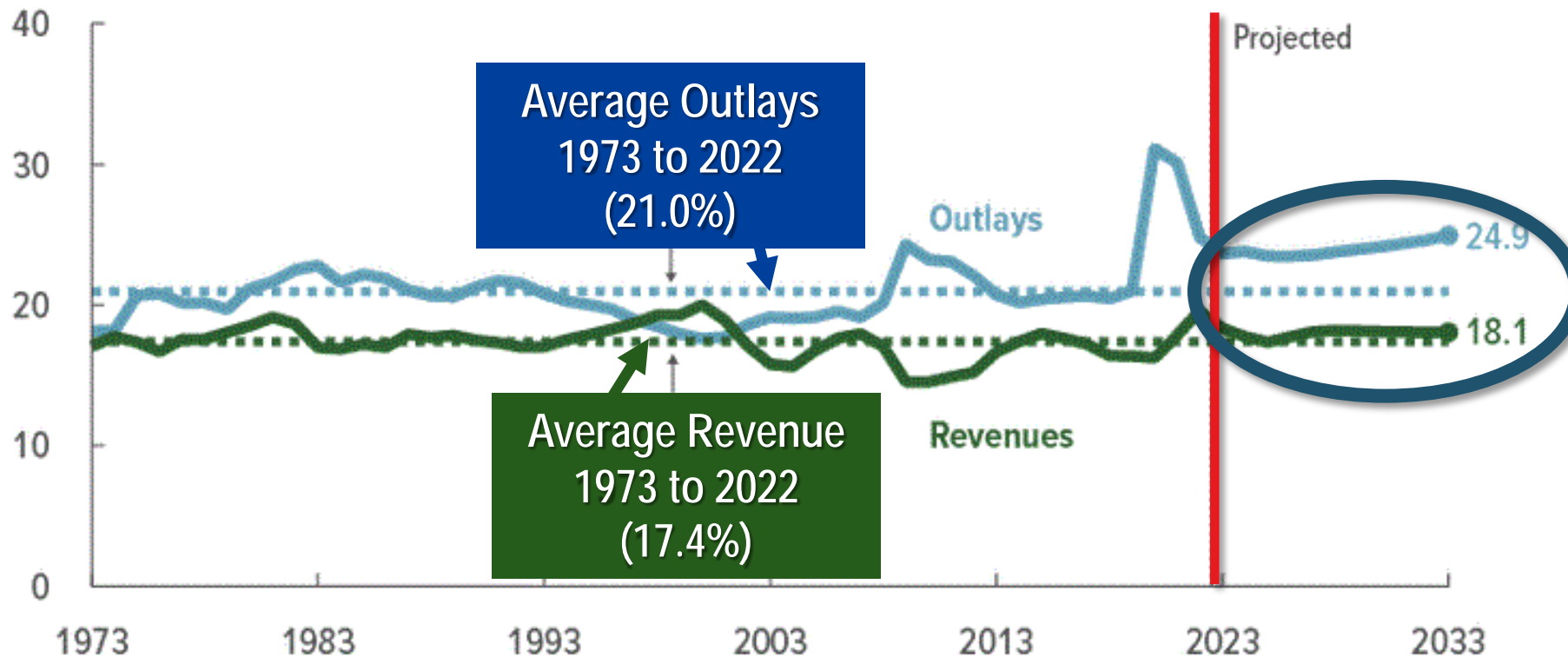
© 2020 InflationData.com  
Updated 12/15/2020



# 3. Federal Budget: Spending Trends

## Total Outlays and Revenues

Percentage of Gross Domestic Product



**OMB projects gap in outlays and revenue from 2023 forward at about \$2 trillion per year!**

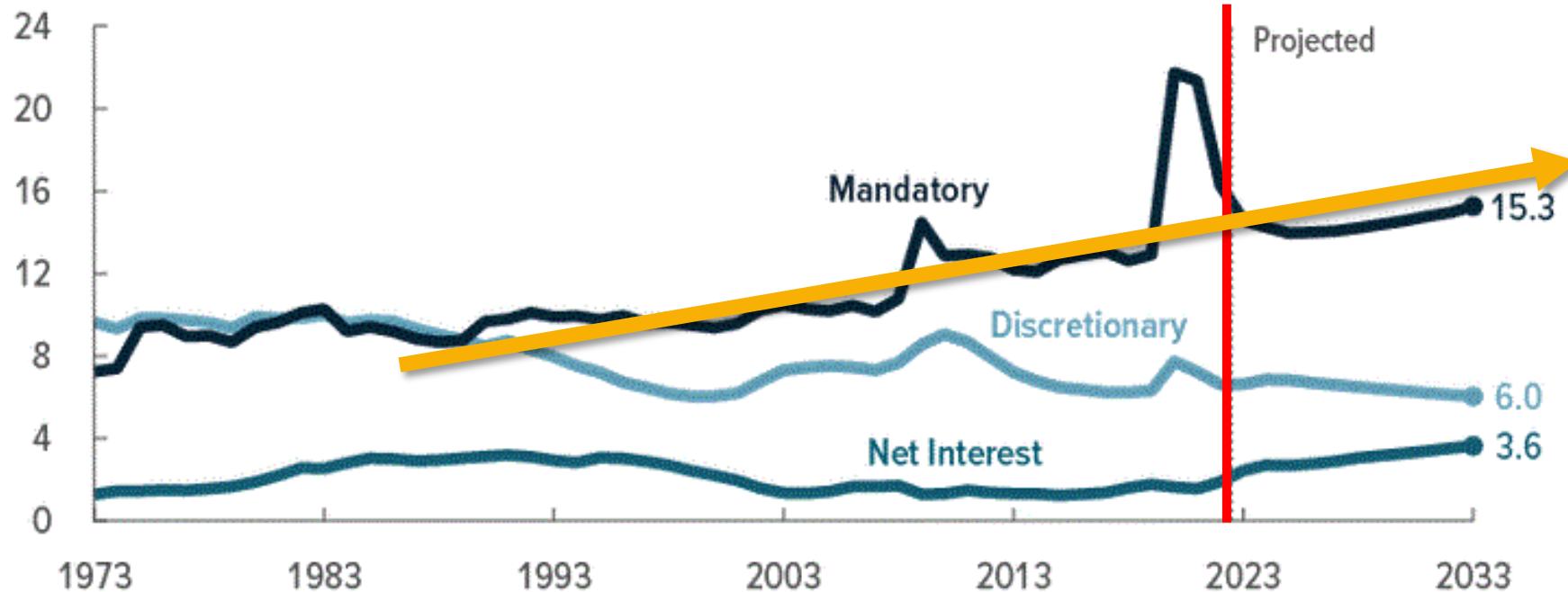
**That's the starting point for future budget deficits.**



# 4. Federal Budget: Outlays by Category

## Outlays, by Category

Percentage of Gross Domestic Product

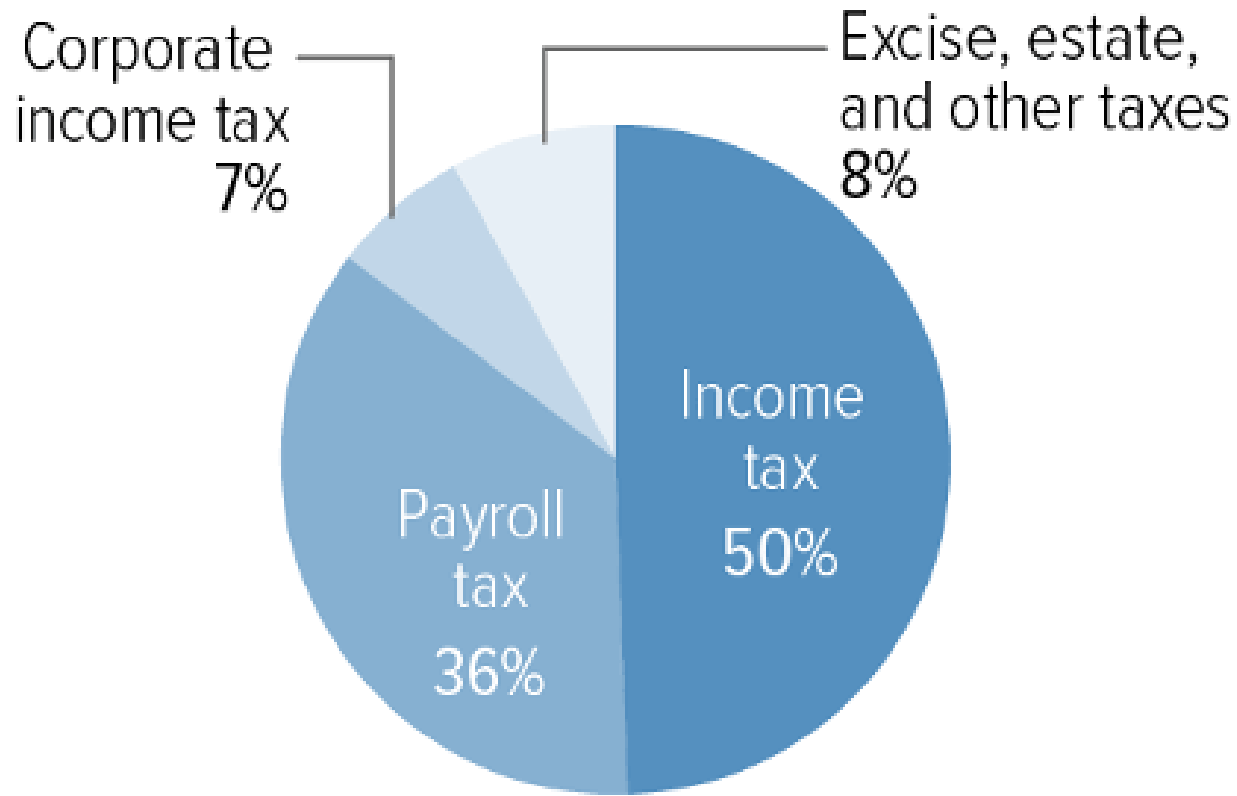


“Mandatory” is Social Security, Medicare, Medicaid

Both Mandatory and Interest projected to rise yearly

Source: Congressional Budget Office, <https://www.cbo.gov/publication/58946>

# Sources of Federal Tax Revenue, 2019



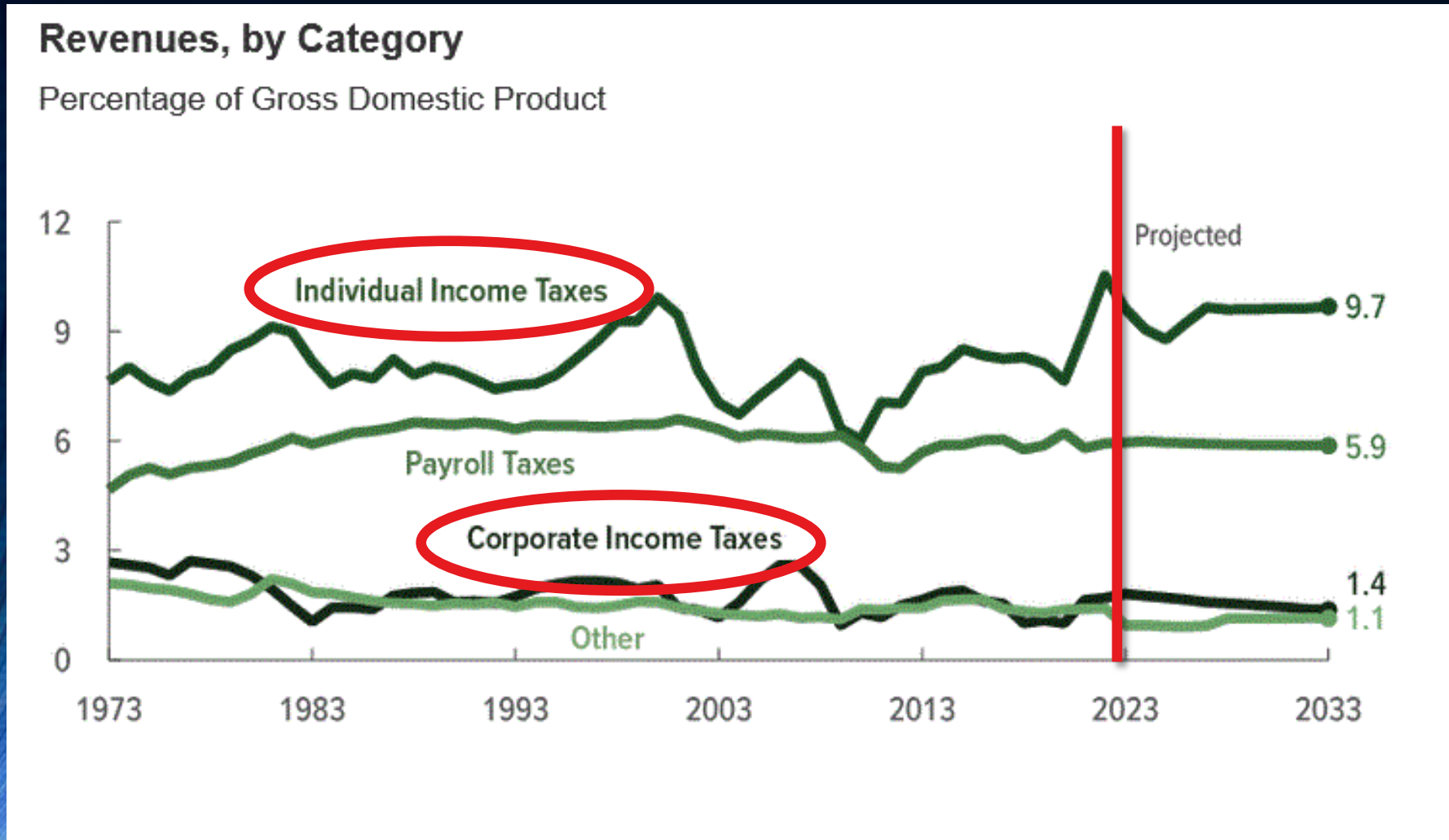
Note: "Other Taxes" category includes profits on assets held by the Federal Reserve. Figures may not add due to rounding.

Source: Office of Management and Budget

## 5. *Did you know...*

- Corporate Income Tax is only 7%
- Excise, all other taxes are only 8%
- Income tax is 50%
- Payroll tax is 36% and goes to Social Security and Medicare

# 6. Federal Budget: Revenue by Category

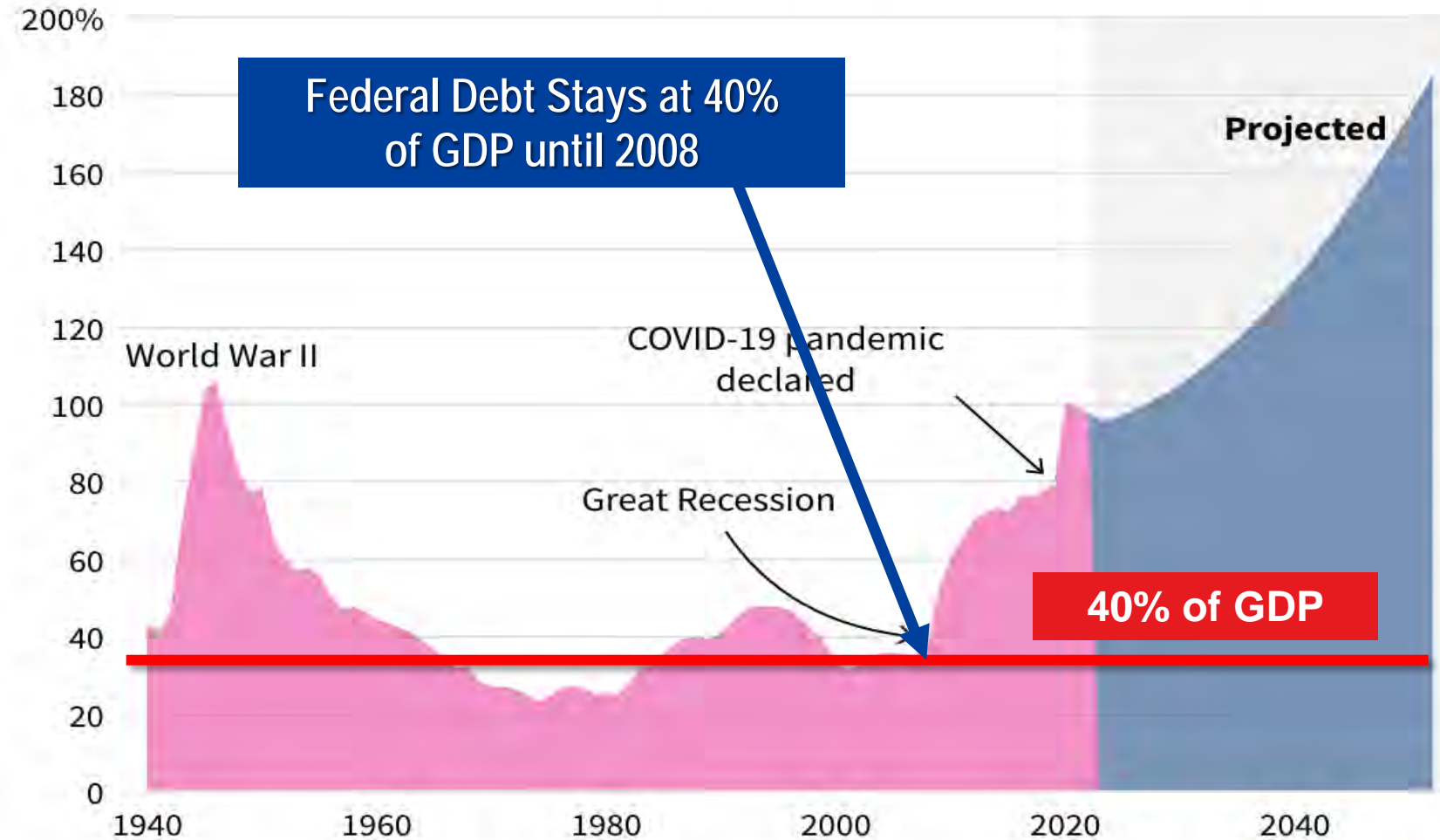


This shows that federal income tax collections are about 8X larger than corporate income tax payments

Source: Congressional Budget Office, <https://www.cbo.gov/publication/58946>

# According to economic forecasts, public debt is expected to outpace GDP for another 30 years.

Federal debt held by the public as a percentage of gross domestic product (GDP)



7.

United States GDP is \$28.5 trillion in 2023

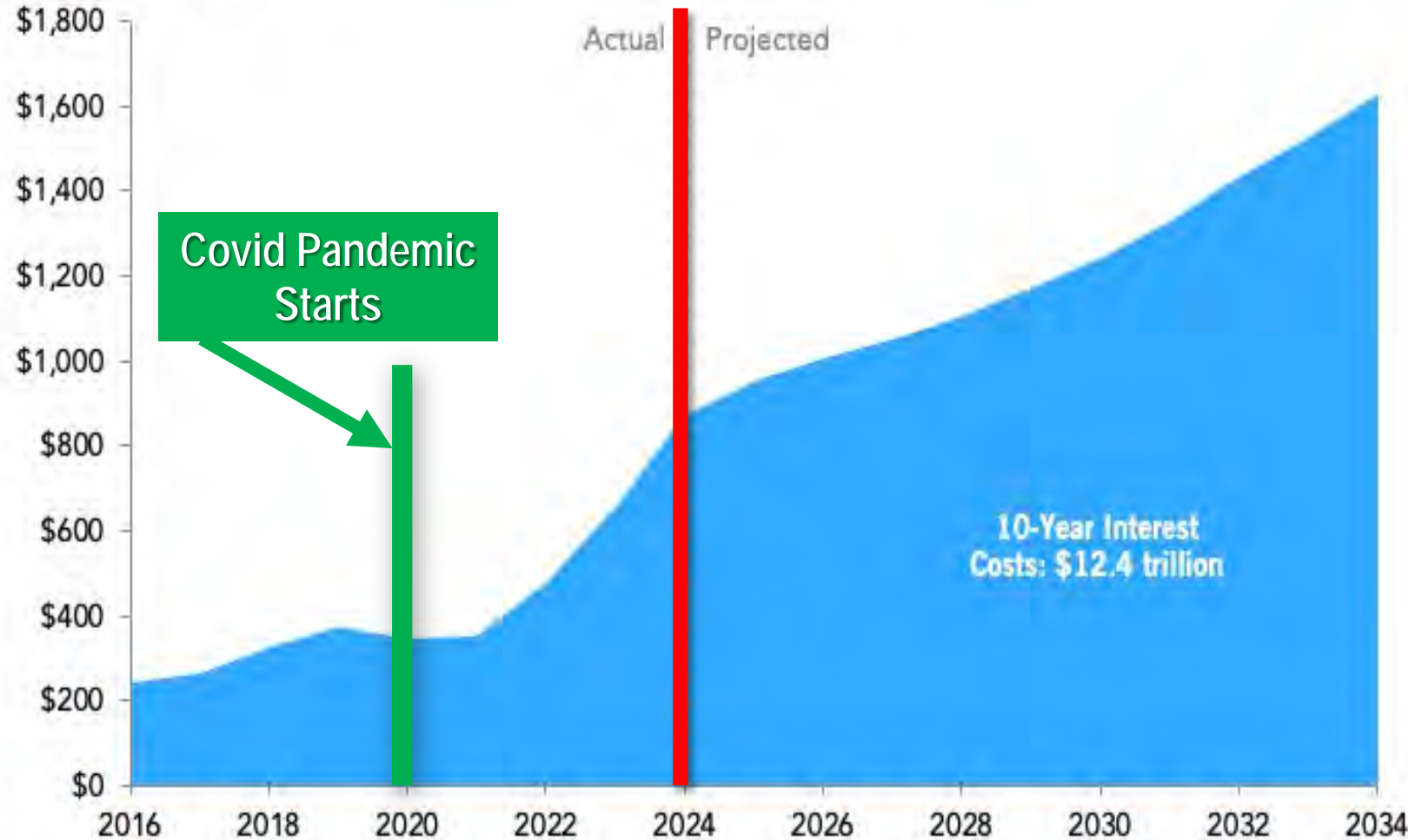
U.S. National debt is currently \$34.7 trillion.

**Debt to GDP is: 122%!**

# 8.

## Net interest costs are projected to rise sharply

Billions of Dollars



SOURCE: Congressional Budget Office, *The Budget and Economic Outlook: 2024 to 2034*, February 2024; and Office of Management and Budget, *Budget of the United States Government: Fiscal Year 2024*, March 2023.

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PGPF.ORG

## Why is this important for labs?

Treasury & Federal Reserve need to monetize Congress' Deficit Spending

This can only happen by keeping interest rates high to attract buyers of federal bonds.

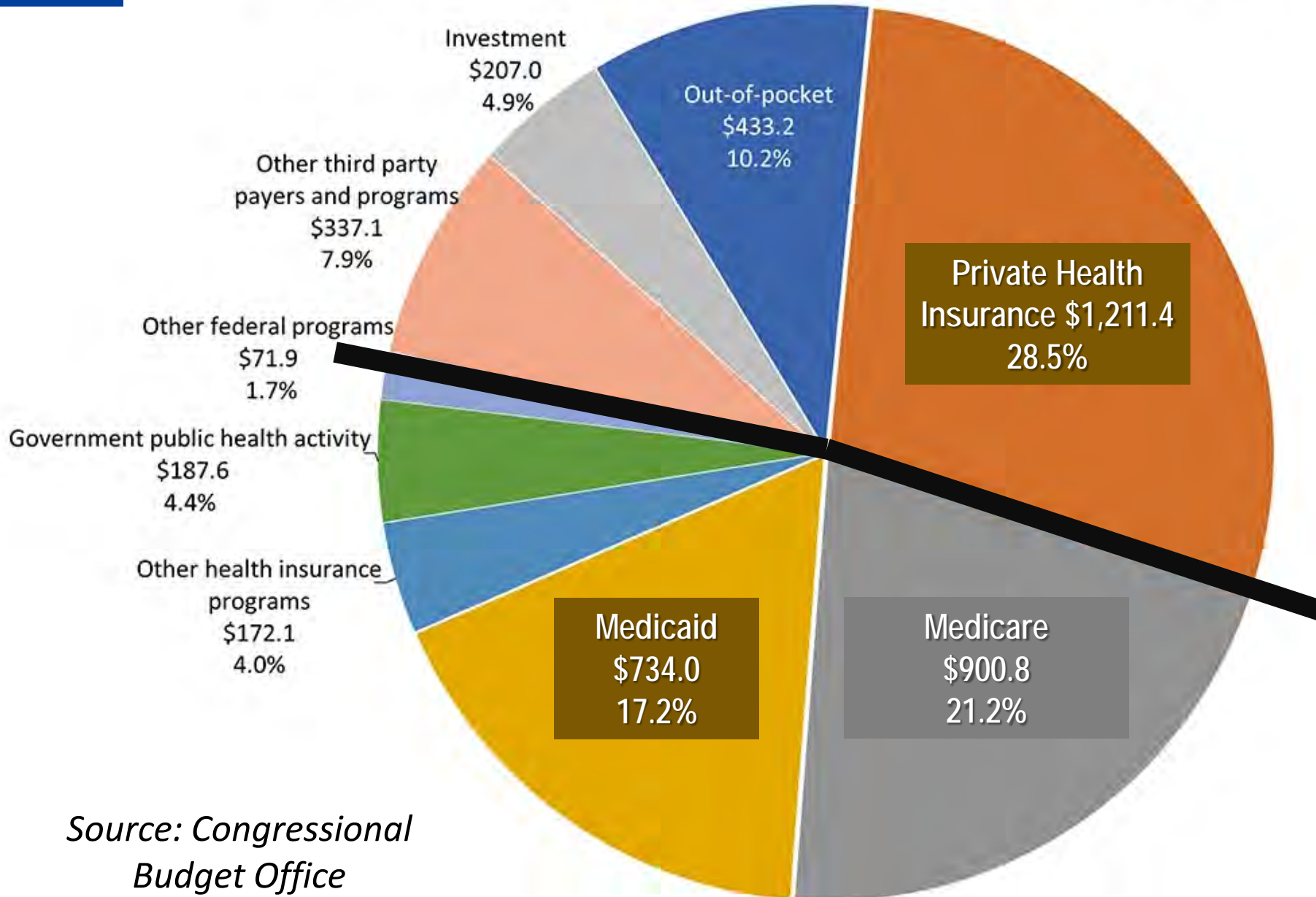
This means hospitals, labs, IVD companies will pay more in interest charges for business lending.

*Goodbye days of easy money!*

9.

# Who pays the bill?

## 2021 health care spending decomposed by source of funds



**Federal Government currently pays 52.5% of all healthcare costs annually**

Source: Congressional Budget Office

10.

Table 1: Key Findings of the 2023 Trustees Reports

	Social Security		Medicare	
	OASI	DI	HI	SMI
Type of benefit paid from the trust fund	Retirement and survivor benefits	Disability benefits	In-patient hospital and post-acute care (Part A)	Physician and out-patient care (Part B); prescription drugs (Part D)
Full scheduled benefits are expected to be payable until	2033	At least through 2097	2031	Indefinitely
Percentage of scheduled benefits payable at time of reserve depletion	<sup>a</sup> 77	—	<sup>b</sup> 89	—
75-year actuarial balance, as a percent of taxable payroll	-3.62	0.01	-0.62	—

Social Security, Medicaid Projected to Soon Go Broke!

Social Security Fund to run out of money in 2033 (That's 9 years from today.)

Medicare Fund to run out of money in 2031 (That's 7 years from today.)

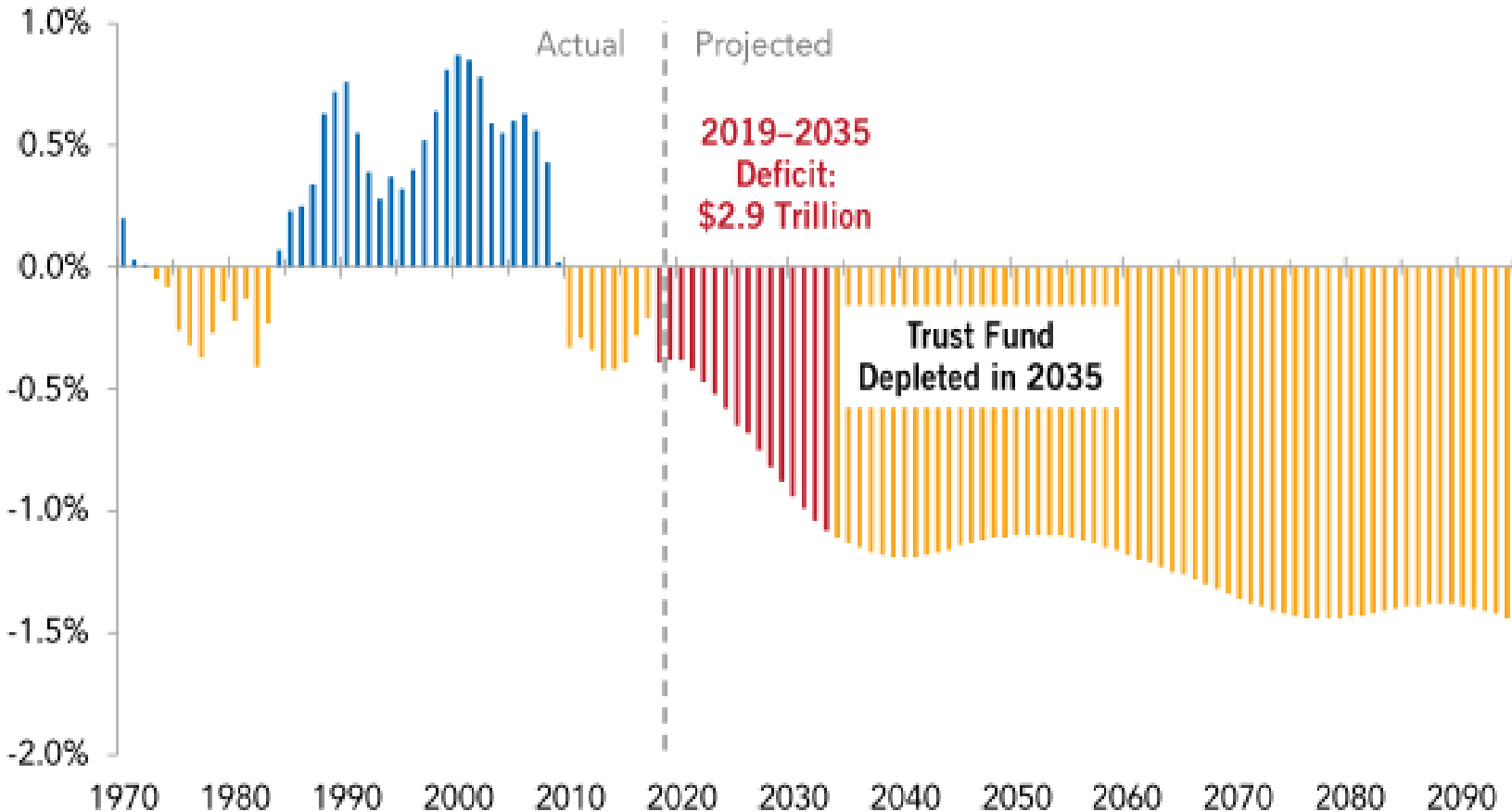
<sup>a</sup> The percent of scheduled benefits payable is projected to decline to 71 percent by 2097.

<sup>b</sup> The percent of scheduled benefits payable is projected to decline to 81 percent by 2047 before gradually increasing to 96 percent by 2097.

# 11.

Social Security will run a cumulative cash deficit of \$2.9 trillion between now and 2035

SOCIAL SECURITY SURPLUSES/DEFICITS (% OF GDP)



Congress Needs to Act to Protect Social Security and Medicare

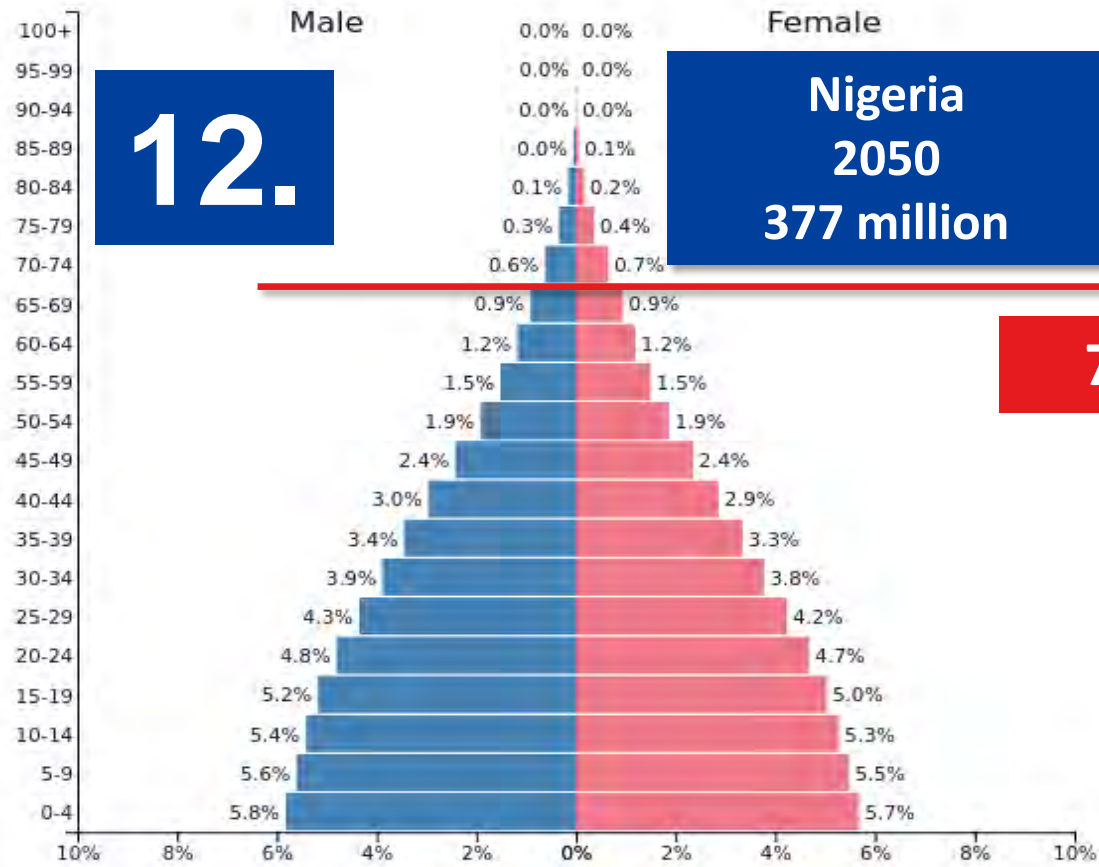
Demographics of Aging Baby Boomers means continuous increases in both programs

SOURCE: Social Security Administration, *The 2019 Annual Report of the Board of Trustees of the Federal Old-Age and Survivors Insurance and Federal Disability Insurance Trust Funds*, April 2019. Compiled by PGPF.

NOTE: Surplus/deficit numbers exclude interest income. The total deficit of \$2.9 trillion is the present value of the cash deficits between 2019 and 2035. The Old-Age & Survivors Insurance trust fund is projected to be depleted in 2034 and lead to a 23 percent cut in benefits that year; the Disability Insurance trust fund is projected to be depleted in 2052 at which time benefits would be reduced by nine percent.



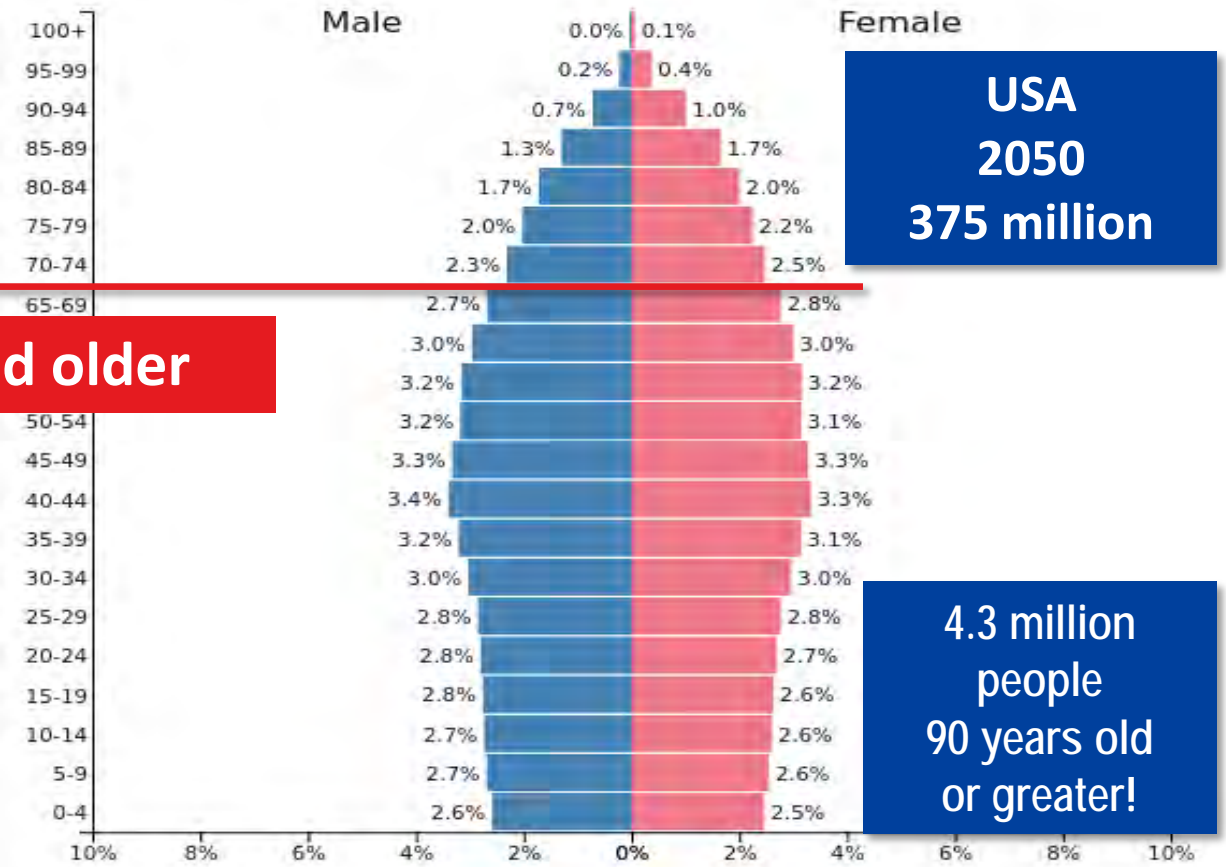
12.



**Nigeria - 2050**  
Population: 377,459,883

PopulationPyramid.net

70 and older



**United States of America - 2050**  
Population: 375,391,962

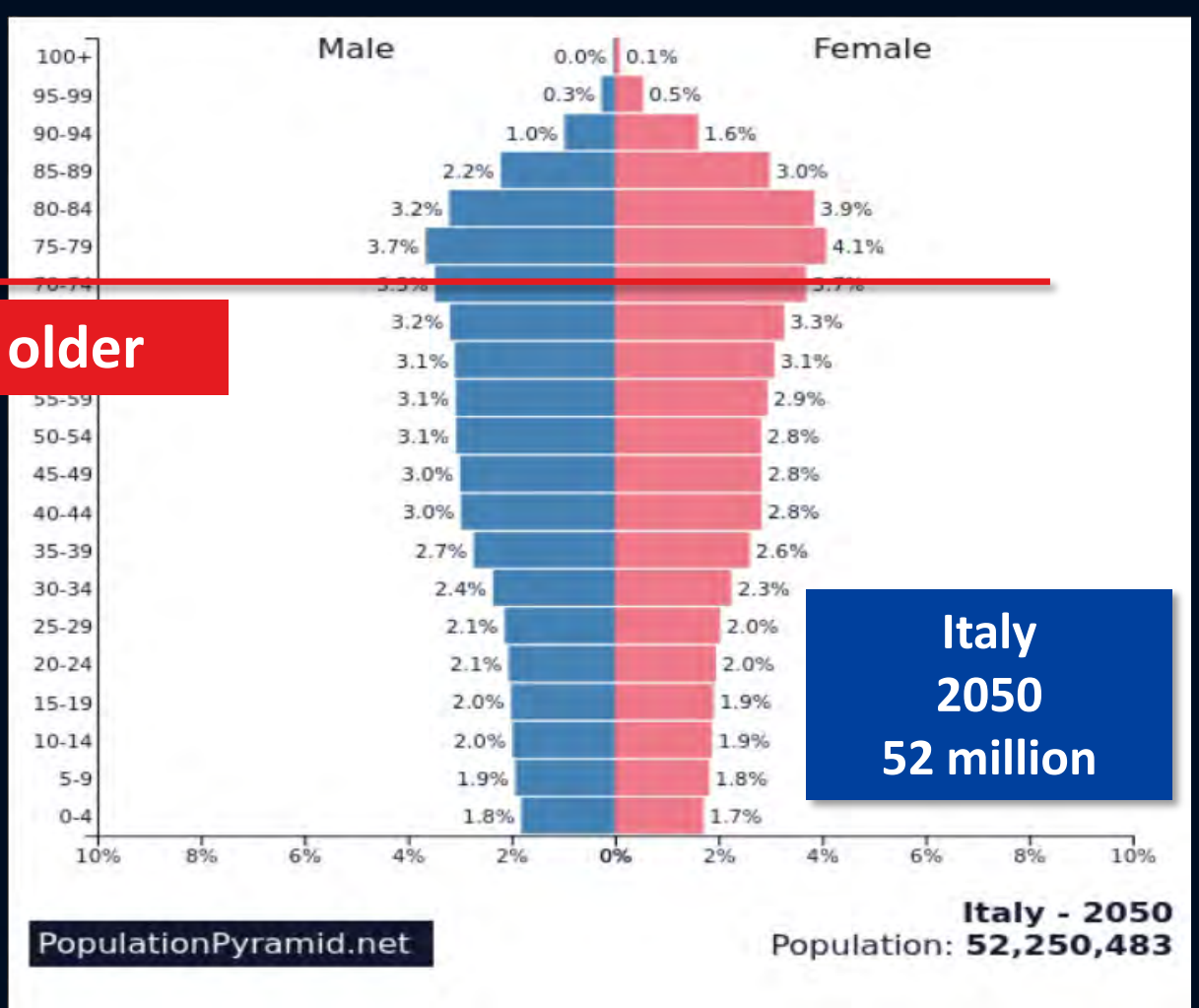
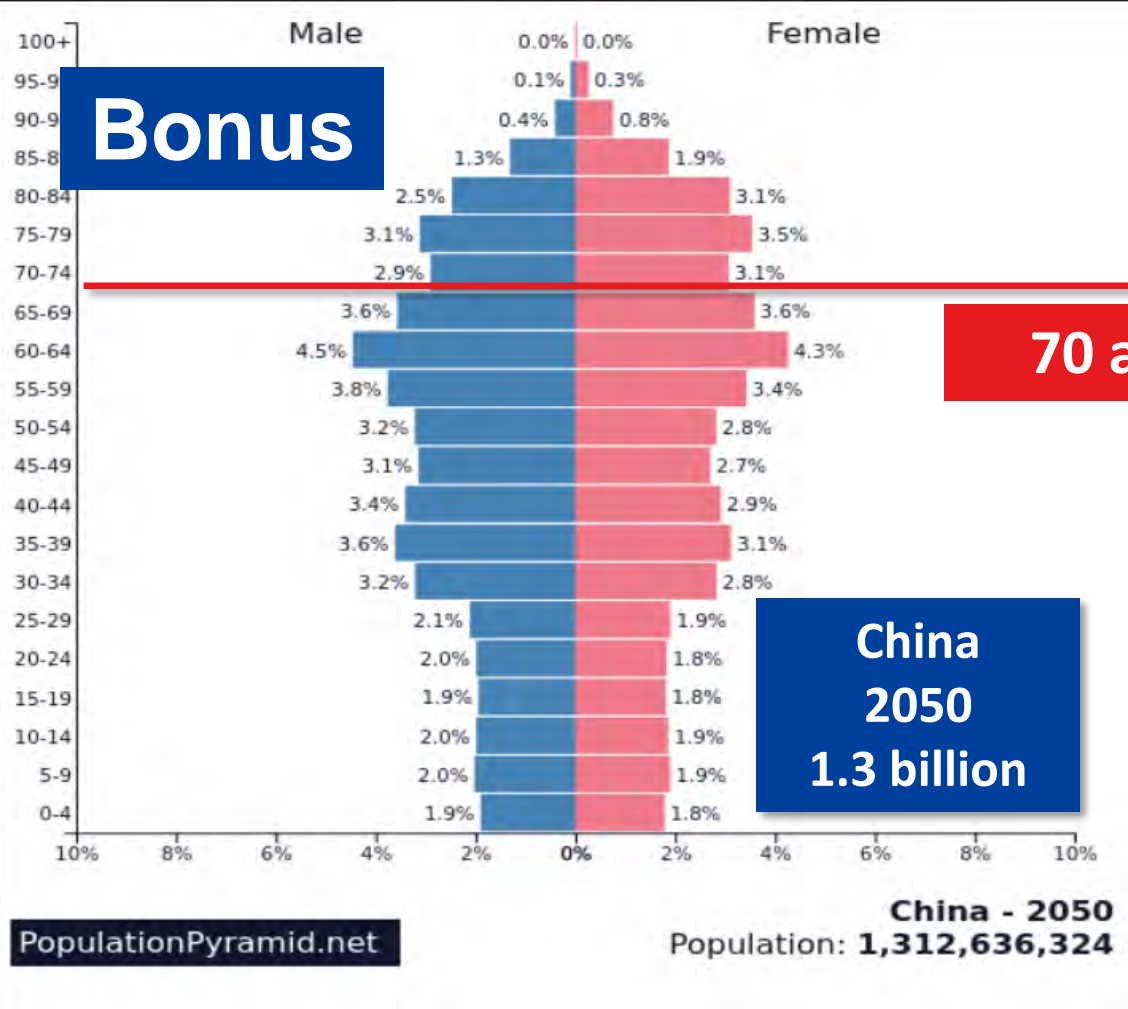
4.3 million  
people  
90 years old  
or greater!

PopulationPyramid.net

Population Pyramid Shows the funding challenges For U.S. government in next 25 years.

More retirees, fewer workers to pay taxes.

**Bonus**



Demographics of other countries predict serious challenges to provide both adequate healthcare and fund that care.

# ***Strategic Planning Take-aways from Inflation, Federal spending Trends***

- Labs can expect Medicare/Medicaid reimbursement to increase less than cost of living in coming years.
- Federal government is unable to properly fund medical training programs; thus squeezing supply of skilled healthcare workers.
- Inflation and high interest rates will continue because feds need to create money to cover deficit spending.
- Self-insured employers will be forced to reduce health benefits and require employees to meet even higher deductibles.

# *Three Themes Today*

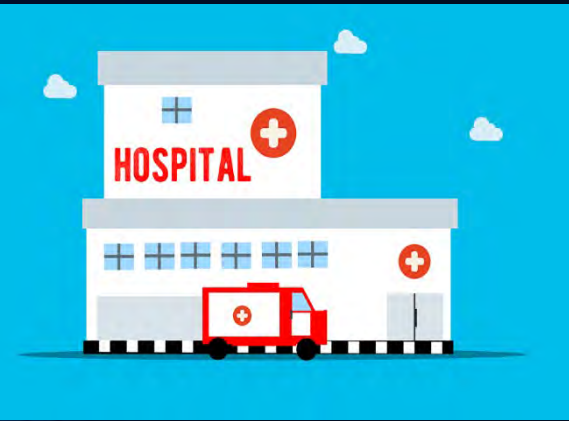
- Snapshot of macroeconomic trends in the United States to inform every lab's strategic planning.
- **Examples of major financial stress already happening in major sectors of U.S. healthcare system.**
- Profitable paths forward for clinical labs and pathology groups.



# *Disruption in Four Major Healthcare Segments*

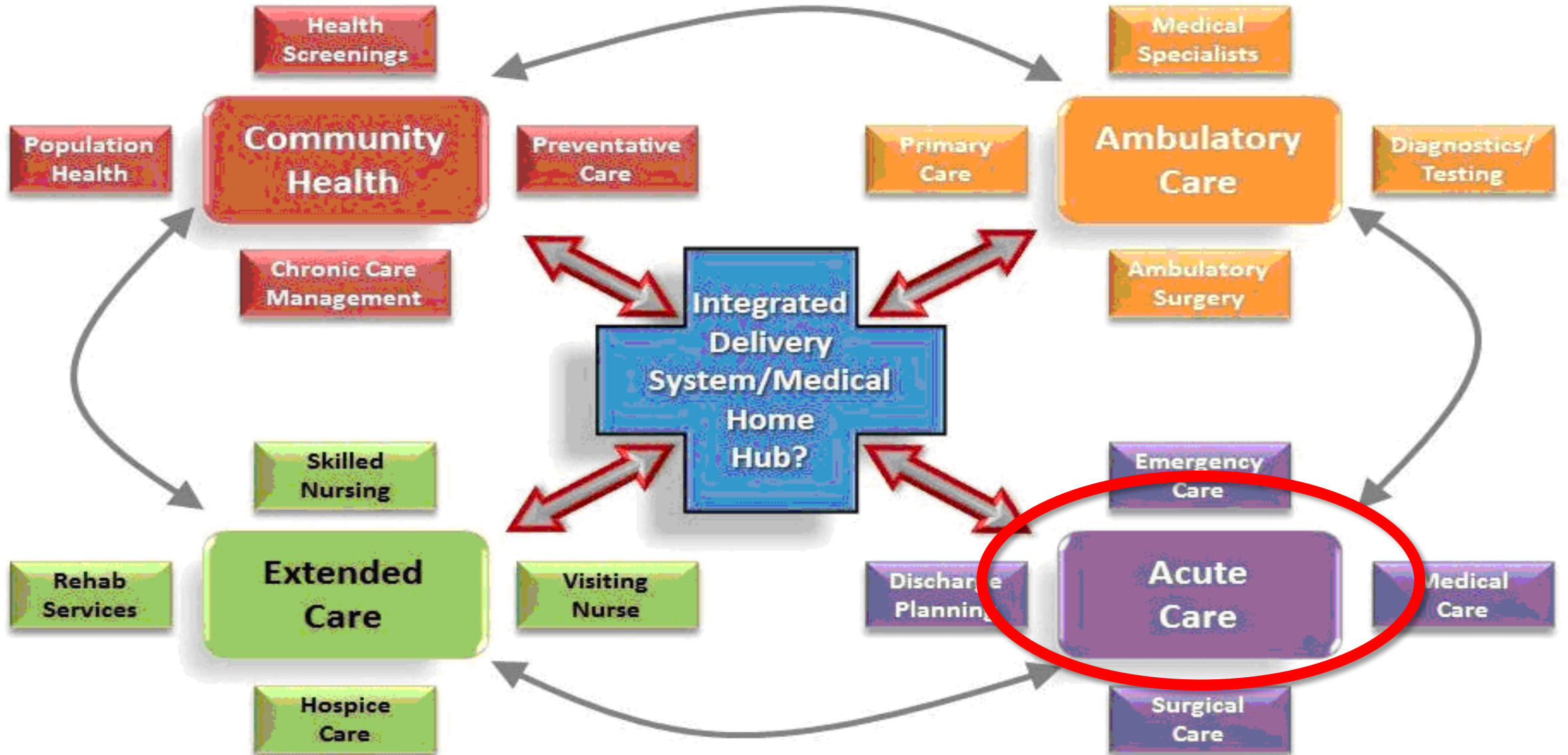
- Hospitals
- Physicians
- Health Insurers
- Retail Pharmacy Chains
- Genetic Testing Companies

# *What's Changing with Hospitals & Integrated Delivery Networks?*



- Ambulatory care tend continues, reducing proportion of patients treated in inpatient settings.
- Need for a seamless care continuum motivates health systems to vertically integrate by acquiring outpatient services.
- Proportion of value-based reimbursement increasing relative to fee-for-service arrangements.
- Many IDNs and hospitals are losing money.

# Integrated Health Systems Are the Future



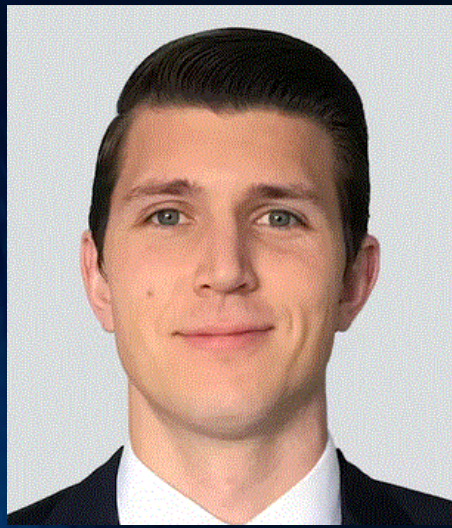
A photograph showing two people in business suits shaking hands. In the background, a sign with the word "HOSPITAL" in blue capital letters is visible on a light-colored wall.

**HOSPITAL**

## *Ongoing Consolidation in Hospital Industry*

- Scott & White Acquires Baylor Health, creating Baylor Scott & White (51 hospitals).
- Atrium Health in Charlotte merges with Aurora Advocate Health of Milwaukee and Chicago (67 hospitals).
- Sanford Health tried to acquire Fairview Health (58 hospitals).
- Kaiser Permanente Acquires Geisinger Health, creates Risant Health, says it will acquire other IDNs.





Daniel  
Kuzmanovich  
Managing Director  
and Expert Partner  
The Advisory Board  
Company

# *Why Hospitals Struggle with Profitability Today*

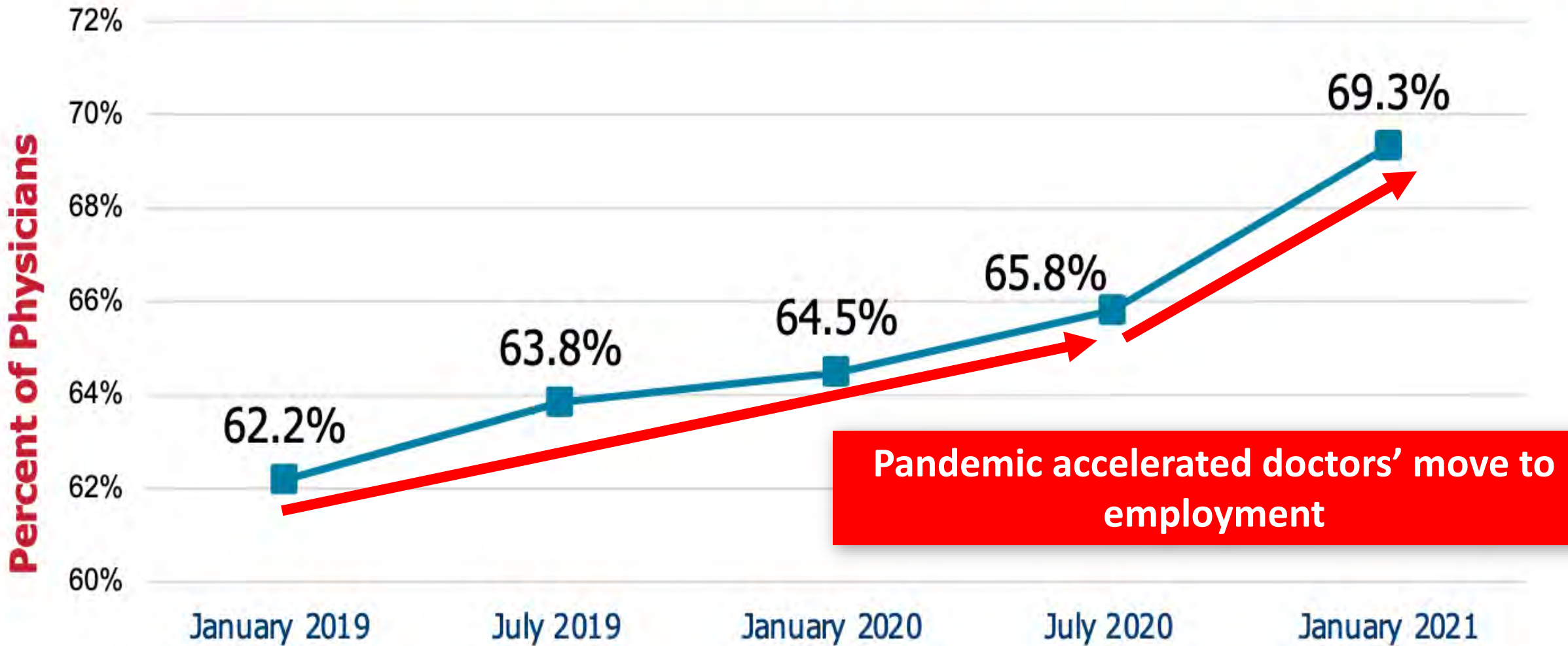
- Since COVID-19, number of people covered by company health insurance declined.
- During and since COVID-19, many individuals put off visiting doctors and scheduling surgeries.
- Private health insurance pays hospitals the **highest prices** for important, revenue-generating procedures.
- Many hospitals report modest increases in revenue and operating profits, but not enough to cover G&A.
- Advisory Board analysis says that many U.S. hospitals experiencing fewer private pay patients undergoing the procedures most profitable to the hospitals.



## *What's Changing with Physicians?*

- Era of private practice physician groups is ending.
- Majority of nation's 1.07 million physicians now employed and on salary.
- UnitedHealth Group's Optum has 90,000 employed or aligned physicians across more than 2,200 locations in 2023.
- Employed or affiliated with:
  - Ascension: 49,000 physicians
  - HCA: 47,000 physicians
  - Kaiser Permanente: 24,000 physicians.

# PERCENT OF U.S. PHYSICIANS EMPLOYED BY HOSPITALS OR CORPORATE ENTITIES IN 2019-20



Source: PAI Report/ Avalere analysis of IQVIA OneKey database



# What's Changing with Payers?

- No future in traditional indemnity insurance.
- Major of large employers now self-insure and use high-deductible health plans (HDHPs).
- Fee-for-service payments on the way out.
- Coming: prospective payer and provider payments, risk-adjusted for an individual beneficiary's chronic conditions, as diagnosed and confirmed by ICD-codes.
- Best example: Medicare Advantage plans.



*Case study of sector disintermediation in medicine*

# **Biggest Health Insurers Spotted Trends and Diversified!**

- **Aetna:** Acquired by CVS in 2018 for \$70 billion.
- **Cigna** acquires **PBM Express Scripts** in 2017 for \$67 billion.
- **Humana:** Acquired home healthcare **Kindred** for \$5.7 billion in 2021.
- **UnitedHealth:** **Optum** division is now \$212 billion, more than half UH's \$357 billion.
- **Elevance Health (formerly Anthem):** rebrands in 2022, acquires **Beacon Health Options**, a behavioral health provider, and **myNEXUS**, a home healthcare company.

*Case study of sector disintermediation in medicine*

# **Retail Pharmacy Chains Disintermediated by PBMs**



- Classic business of a retail pharmacy was to fill prescriptions generated by local physicians.
- First disintermediator: pharmacy benefit management firms.
- Second disintermediator: **Amazon** acquires **Pill Pack** for \$1 billion in 2018.
- PBMs and Pill Pack interpose themselves between patients and retail pharmacies



# *Rapid Growth of PBMs*

- CVS Caremark: 34%
- Express Scripts: 24%
- **OptumRx (UnitedHealth): 21%**
- Humana Pharmacy Solutions: 8%
- Prime Therapeutics: 6%
- MedImpact Healthcare Systems: 5%
- All other PBMs: 3%

Total PBM Revenue  
in 2021:  
**\$484.4 billion**

Total Prescription drug  
spending in 2021:  
**\$576.9 billion**

**PBMs control 84%  
of prescription  
drug market!**



## *Retail Pharmacy Chains Losing Money, Downsizing*

- **RiteAid** (1,392 stores) filed Chapter 11 bankruptcy in 2023 and is closing 200 stores.
- **CVS** (9,962 stores) closed 244 stores between 2018 and 2020, followed by 2021 plans to shutter another 900 stores by 2024.
- **Walgreens** (9,021 stores) closing 150 locations in the U.S.; also closing 160 VillageMD primary care clinics.

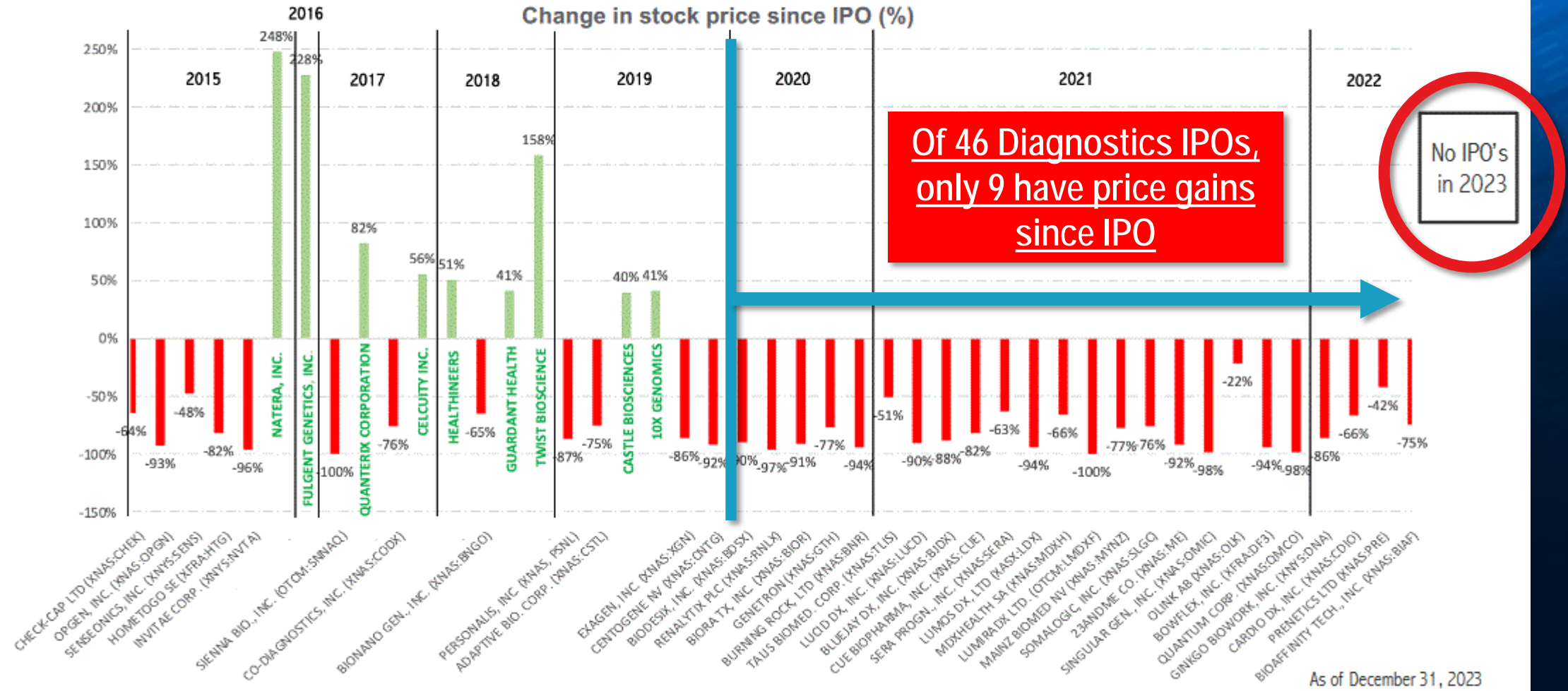




# *Genetic Testing Companies Dealing with What Wall Street Calls “Headwinds”*

- Getting paid for a genetic test (typically an LDT) is challenging—coverage guidelines, reimbursement.
- Payers are overwhelmed with genetic test claims at the same time that payers are laying off staff!
- Invitae files bankruptcy in February, 2023—specifically to find a buyer!
  - Raised \$2.7 billion from investors, lost \$1.6 billion, has \$1.6 billion in debt.
  - Yesterday, Labcorp was announced as buyer, for a price of \$239 million.

# If You Bought \$1 of these Diagnostics Companies at their IPO Initial Price ...



6 Data Source: Evercore and internal analysis of public filings

From presentation by Mara G. Aspinall, Partner, Illumina Ventures

# *Three Themes Today*

- Snapshot of macroeconomic trends in the United States to inform every lab's strategic planning.
- Examples of major financial stress already happening in major sectors of U.S. healthcare system.
- Profitable paths forward for clinical labs and pathology groups.



## ***Premise: FFS Era Ending, Value-Based Era Beginning***

- Flaws in fee-for-service reimbursement widely recognized.
- FFS encourages medically-unnecessary care.
- Fraudsters find it easy to originate, submit, and be paid for fraudulent claims.
- Cost of preparing, filing, and reimbursing FFS claims is substantial.
- Both government and private payers interested in developing value-based payment models that eliminate FFS claims.




# *Value-based reimbursement is opportunity for labs*

- Lab leaders should understand **HEDIS scores** and **STAR ratings for Medicare Advantage and Part D**.
- Health insurers are rewarded when their health plans and providers produce improved patient care, as measured in specific ways.
- Clinical labs and pathology groups can help both health insurers and physicians achieve better patient outcomes at less cost.


# Risk Adjustment in Medicare Advantage

If Base payment for region is \$12,000/year

1  Plans submit members' health diagnoses from prior year.

For example:

If the base monthly payment for a particular plan is \$1,000


2  CMS uses members' diagnoses along with their age, gender, disability status, whether they're eligible for Medicaid, and whether they live in an institution, to assign each member a risk score.

↳ And a 77-year-old woman with diabetes and congestive heart failure has a risk score of 1.344

Senior with two morbidities \$16,123/year

The risk score is a ratio that represents the expected cost of caring for each enrollee relative to the cost of the average Medicare beneficiary.

↳ Then, the monthly payment for that woman would be: \$1,344

3  CMS adjusts plans' monthly payments to reflect the health of each member, based on these risk scores.

A 65-year-old man with no chronic conditions might have a risk score of 0.4

↳ The monthly payment for that man would be: \$400

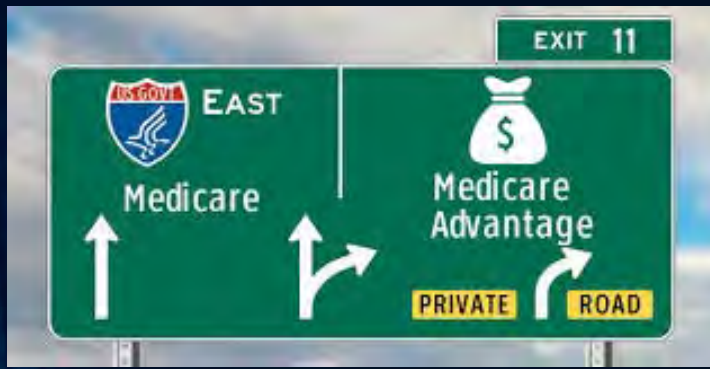
Healthy Senior: \$4,800/year

Source: Martha Hostetter and Sarah Klein, "Taking Stock of Medicare Advantage: Risk Adjustment," To the Point (blog), Commonwealth Fund, Feb. 17, 2022. <https://doi.org/10.26099/jxrq-5m12>



# *Medicare Advantage Changes Incentives vs. FFS*

- With fixed, risk-adjustment payment, health plans and physicians have incentive to keep beneficiaries healthy.
- Not diagnosing beneficiaries with a chronic condition, like diabetes or CKD, means plan and doctor are not paid for additional costs of caring for that patient.
- Going forward, savvy payers and physicians will want their labs to help in identifying undiagnosed patients, alerts for care gaps, and flagging patients at high risk for an acute event.
- Labs have opportunity to use lab test data and other data to create actionable intelligence and be paid for that intelligence.



# *Medicare Advantage Is the Value-Added Model to Study*

- Key concept: risk adjustment
- In simplest terms, insurers with Medicare Advantage plans are paid a risk-adjusted fee.
- Annual payment for a healthy senior is less than risk-adjusted payment for a senior with documented chronic conditions.
- Both health insurer and physician have motive to diagnose undiagnosed conditions and commence appropriate treatments.
- Labs can help by contributing to earlier diagnosis, better patient management, and alerting physicians to care gaps.



## ***Understanding 'Clinical Lab 2.0'***

- **'Lab 1.0'** is transactional. As a lab increases test volume, it can lower the cost per test.
- **'Lab 2.0'** helps labs deliver more value.
- Value measured by improved patient outcomes, lower costs for entire episode of care.
- Resource for more information:



# ***Not Discussed and Covered by Other Sessions This Week***

- Demand for Pathologists, Clinical Laboratory Scientists, other staff positions exceeds supply.
- Artificial Intelligence (machine learning, natural language processing, neural networks, generative AI, etc.)
- Genetic Testing and Whole Genome Sequencing (WGS) performed in community hospitals.
- Companion diagnostics and more complexity in diagnosing cancer.
- New business models and growth in subspecialty pathology.



# Summary

- Fundamentals of federal budget argue that inflation will continue, as Congress unlikely to rein in spending.
- Disintermediation is causing traditional health service providers to diversify in unexpected ways to ensure survival.
- End of fee-for-service era will open new doors for clinical labsto add value and be paid for that value.

***What's in the future  
for labs & pathology groups?***

***"If you don't know  
where you are going,  
you'll end up  
someplace else."***

***— Yogi Berra, former  
New York Yankees  
catcher***

