

AVALON HEALTHCARE SOLUTIONS **MANAGING GENETIC TESTS: NAVIGATING COMPLIANCE AND AVOIDING POTHOLES**

March 19, 2024



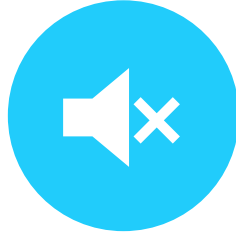
WELCOME & INTRODUCTIONS

Amanda Bruemmer – Senior Manager, Product Marketing

Before We Start



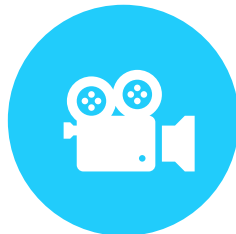
This meeting is being recorded.



We will be **MUTING** everyone except the presenter to make sure the audio is clean and clear.



Q&A will be done by using the “**Questions**” feature.



The recording and slides will be **available** on our website later during the week.

Agenda

WELCOME & INTRODUCTIONS

Amanda Bruemmer – Senior Manager, Product Marketing, Avalon

GENETIC TESTING DRIVERS

Commander Patrick Neubert – Opioid Rapid Response Coordinator, HHS Office of Inspector General

NAVIGATING MARKET GROWTH

Sarah Bretz – Product Manager, Avalon

EVIDENCE-BASED POLICY DELIVERY

Ben Horton MD, MHA – Vice President, Senior Medical Director, Avalon

THE LONG ROAD TO TEST APPROVAL

Mike Snyder – Executive Vice President, Network, Avalon

Q&A

Amanda Bruemmer – Senior Manager, Product Marketing, Avalon



GENETIC TESTING DRIVERS

Commander Patrick Neubert – Opioid Rapid Response Coordinator, HHS Office of Inspector General



Genetic Testing Priority

- 10 genetic tests are developed per day
- HHS-OIG OEI Report December 2022
- Top Codes 81407 and 81408 not even paid in 2022 or 2023
- Five Codes in 2021 paid \$803M
 - \$624M Non MolDx, \$130M on Reference Labs

Exhibit 5: Medicare Part B spent \$5.48 billion on the top 25 lab tests in 2021.

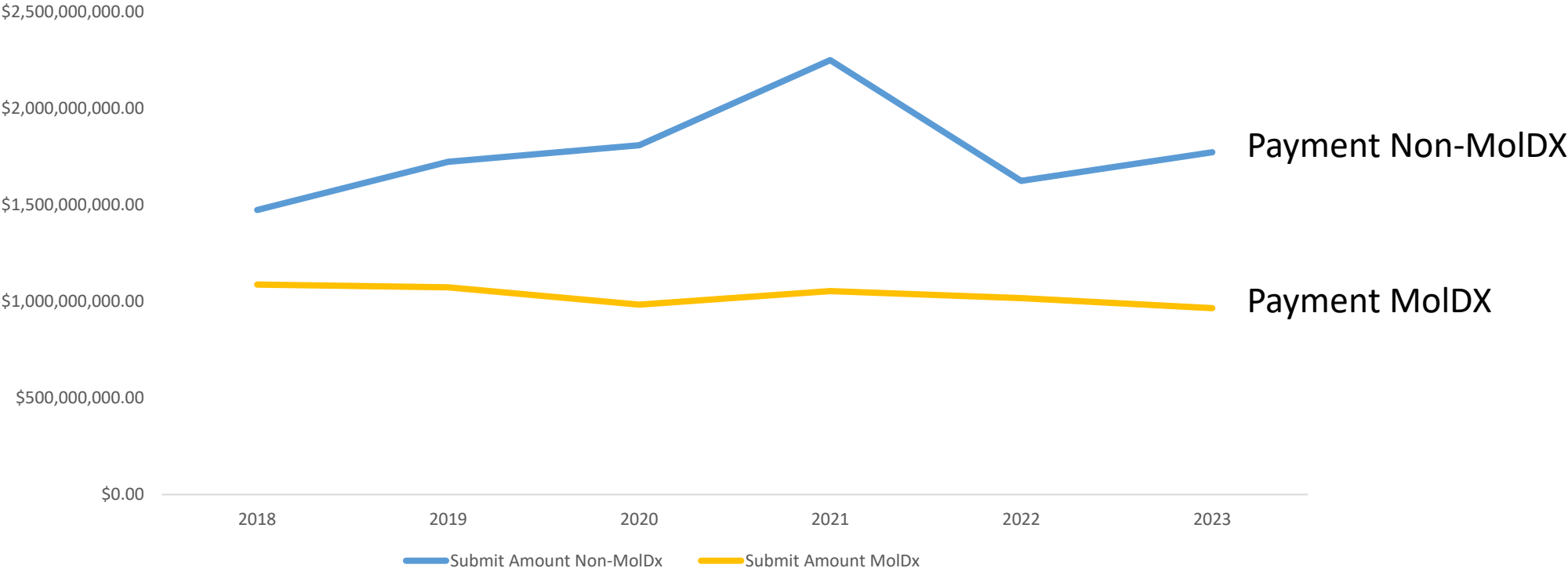
	Test Description (Procedure Code)	2021 payment rate	2021 volume (millions)	Volume change from 2020	2021 spending (millions)
1	COVID-19 test: Infectious agent detection by nucleic acid for COVID-19, high-throughput (U0003)	\$75.00	12.5	↑ 22.2%	\$935.9
2	Blood test, comprehensive group of blood chemicals (80053)	\$10.56	39.5	↑ 4.7%	\$425.3
3	Blood test, lipids (80061)	\$13.39	26.5	↑ 4.9%	\$355.2
4	Blood test, thyroid stimulating hormone (84443)	\$16.80	19.9	↑ 5.3%	\$334.4
5	COVID-19 test: Add-on payment for high throughput tests completed within 2 calendar days of specimen collection (U0005)	\$25.00	12.3	New in 2021	\$305.4
6	Complete blood cell count, automated test (85025)	\$7.77	37.8	↑ 3.1%	\$300.2
7	Genetic test: Molecular pathology procedure level 9 (81408)	\$2,000.00	0.1	↑ 36.4%	\$282.2
8	Vitamin D-3 level (82306)	\$29.60	9.1	↑ 11.8%	\$267.2
9	Genetic test: Gene analysis (colorectal cancer) (81528)	\$508.87	0.5	↑ 20.6%	\$252.6
10	COVID-19 test: Any technique, high-throughput technologies (U0004)	\$75.00	2.9	↑ 20.7%	\$220.8
11	Detection test for organism (87798)	\$35.09	6.1	↑ 16.2%	\$213.7
12	Drug test(s), definitive, 22 or more drug class(es) (G0483)	\$246.92	0.8	↓ -9.2%	\$203.0
13	Hemoglobin A1C level (83036)	\$9.71	18.6	↑ 5.9%	\$182.3
14	Testing for presence of drug (80307)	\$62.14	2.5	↓ -3.6%	\$156.4
15	Drug test(s), definitive, 15-21 drug class(es) (G0482)	\$198.74	0.7	↑ 1.3%	\$130.2
16	COVID-19 test: Amplified probe technique (87635)	-	2.0	↑ 46.9%	\$104.8
17	COVID-19 test: ELISA detection of severe acute respiratory syndrome coronavirus 2 (COVID-19) (87426)	-	2.6	New to top 25	\$101.5
18	Parathormone (parathyroid hormone) level (83970)	\$41.28	2.5	↑ 8.6%	\$101.4
19	Genetic test: Gene analysis (breast cancer 1 and 2) (81162)	\$1,824.88	0.05	↑ 7.7%	\$94.0
20	Genetic test: Test for detecting genes associated with breast cancer (81519)	\$3,873.00	0.02	↑ 20.1%	\$92.7
21	Blood test, basic group of blood chemicals (80048)	\$8.46	10.3	↓ -0.1%	\$90.3
22	Cyanocobalamin (vitamin B-12) level (82607)	\$15.08	5.8	↑ 11.4%	\$87.9
23	Drug test(s), definitive, 1-7 drug class(es) (G0480)	\$114.43	0.8	↓ -2.6%	\$86.6
24	Genetic test: Molecular pathology procedure level 8 (81407)	\$846.27	0.1	New to top 25	\$81.6
25	Drug test(s), definitive, 8-14 drug class(es) (G0481)	\$156.59	0.5	↓ -2.5%	\$79.1
Total 2021 spending on the top 25 tests:					\$5.48 billion

[Medicare Part B Spending on Lab Tests Increased in 2021, Driven by Higher Volume of Tests, OEI-09-22-00400 \(hhs.gov\)](https://www.hhs.gov/oig/oei/reports/2022/09/09-22-00400)



Explosion in Mod 90 Growth the last 3 years

MolDX Reference Medicare Submit Amounts
now average \$1.9 Billion a year





Operation Double Helix Update

- Indictments – 302
- Convictions – 163
- Monetary Recoveries - \$550 million
- Double Helix Historical Mod 90 - 78 labs/\$2.2 billion billed



Minal Patel
Lab Solutions
\$463 million in CGx fraud
Sentenced to 27 years in prison



Khalid Satary
Clio Labs et al.
\$547 million in CGx fraud
Currently a fugitive

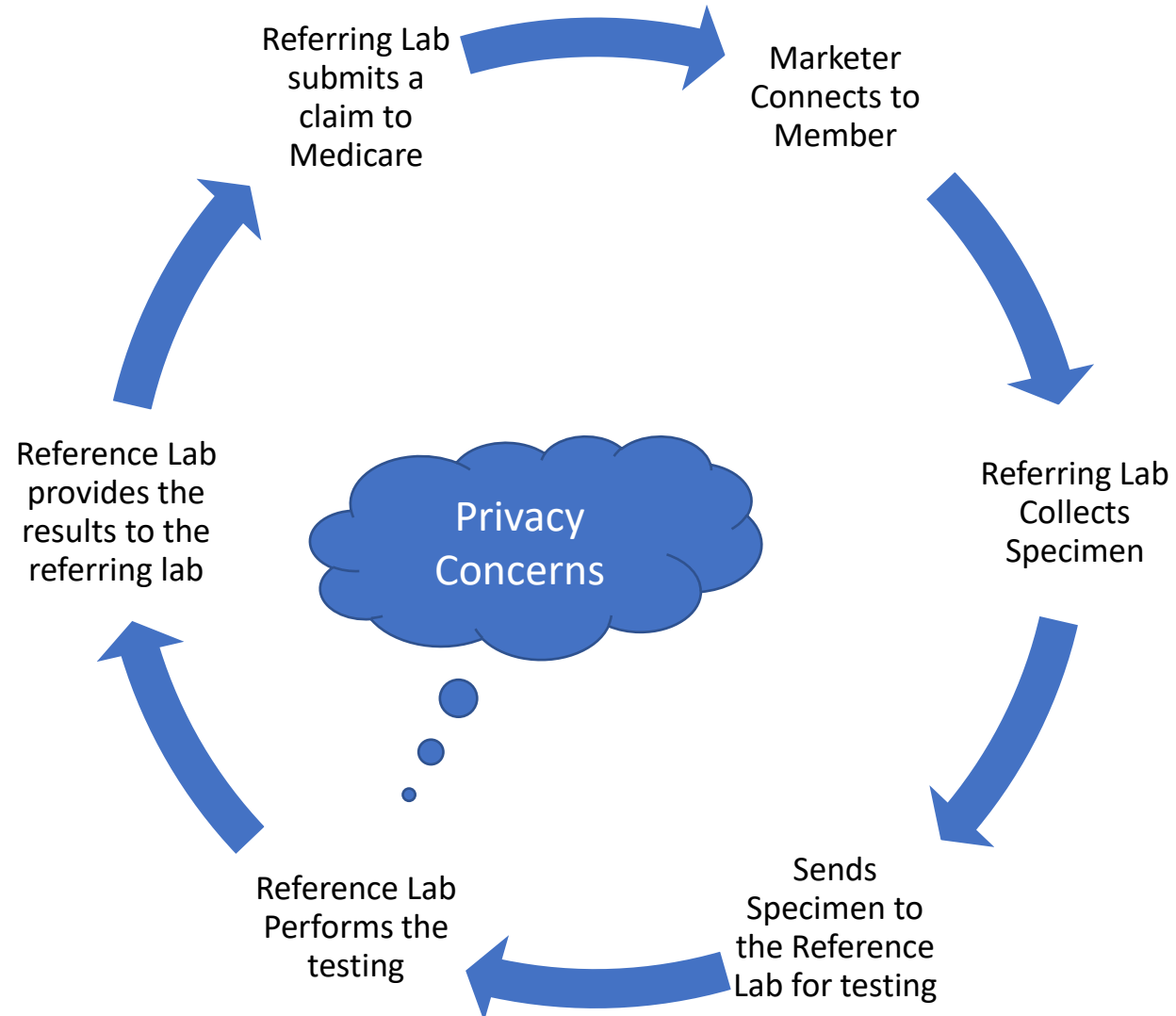


Operation Double Helix Themes

- Laboratories target non-MolDx jurisdictions
- Lead generators
- Move operations
- Lack equipment
- Share space
- Recycle laboratory directors
- Utilize reference labs



Reference Lab Process

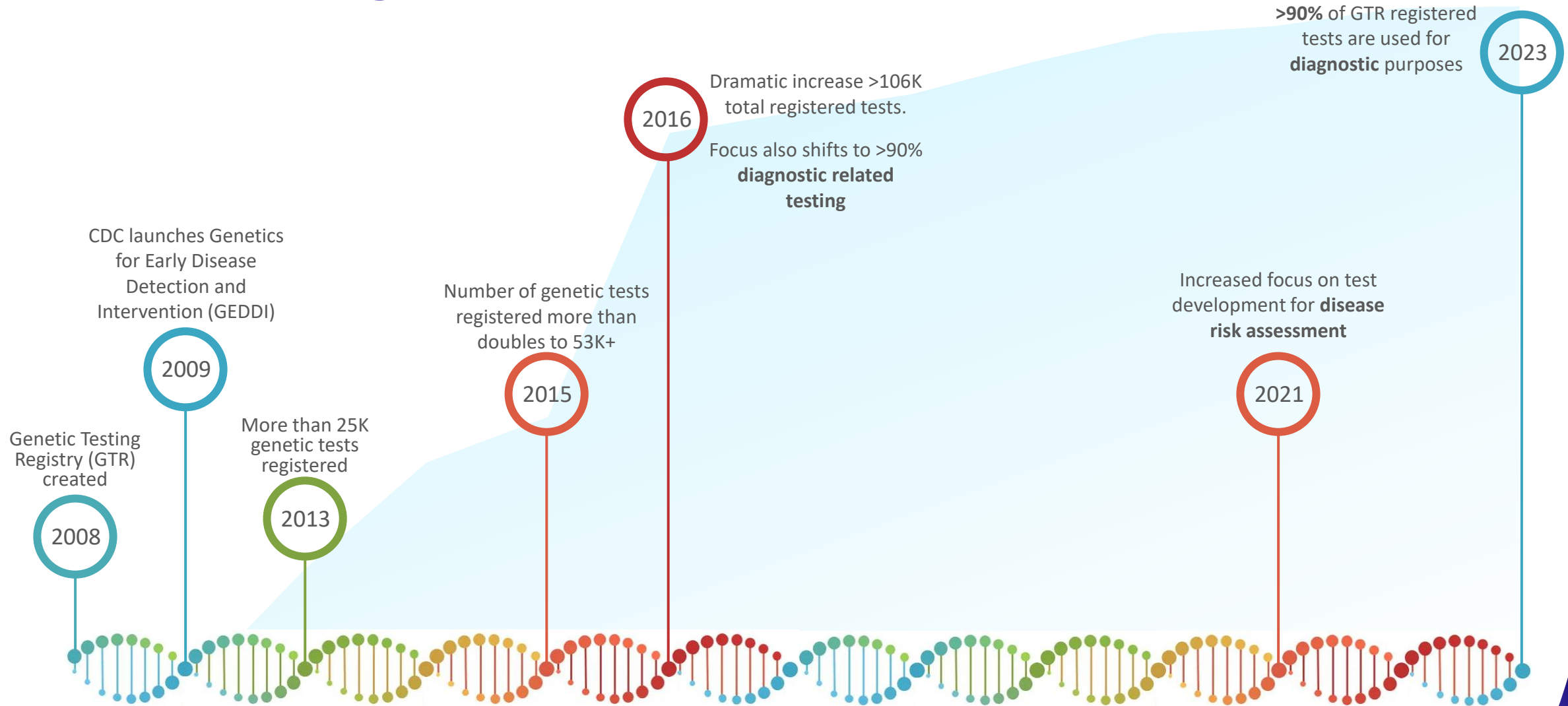




NAVIGATING MARKET GROWTH

Sarah Bretz – Product Manager, Avalon

Genetic Testing Growth

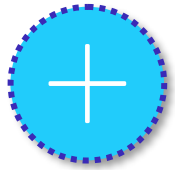


NIH. (2023, Oct) *NIH Genetic Testing Registry (GTR)*. <http://www.ncbi.nlm.nih.gov/gtr/>

Genetic Market Size



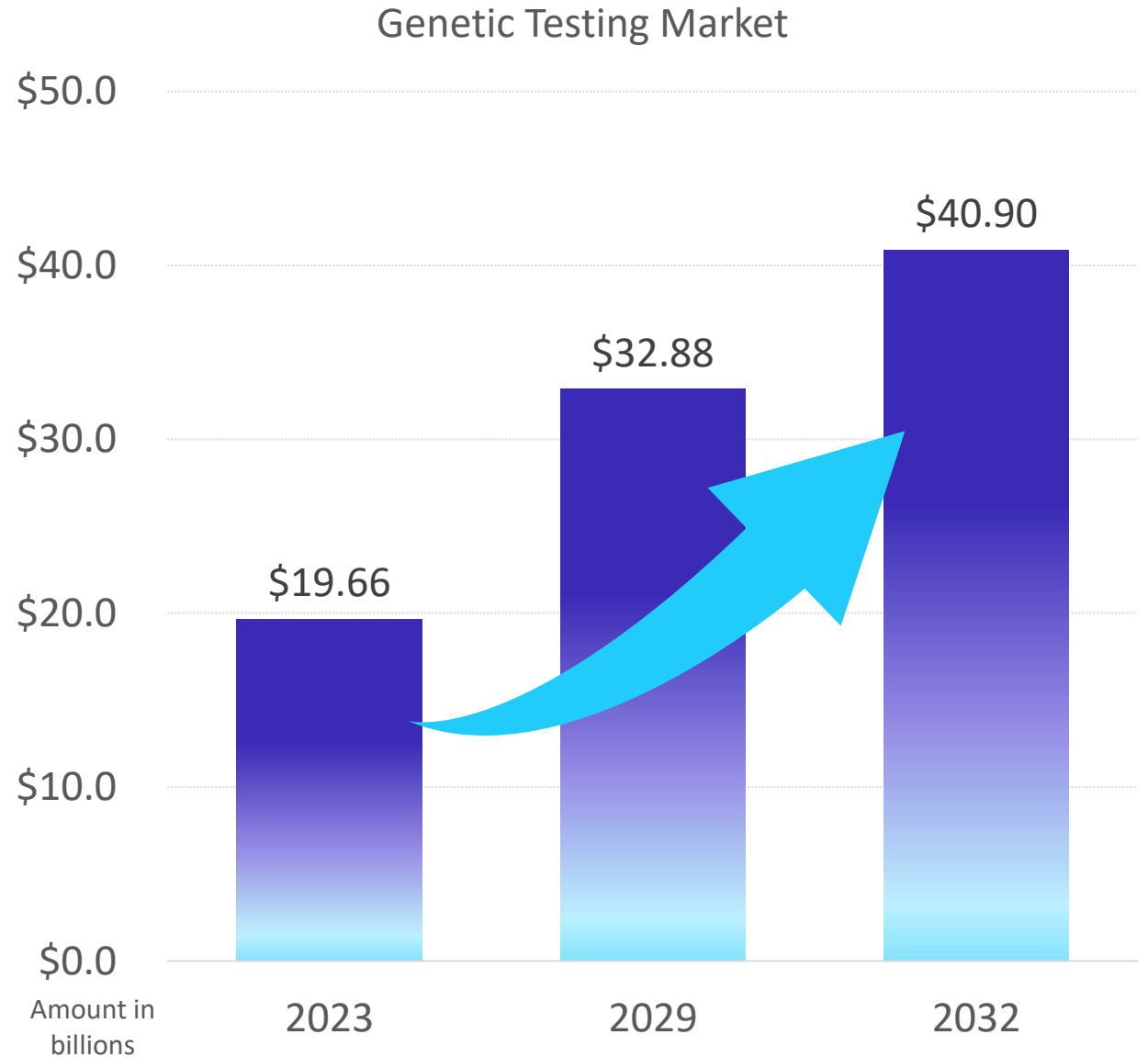
10.2% CAGR



10+ new genetic tests
per day



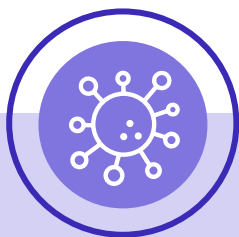
~\$41 Billion by 2032



Market Drivers



Technology



**Prevalence of
Chronic Disease**



**Personalized and
Precision Medicine**



**Changes in
Clinical Guidelines**



**Reducing Prior
Authorization Barriers**

Top Growth Categories for New Genetic Tests

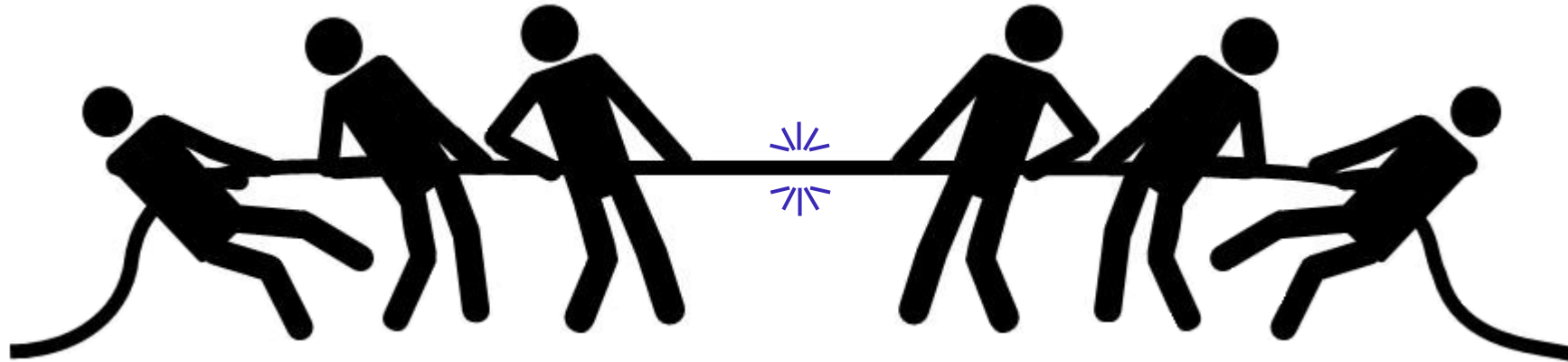
Prenatal

Oncology

Pharmacogenomics

Financial Motivators

- Plans are mandated to cover tests
- Investigational/experimental tests not covered
- Prior authorization requirements
- Labs want to develop more tests, faster
- Lab development of new tests is expensive



Potholes in the Care Path

- Ordering Physician
 - Overuse, unnecessary tests, lack of CU understanding
- Rendering Labs
 - Lack of quality controls, inaccurate tests
- Reference Labs
 - Unnecessary outsourcing, lack of oversight
- Health Plans
 - Inadequate review of claims, limited ability to oversee medical necessity of testing



EVIDENCE-BASED POLICY DELIVERY

Ben Horton, MD, MHA – Vice President, Senior Medical
Director, Avalon

Molecular Tests Require Knowledge and Experience that Most Clinicians (and Policy Writers) May Lack

Challenges to maintain effective policies:



Novel
technology



Rapidly
evolving
science



Pace of
genetic test
introduction



Lab or
consumer-
directed



Maldistribut-
ion of
geneticists



THE LONG ROAD TO TEST APPROVAL

Mike Snyder – Executive Vice President, Network, Avalon

"Genetic Testing" Describes a Broad Array of Testing with Respect to Providers, Domain, and Clinical Use



Oversight of genetic testing is not coordinated

- AMA: assigns procedure coding (HCPCS)
- CMS: approval for reimbursement for the Medicare program
- FDA: approval of invitro diagnostic products (IVD); approval of LDT is pending
- Medical societies (NCCN, etc.): render "opinions"



Determining the "value" of a test

- Analytical value
- Clinical value
- Clinical utility



Reimbursement

- Delay from CMS approval to assignment of reimbursement
- Procedure: Gap-fill or crosswalk
- Commercial insurance:
 - Approval and reimbursement assigned by the individual plan (medical policy)
 - Utilize CMS reimbursement as a benchmark



Ordering provider education

- Primary: Rendering lab
- Medical policy
- Intellectual curiosity



Commander Patrick Neubert – HHS Office of Inspector General



Sarah Bretz – Product Manager, Avalon



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PANEL DISCUSSION AND Q&A



Amanda Bruemmer – Senior Manager, Product Marketing



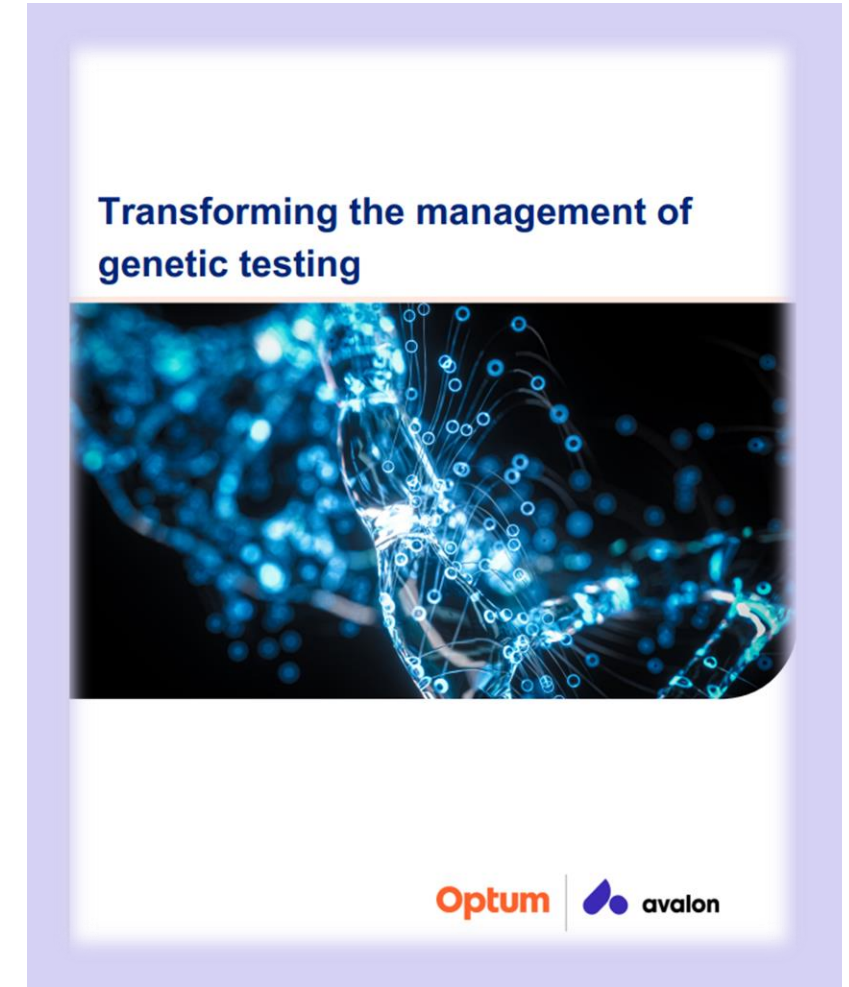
CLOSING REMARKS

Amanda Bruemmer – Senior Manager, Product Marketing

Available on Avalon Website: Transforming The Management of Genetic Testing – Chapter 2

As the genetic testing market continues to grow exponentially in size and cost, the challenge of determining which genetic tests may produce results that effectively guide treatment decisions is becoming increasingly difficult for health plans. In Chapter 2 of Transforming the Management of Genetic Testing e-book, we discuss:

- The critical role of science-backed, evidence-based lab policies in genetic test management systems
- An improved, next-generation solution to ensure the right test is ordered to inform the right care at the right time



Thank you

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Avalon Webinar – May 7, 2024

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