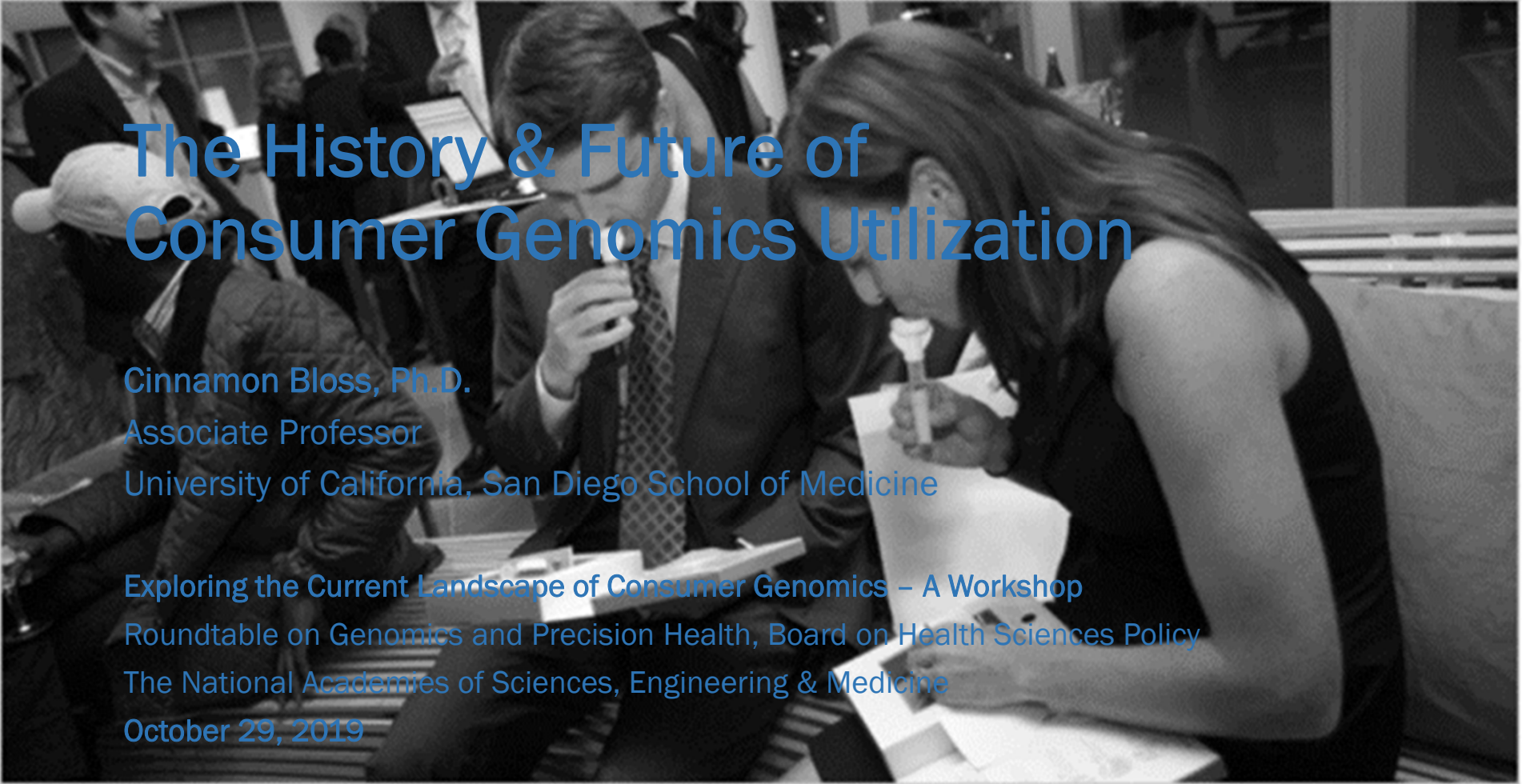




The History & Future of Consumer Genomics Utilization

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Exploring the Current Landscape of Consumer Genomics – A Workshop

Roundtable on Genomics and Precision Health, Board on Health Sciences Policy

The National Academies of Sciences, Engineering & Medicine

October 29, 2019

FASHION & STYLE

The New York Times

When in Doubt, Spit It Out

By ALLEN SALKIN SEPT. 12, 2008



A DATE WITH DNA K. C. Dustin and his wife, Debra Netschert, give saliva samples.

Michael Nagle for The New York Times

Overview

- History of consumer engagement with DTC genomic tests
- Review of consumer utilization and impacts
- Speculation on future trends

Key Takeaways

- 1) Limited Data – Major existing studies a decade old, little or no public data on recent consumers
- 2) Consistent Motivations for Testing & Few Health Behavior Impacts – Snapshot from available studies
- 3) Significant Physician Impact – 1/3 of consumers bring results to at least one healthcare provider
- 4) Upward Trajectory – Recent increases in consumer purchasing are likely to continue

U.S. | THE DNA AGE

My Genome, Myself: Seeking Clues in DNA

By AMY HARMON NOV. 17, 2007

BUSINESS DAY

Consumers Slow to Embrace the Age of Genomics

By ANDREW POLLACK MARCH 19, 2010

I Had My DNA Picture Taken, With Varying Results

BUSINESS DAY

Is a DNA Scan a Medical Test or Just Informational? Views Differ

By ANDREW POLLACK MARCH 19, 2010

U.S.

With DNA Testing, Suddenly They Are Family

By RACHEL L. SWARNS JAN. 23, 2012

HEALTH

F.D.A. Faults Companies on Unapproved Genetic Tests

By ANDREW POLLACK JUNE 11, 2010

F.D.A. Orders Genetic Testing Firm to Stop Selling DNA Analysis Service

Opinion

23andMe Said He Would Lose His Mind. Ancestry Said the Opposite. Which Was Right?

By Laura Hercher



BUSINESS DAY

Gene Testing Questioned by Regulators

By ANDREW POLLACK JUNE 26, 2008

SCIENCE

Heavy Doses of DNA Data, With Few Side Effects

Findings

By JOHN TIERNEY JAN. 17, 2011

BUSINESS DAY

DNA Profile Provider Is Cutting Its Prices

By ANDREW POLLACK SEPT. 9, 2008

Don't Count on 23andMe to Detect Most Breast Cancer Risks, Study Warns

F.D.A. Will Allow 23andMe to Sell Genetic Tests for Disease Risk to Consumers

U.S.

Experts Advise a Grain of Salt With Mail-Order Genomes, at \$1,000 a Pop

By NICHOLAS WADE NOV. 17, 2007

EDUCATION

College Bound, DNA Swab in Hand

By TAMAR LEWIN MAY 18, 2010

History of DTC Genomics Uptake

2003	Human Genome Project complete
2006	23andMe founded, controversy and debate about pros/cons
2007	Navigenics founded
2008	TIME names retail DNA test (23andMe) invention of the year
2009	30 companies offering DTC tests
2010	Estimated ~\$10 million market
2010	Pathway announces Walgreens partnership to sell in stores
2010	GAO report released on July 22
2011	AMA letter to FDA suggesting all genetic testing involve a physician
2013	FDA issues notice to cease and desist
2015	FDA approves 23andMe Bloom Syndrome test
2016	Beginning of DTC genetic test inflection point
2017	Estimated ~\$600 million global market value
2017	23andMe claims > 2 million consumers
2017	April 6, FDA approves 23andMe risk test for 10 diseases/conditions
2017	Among leading companies, total consumers > 12 million
2018	FDA grants 23andMe marketing authorization for BRCA tests
2018	GlaxoSmithKline invests \$300 million in 23andMe for drug dev
2018	Estimated ~\$830 million global market value for DTC genetics
2019	Total number of consumers projected at > 26 million
2021	MIT Tech Review predicts ~100 million customers
2025	Global DTC genetics market predicted at > \$2.5 billion

↑ Market Value

↓ Cost of Tests

↑ Consumer
Purchasing

Rapid Review

DTC Genetic Health Risk Tests

- Conducted rapid review
 - Keyword search in PubMed, Web of Science
- Augmented two prior reviews
 - Stewart et al. 2018
 - Covolo et al. 2015
- Impacts of testing
 - Motivations
 - Behavioral
 - Psychological
 - Medical utilization

Example Risk Results		
23andMe Discoveries		
Disease Risks (116) ?		
↑ Elevated Risks	Your Risk	Average Risk
Coronary Heart Disease	38.5%	24.4%
Gallstones	21.7%	14.3%
Multiple Sclerosis	1.0%	0.7%
Ulcerative Colitis	0.7%	0.5%
Scleroderma (Limited Cutaneous Type)	0.2%	0.2%
See all 116 risk reports...		
Drug Response (20) ?		
Clopidogrel (Plavix®) Efficacy	Reduced	
Response to Hepatitis C Treatment	Reduced	
Warfarin (Coumadin®) Sensitivity	Increased	
Abacavir Hypersensitivity	Typical	
Alcohol Consumption, Smoking and Risk of Esophageal Cancer	Typical	

Results

- 69 total articles, 18 new (from 2017-present)
- Mix of standard methodological approaches
- Few unique cohorts (~50% of all studies based on only 3 cohorts)
 - Impact of Personal Genomics (PGen)
 - Scripps Genomic Health Initiative (SGHI)
 - Multiplex Initiative
- Participants early adopters (recruited ~ decade ago)

Characteristics & Motivations

- Participants in cohort studies to date mostly White and high SES
- Primary motivations for seeking testing are (consistent finding):
 - Ancestry
 - Health
 - Curiosity
 - Family Health History
- Few studies on differences in motivations and outcomes as a function of demographic diversity
- Landry et al. (2107, PGen) found few differences in motivations as a function of race (small N)

Health Behavior Changes

- When asked directly, less than 1/4 people self-report any health behavior change
 - Exercise
 - Diet
 - Smoking behavior
 - Vitamin/medication use
- Objective/validated measures of behavior find few or no changes
- In studies where changes have been observed, difficult to ascertain:
 - Size of effects
 - Whether (positive) changes are maintained and appropriate

Psychological Impacts

- Critics have raised concern for adverse psychological responses, such as anxiety and depression
- Currently little evidence for statistically significant adverse psychological changes among groups consumers in existing studies
- Although percentages of people with adverse responses appear low, consequences when it does happen may be significant
- Resources should be available

Physician Sharing & Healthcare System

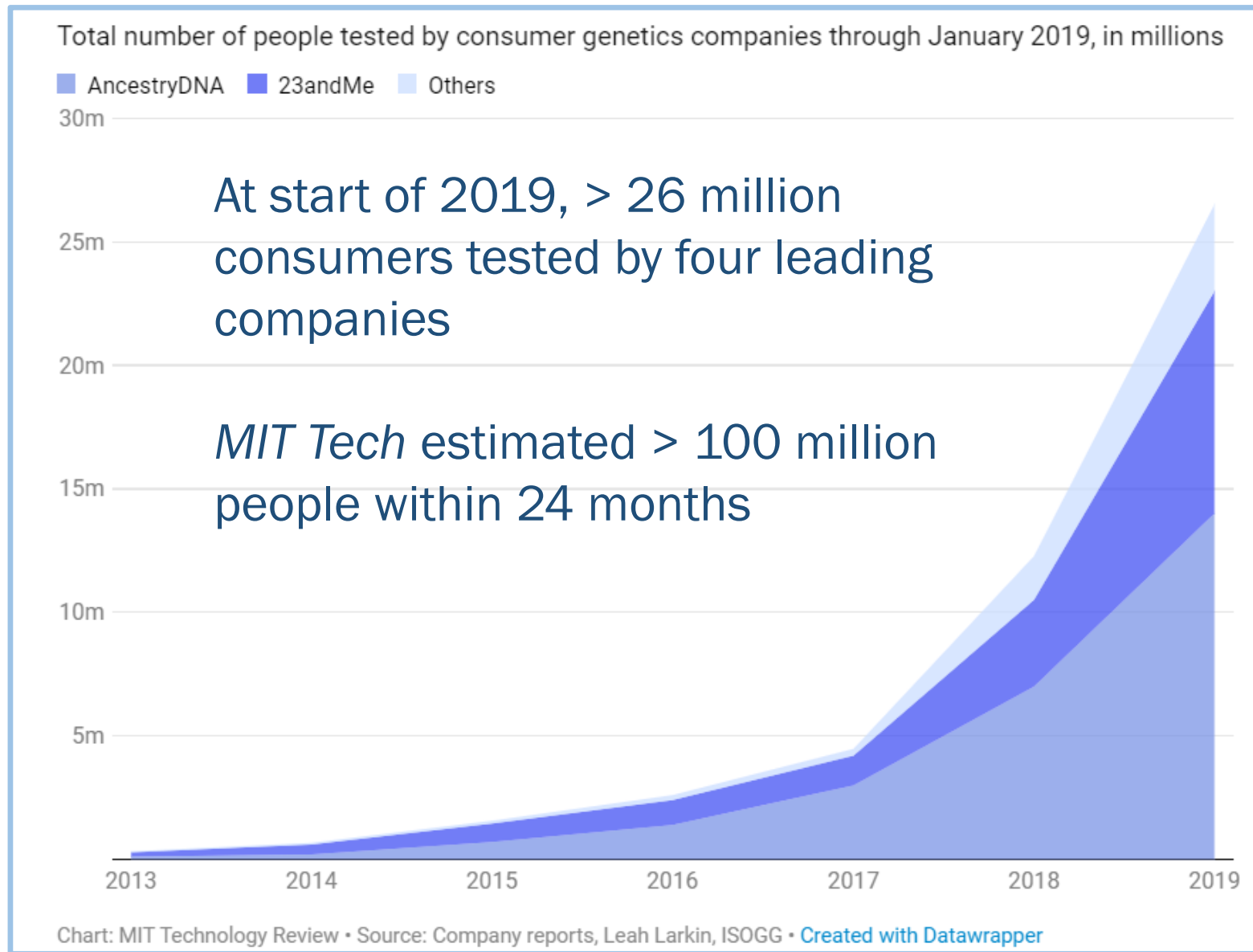


Findings similar for results
from third-party
interpretation

- Estimates that about a third share with at least one HCP (range 25-46%), usually PCP
- Findings inconsistent regarding characteristics of sharers
- Outcomes of sharing vary
 - In general, provision of reassurance more common than change in management
- Consumers express belief in right to access without physician
- But also that physicians should be available and able to provide counsel for these tests (that they did not order)

Future Trends

Consumer Uptake Increasing



Aggressive Marketing



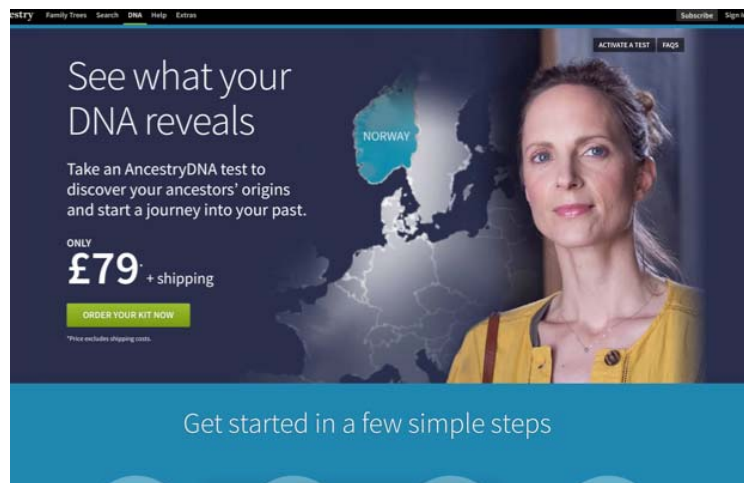
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your ancestors?

Discover Your Ancestors' birth records,
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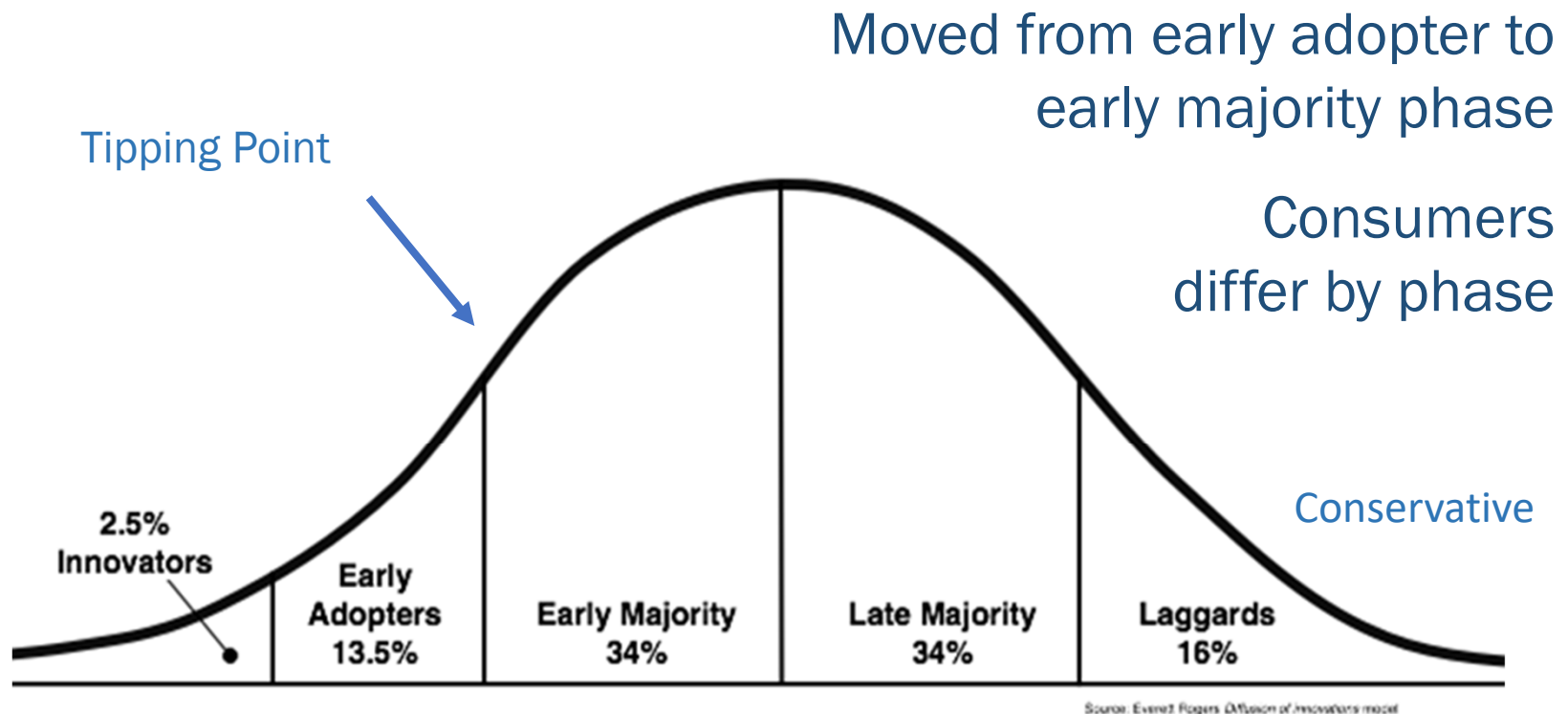


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- Key Implication: Advertising (with low cost) will drive purchasing until market saturation

Adoption Curve



- Key Implication: Existing studies may not accurately inform utilization and impacts on current consumers (need new studies with new approaches)

Broad & Shifting Consumer Health Landscape



- Key Implication: Consumers will increasingly seek after-the-fact physician guidance regarding genomic and other health tests purchased DTC

Takeaways & Recommendations

- 1) Limited Data – Need studies of recent consumers (that leverage new approaches, e.g., social media studies), studies that assess influence of demographic factors, impact of emerging issues
- 2) Consistent Motivations & Few Health Behavior Impacts – Monitor for later stage adopters, make resources available to address adverse psychological impacts when they occur
- 3) Significant Physician Impact - Current US consumer base estimates suggest ~3.6 million instances of sharing with a physician (juxtaposed with only 850k practicing in US)
 - Learn about phenomena, develop/teach ways to approach these interactions in shifting health care landscape, treat as an opportunity
- 4) Upward Trajectory – More people tested outside vs. inside medical model, part of broader trend of consumer interest in DTC health products and devices and likely to continue

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UC San Diego

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