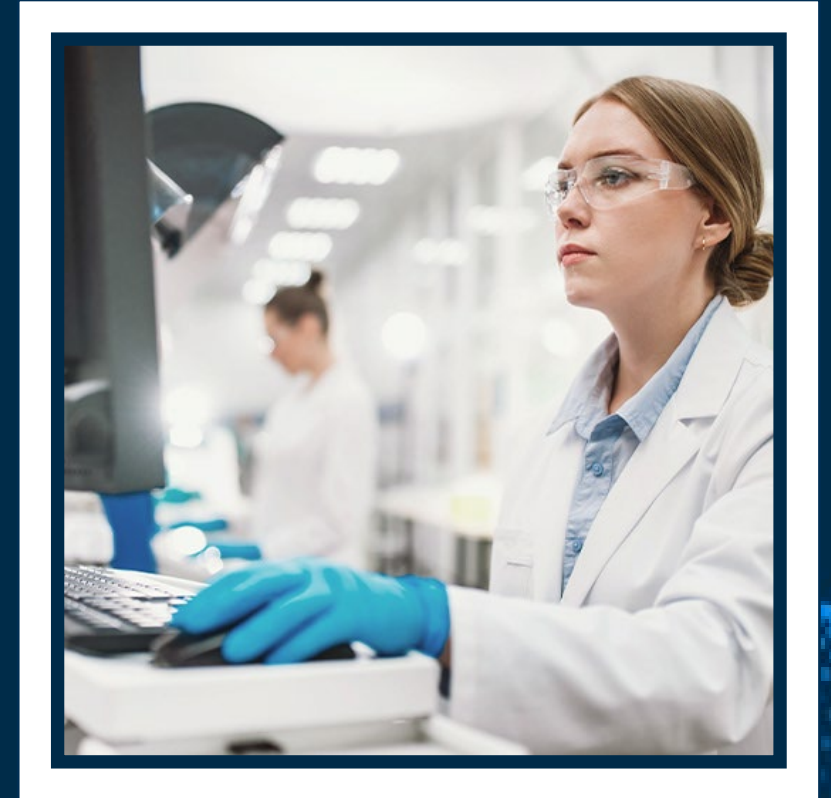


# BIG CHANGES IN HEALTHCARE:

NEW REGULATIONS AND NEW  
DIAGNOSTICS PLAYERS POISED TO  
RESHAPE LAB TESTING



Lâle White, Chairman and CEO  
XiFin, Inc.

# Multiple Dynamics Impacting Healthcare Economics and Outcomes



Post-COVID healthcare demand increased, along with late-stage chronic disease detection. 95% of seniors have one chronic condition, while 80% have more.

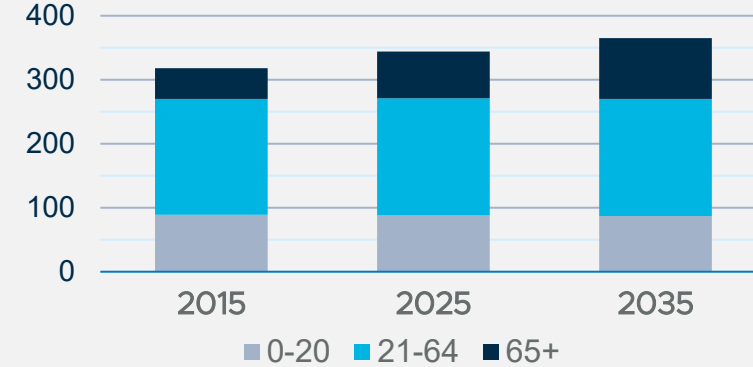
Increasing Healthcare costs and shortages in healthcare workers (Drs, Nurses, Technicians) causing wage increases.

Hospitals operating at a loss grew from 28% to 53% currently. New entrants are encroaching on traditional profit centers, while vertical integration gaining traction.

Consumer driven demand priorities drive access points based on Convenience, Cost, and Quality.

FDA proposed LDT rule would limit access to life saving tests that would be too costly to develop; resulting in late-stage treatment.

**Ratio of Working-age Adults to Seniors Will Be 2-1 by 2035**



The ratio of working-age to senior adults will be 2:1 within the next decade. Medicare trust fund will run out of money in 2031.

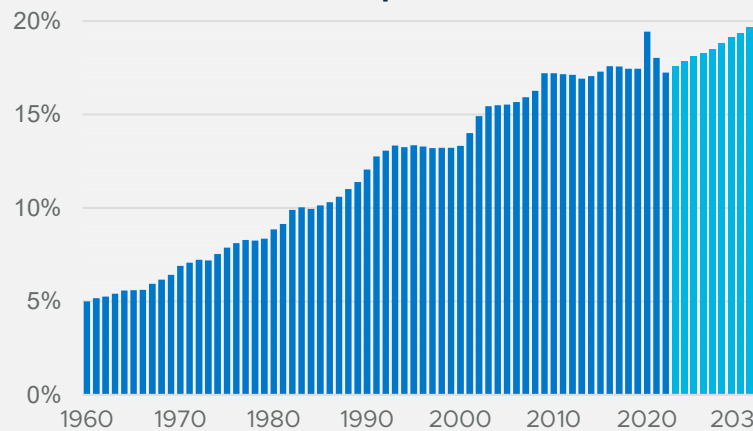
Medicare outlays will increase from \$744B in 2022 to \$1.7T by 2035. Shift of Medicare to Advantage and Medicaid to MCOs.

Medicare introduced a new 3-year risk adjustment model, reducing payments to Advantage payors and adjusting star ratings, resulting in lower bonus payments.

You can expect Insurers to adjust benefits or rates to mitigate the impact. This will include stiffening prior authorization requirements, shrinking provider networks or cut reimbursement to preserve margins.

PAMA related Lab reimbursement cuts continue, potentially at a slower rate with SALSA.

**National Health Expenditures as % GDP**



Sources: Oliver Wyman and Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group; Bureau of Economic Analysis, and National Bureau of Economic Research

# Disruptors Impacting Economics of Healthcare

CVS | Aetna | Cigna | Express Scripts | UHC | Catamaran

- 3 largest PBMs vertically integrate with insurers (UHC/Catamaran 2015 & Cigna/Express Scripts 2018)
- CVS (2019 Merger with Aetna) has 9700 pharmacies & 1100 walk in clinics: Plan Health Hubs
- Delivering care close to consumer- 2022 Rolling out Test to Treat
- Oct 2022 – Acquires Signify Health followed in Mar 2023 with an acquisition of Oakstreet Health

## Optum | Change

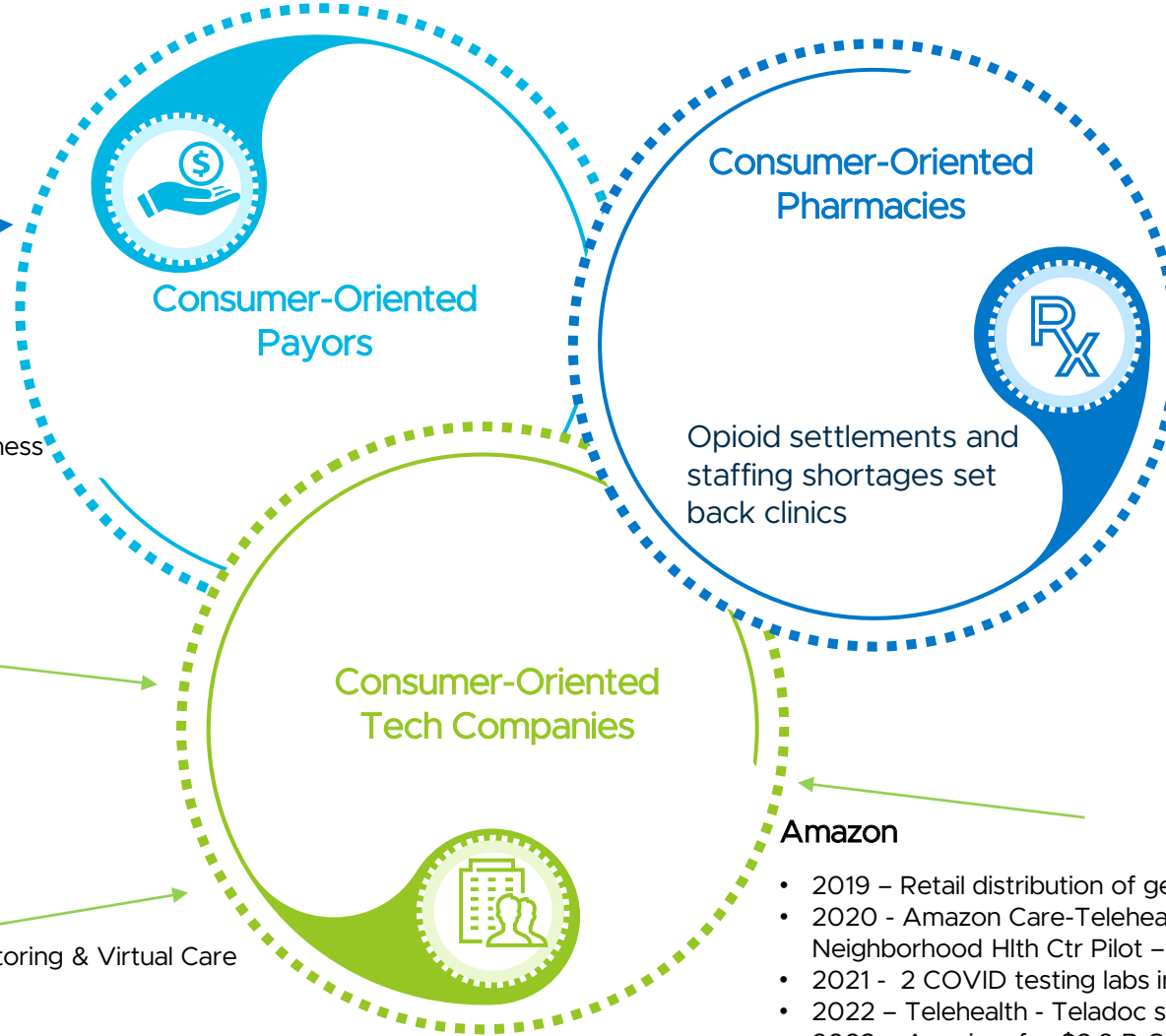
- 9-19-22 Optum acquires Change
- Partners with Avalon, MoIDx
- 2024 - Change Healthcare cybersecurity event demonstrate vulnerability of healthcare cashflow and interoperability
- 4-25-24 – Optum confirms discontinues telehealth business

## Microsoft Apple | Amazon Google

- Amazon, Apple, Google, Microsoft focused on EMR interoperability & data aggregation democratizing access to patient data
- 2021 - Google acquired Fitbit
- 2021 - Microsoft acquired Nuance
- Strength in consumer orientation. Provider participation and domain expertise challenges
- 2024 – Google AI tool to translate digital path slides
- 2024 – Apple plans to launch Health Insurance

## Companies to watch

- 2021 - Best Buy acquires Current Health Remote Dx monitoring & Virtual Care
- 6-22 Oracle completes Cerner acquisition
- 2022 EPIC moving to cloud
- 2024: Multiple pharmacies shutting down primary care clinics



## Walmart Humana

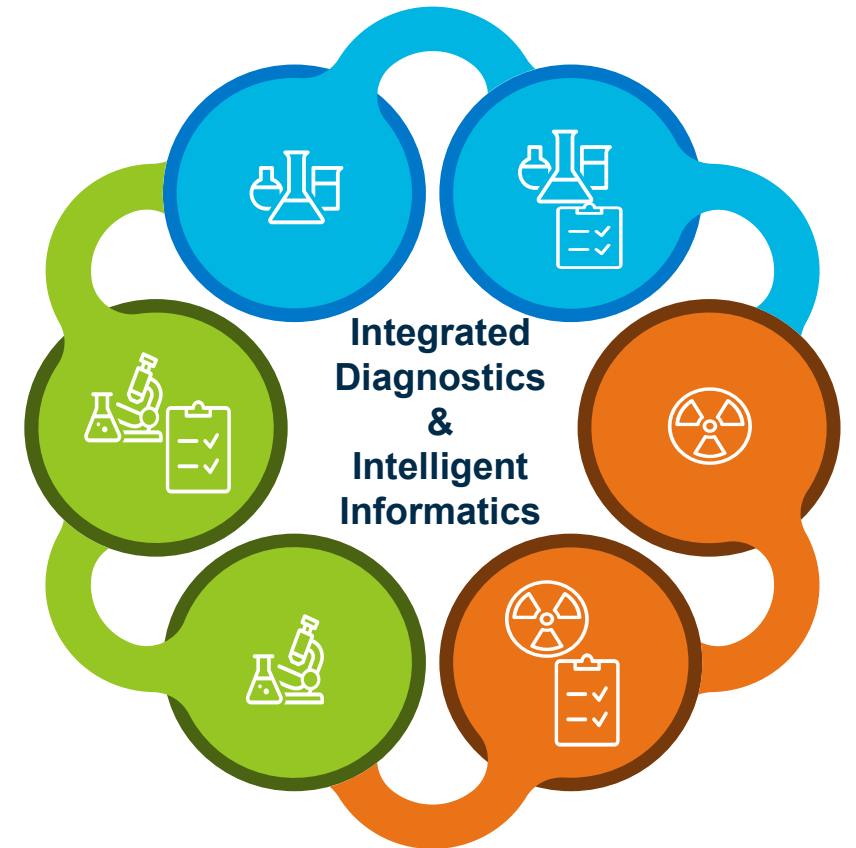
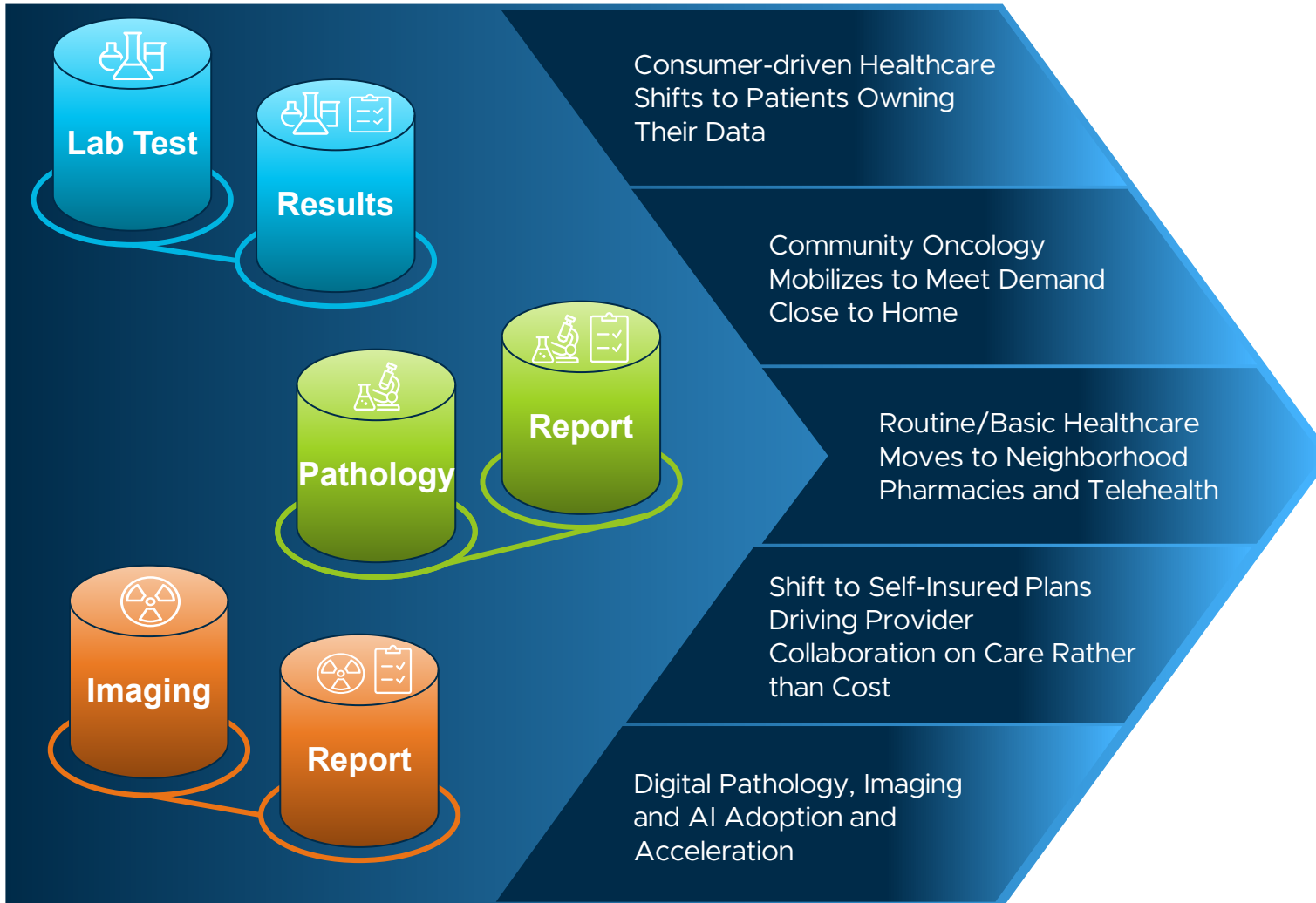
- Walmart acquires MeMD telehealth 2021
- Walmart has 5100 stores & plans 4000 standalone clinics by 2029 (medical, dental, lab, rad, hearing, counseling)
- Medicare Advantage growth – better care/lower cost
- Delivering care close to consumer- 2022 Rolling out Test to Treat

## Amazon

- 2019 – Retail distribution of generics and DME & acquisition of PillPack
- 2020 - Amazon Care-Telehealth Acquired Health Navigator Neighborhood Hlth Ctr Pilot – 20 clinics for employees
- 2021 - 2 COVID testing labs in CA & KY opened – Closed KY in Aug 22
- 2022 – Telehealth - Teladoc services roll out on Alexa 24/7 for \$75
- 2023 – Acquires for \$3.9 B One Medical & shut down of Amazon Care
- AI Convergence with Telehealth -Alexa will influence consumer access

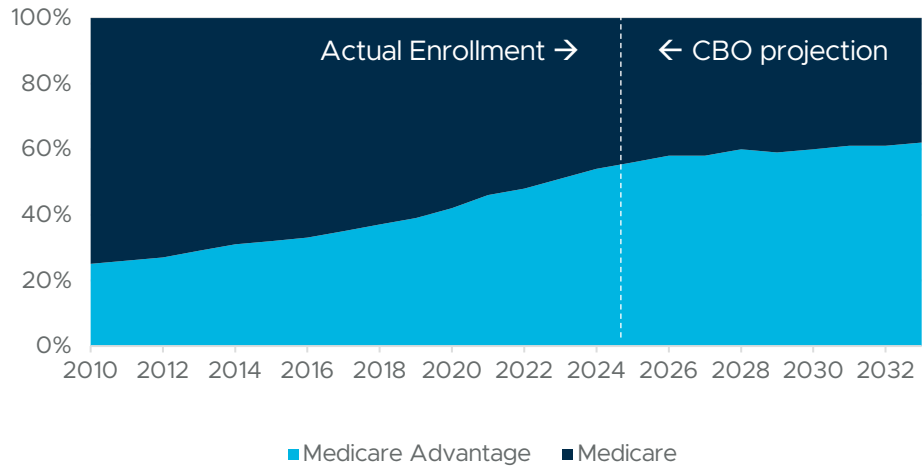
# Shift To Personalized Medicine for Improved Outcomes

From Segregated Diagnostics Towards Vertically Integrated Diagnostics & Specialties

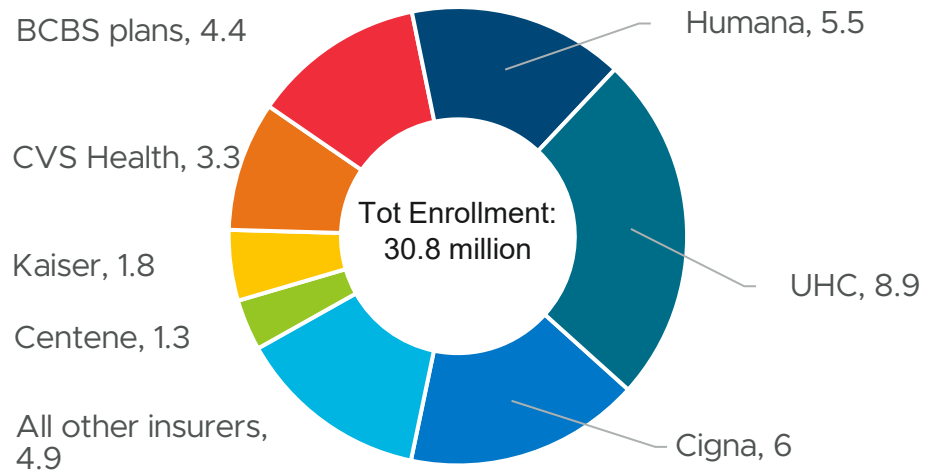


# Medicare Part C Growth

Traditional Medicare and Medicare Advantage Enrollment Rates

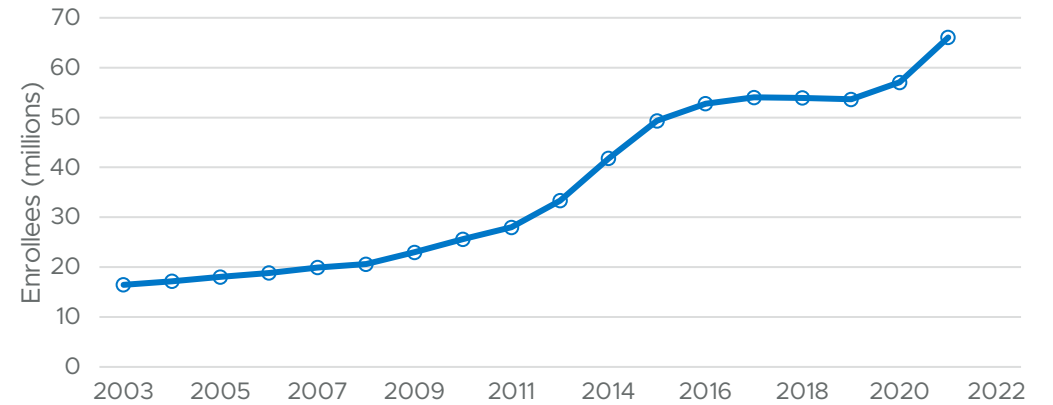


Medicare Advantage Enrollment, 2023 (millions)

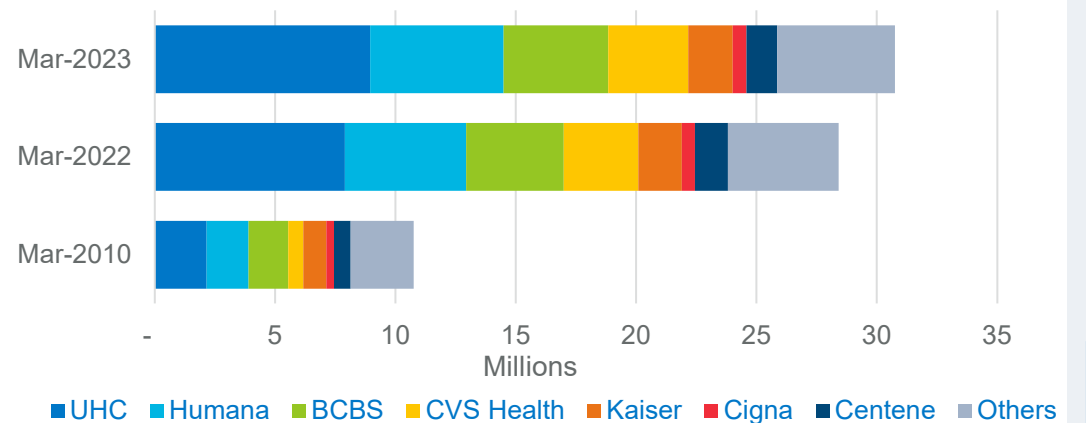


# Medicaid MCO Growth

Medicaid MCO Enrollment 2003-2021



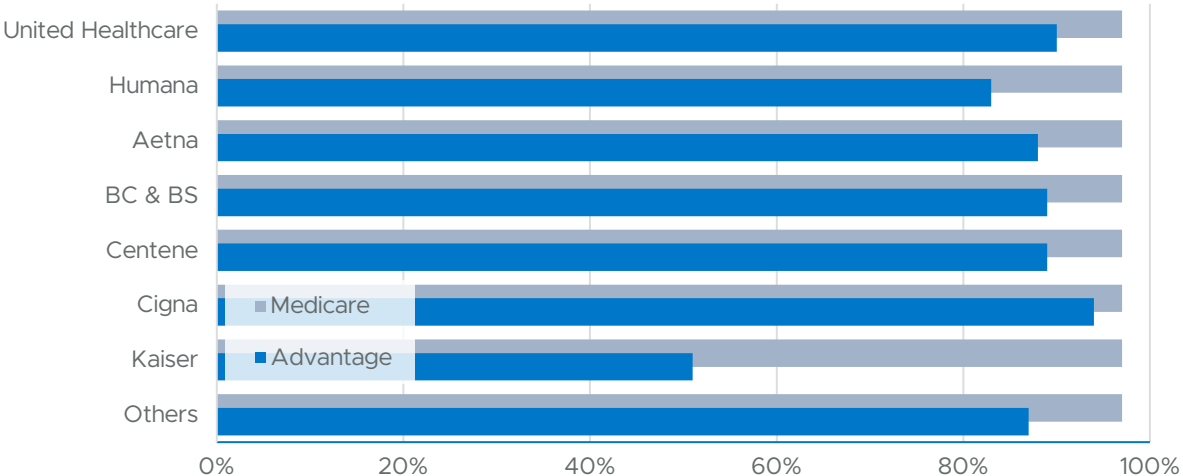
MCO Enrollment Remains Highly Concentrated



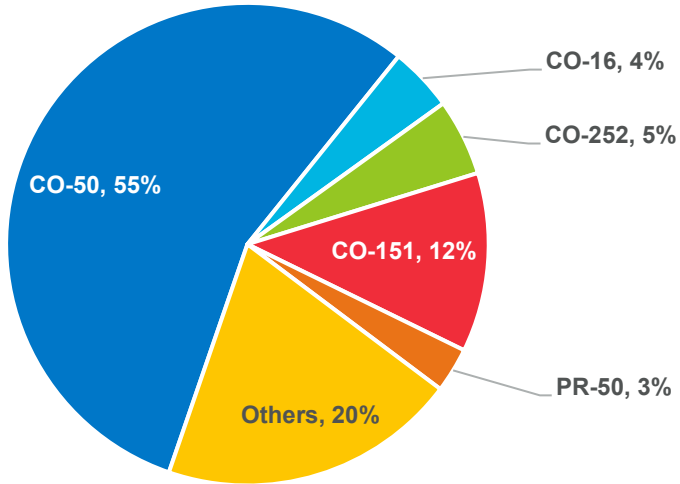
Sources: KFF: <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/> <https://www.kff.org/other/state-indicator/total-medicare-mco-enrollment>

# Medicare Advantage Denials Greater Than Medicare

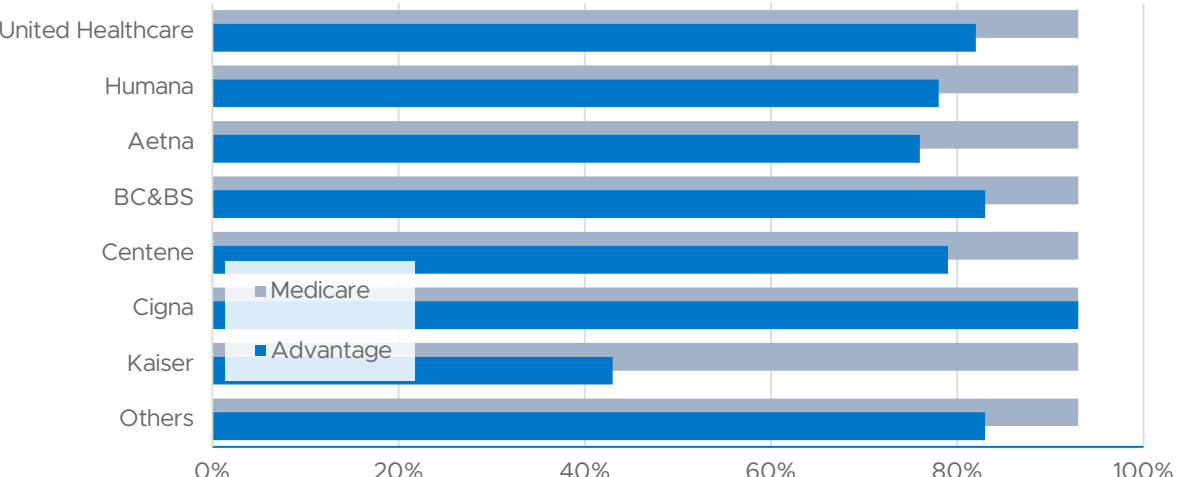
**Paid Medicare vs Medicare Advantage (All Lab Procedures)**



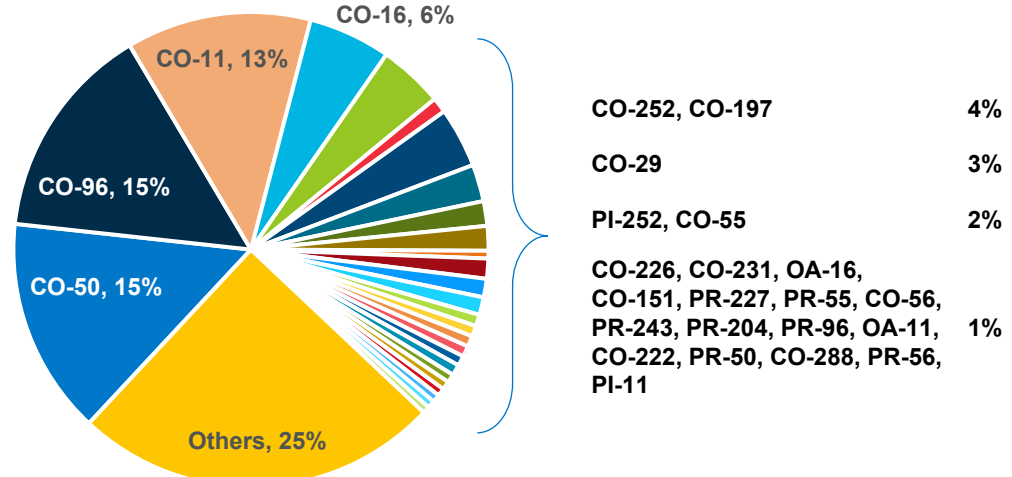
**Medicare Denials (Limited Coverage Tests)**



**Paid Medicare vs Medicare Advantage (Limited Coverage Tests)**



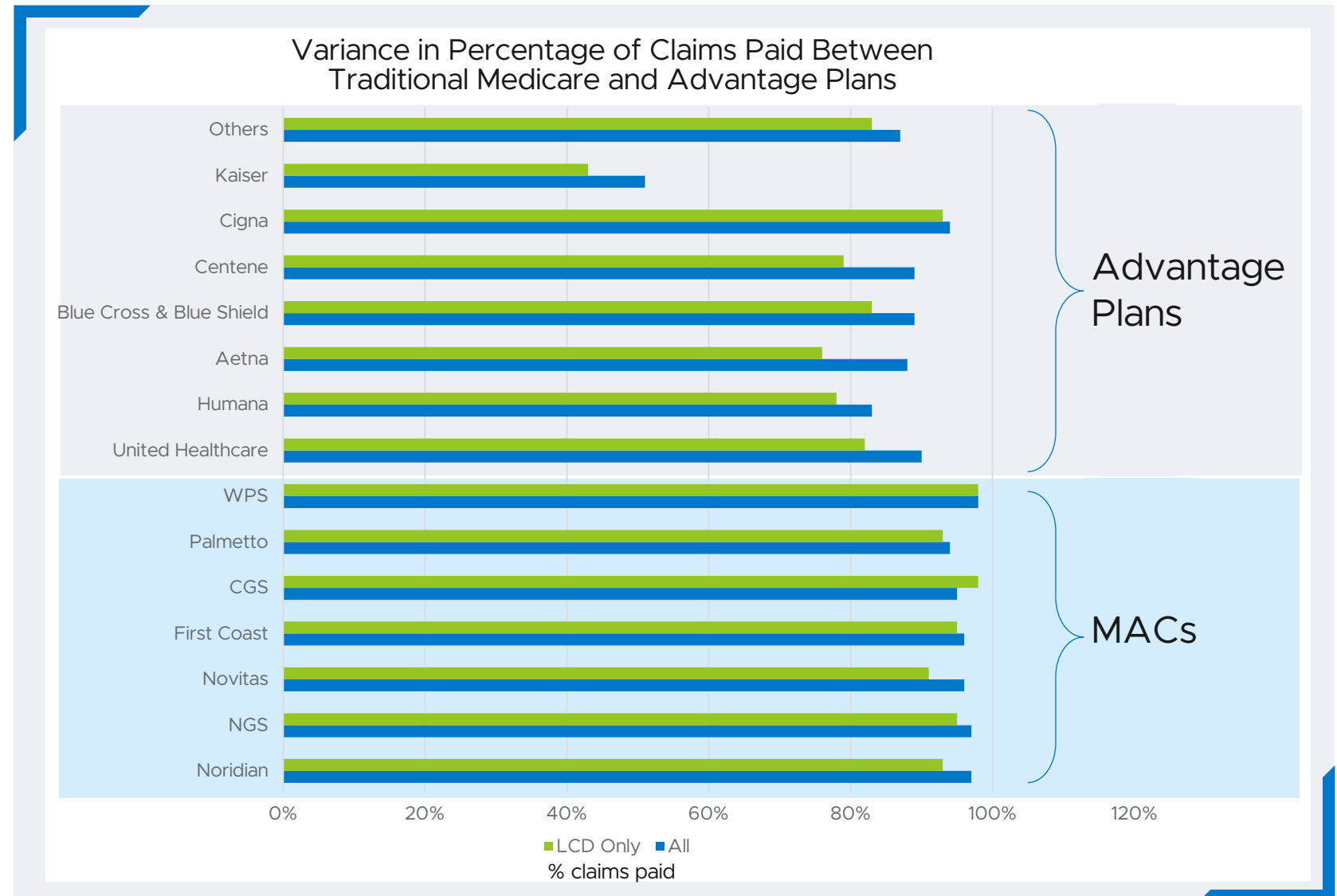
**Medicare Advantage Denials (Ltd Coverage Tests)**



# A Spotlight on Payor Behavior

## XiFin Key Analysis Highlights:

- Denials rates for medical necessity reasons are about the same
- Rates for all denials showed more variety
- The largest variances are specific for denials based limited coverage determination





# Middlemen Are Impacting Healthcare

Disruptors Driving More Balance by Putting Consumers in the Driver's Seat



Pharmacy Benefits Managers



Laboratory Benefits Managers



PALMETTO GBA  
MoIDX

EVERCORE



Consumer Driven Disruptors

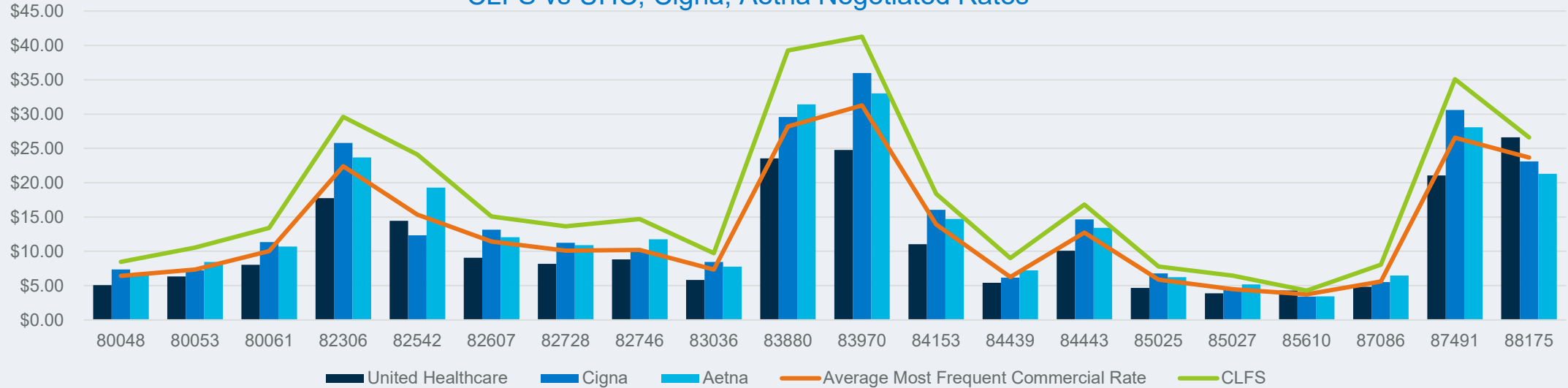


Purchaser Business  
Group on Health

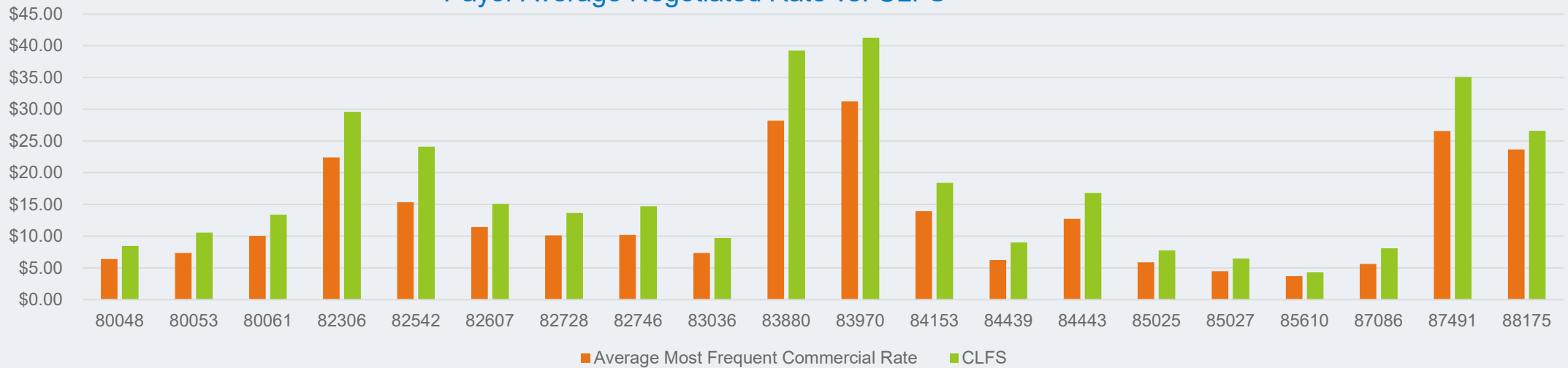


# Top 20 PAMA Test Comparison: CLFS vs. Top Payors

## CLFS vs UHC, Cigna, Aetna Negotiated Rates



## Payor Average Negotiated Rate vs. CLFS



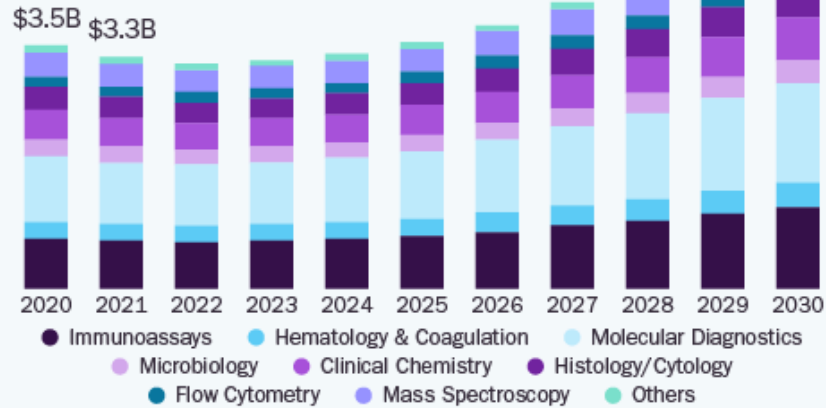
Source: XiFin Data and XiFin Payor Rate Transparency Monitor Data

[https://www.accenture.com/\\_acnmedia/pdf-83/accenture-becoming-data-driven-enterprise-data-industrialization.pdf](https://www.accenture.com/_acnmedia/pdf-83/accenture-becoming-data-driven-enterprise-data-industrialization.pdf)

# The Innovation Paradigm

## U.S. Laboratory Developed Tests Market

size, by technology, 2020 - 2030 (USD Billion)



6.0%

U.S. Market CAGR,  
2023 - 2030

Source:  
www.grandviewresearch.com

## AHA to Congress: FDA proposed rule for laboratory developed tests overreaches



Apr 1, 2024

The Food and Drug Administration's proposal to regulate laboratory developed tests would undermine innovation and reduce access to effective and appropriate care for patients, AHA April 1 told the Senate Health, Education, Labor & Pensions Committee Ranking Member.

## Lawsuits take aim at use of AI tool by health insurance companies to process claims



By Elizabeth Napolitano  
December 18, 2023 / 2:32 PM EST / MoneyWatch



American Medical Association

<https://www.ama-assn.org> > ... > Prior Authorization

## Oversight needed on payers' use of AI in prior authorization

Jun 14, 2023 — "As health insurance companies increasingly rely on AI as a more economical way to conduct prior-authorization reviews, the sheer volume of ...

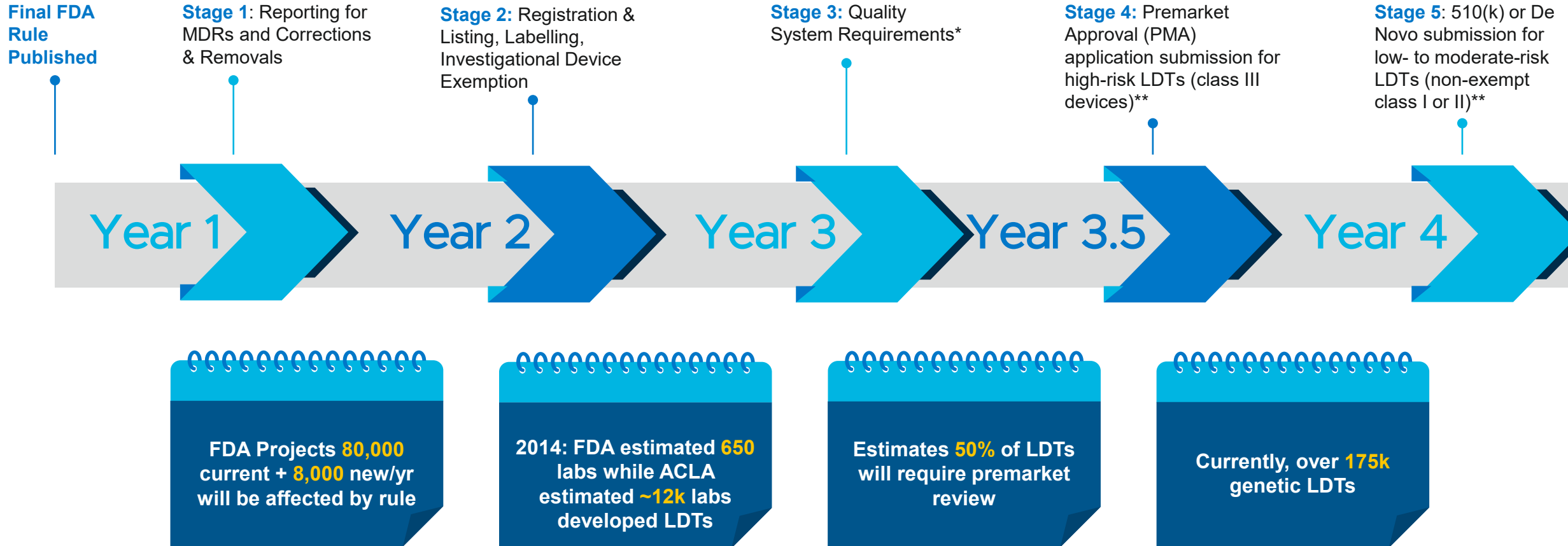
91% of Respondents

suggested that the change in regulations will curb innovation for LDTs.

Source: Laboratory Developed Tests Market Size & Share Report, 2030 (grandviewresearch.com)

# FDA Timeline

## Lengthy Phase-in for Burgeoning Number of Tests



\* For traditional LDTs designed, manufactured, and used in same CLIA-certified, high-complexity laboratory, these requirements are limited to: design controls, purchase controls, acceptance activities, correction and preventative actions, and records.

\*\* LDTs may continue to be offered after this date if a premarket submission (PMA, 510(k) or de novo) is under review.

# Technology Focus Is More Critical Than Ever

## A tech trifecta drives the biggest impact for labs

1

### Efficiency and Patient Centricity

- Consumers are demanding and expecting to get their healthcare from various disparate and changing entities
- Patients own their data, and it should be securely shareable
- Technology needs to be patient centric

2

### Innovation and comprehensive AI

- Moving beyond Clinical AI applications into financial, administrative and experience is critical
- AI might even be the great equalizer to disruptors and industry middlemen
- Fight payor-based AI with AI enabled RCM (i.e., Prior Authorizations)

3

### Interoperability and Security

- Now more than ever – interoperability across multiple entities and continued cybersecurity rigor is an imperative



# What Can Be Done? Get Involved To Shape The Future

## Labs & Diagnostics Must Unite

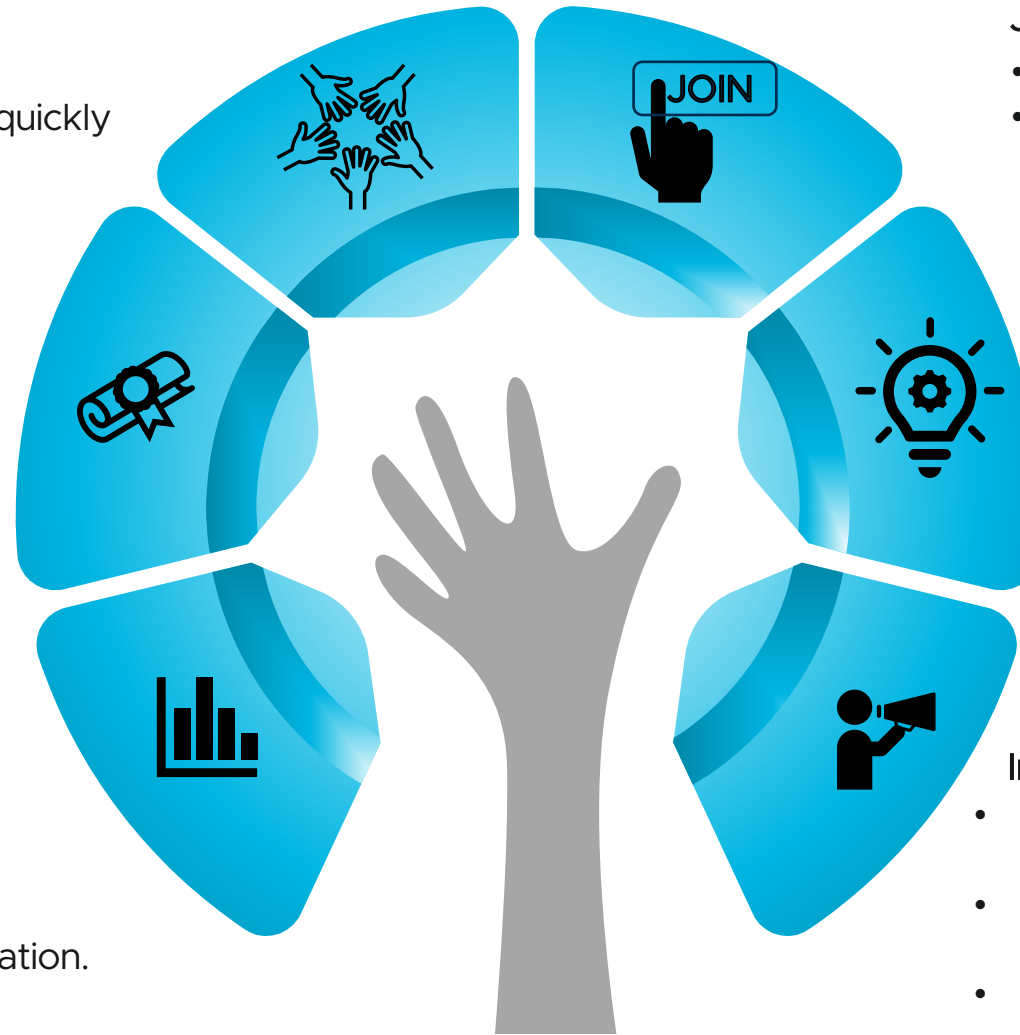
- These issues are bigger than PAMA
- Lost innovation can't be recovered quickly
- Important to look at the big picture

## VALID Act

- Support the VALID Act and push to use the CLIA Structure as a template
- KRAS is an example of an short innovation cycle

## Get Evidence

- How many LDTs
- Quantify cost/impact to counter underestimated view from FDA
- Price of the worldwide loss of innovation.



## Join an Association

- If you haven't, do so right after EWC
- Participate, participate, participate

## Promote Role of Lab in Healthcare

- Innovators
- Practice of medicine
- Connectors in a disparate and distributed healthcare ecosystem

## Inject Your Expertise

- Labs have insight and knowledge, don't wait to be asked
- Government need experts to feed them info so they can regulate
- Its not about population management, we need precision/personalization

# THANK YOU

Big Changes in Healthcare

Lâle White, Chairman and CEO

XiFin, Inc.

