SESSION 1: Overview of Multicancer Detection Testing

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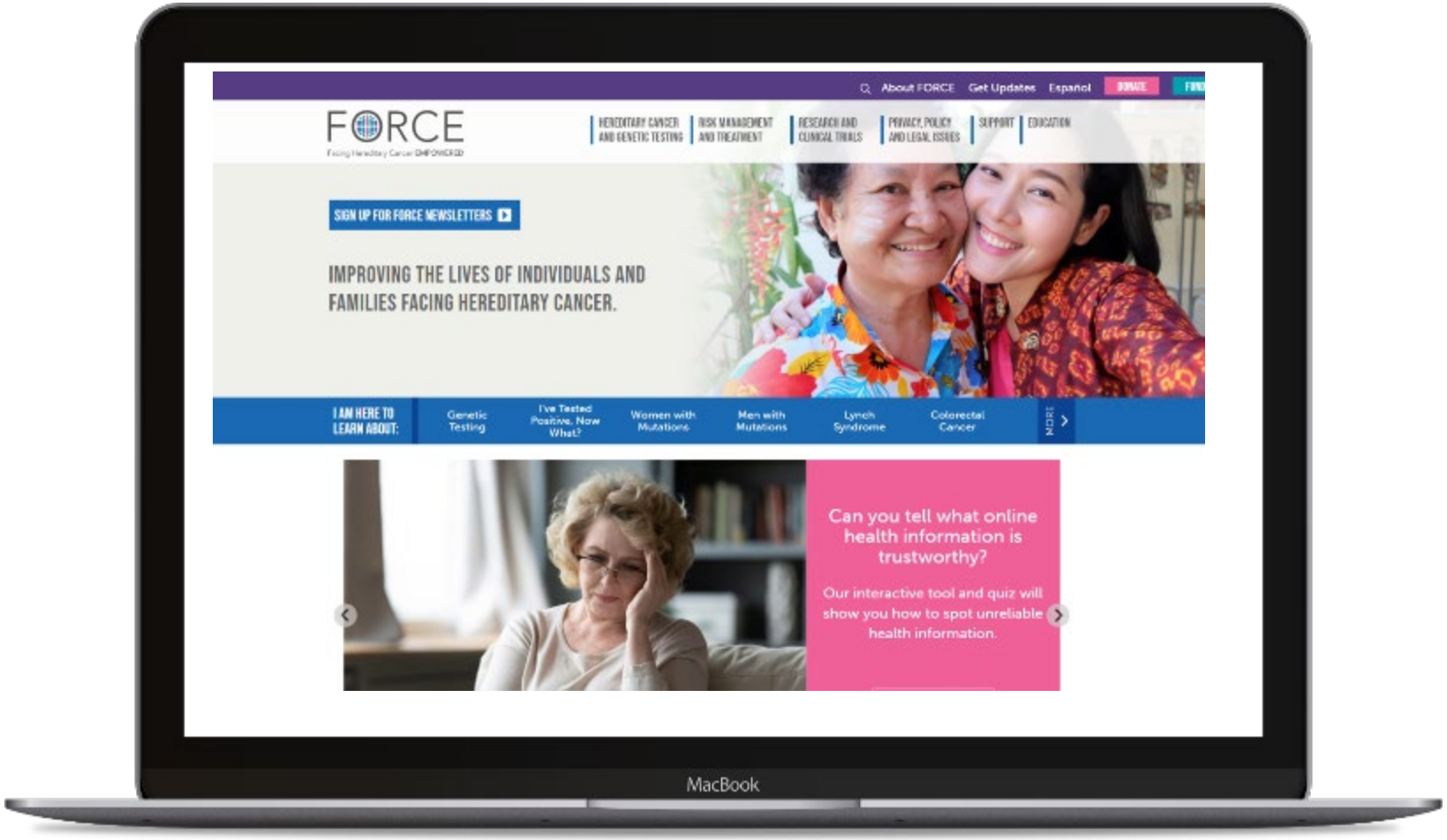
FORCE
Facing Hereditary Cancer EMPOWERED

Disclosure

I have no conflicts to disclose

Note: opinions expressed in this presentation are my own.

ABOUT **FORCE**



FORCE serves people and families affected by Lynch syndrome or an inherited mutation in BRCA, ATM, CHEK2, PALB2,, PTEN or other gene linked to cancer. We accomplish this through our education, support, advocacy and research efforts.

The Burden of Hereditary Cancers

- Increased lifetime risk for cancer
- Younger-onset cancer risks.
- Risks for multiple primary cancer diagnoses.
- Risks run in families and are shared with blood relatives.

Risk for Multiple Types of Cancer

Lynch Syndrome

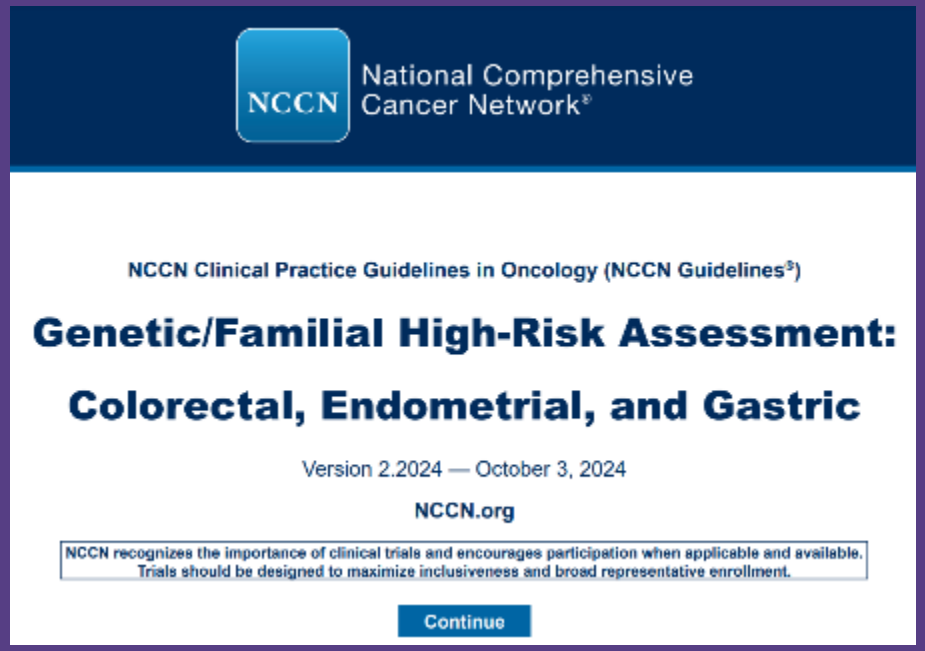
- colorectal
- endometrial
- ovarian
- pancreatic
- other

BRCA1/BRCA2

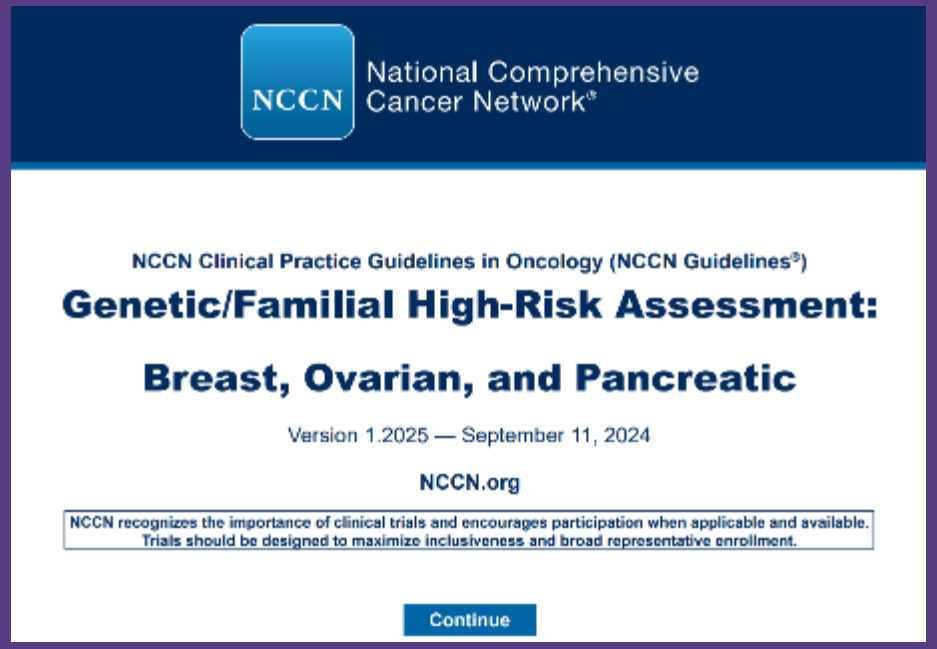
- breast
- ovarian
- pancreatic
- prostate

Intensive Risk-Management Recommendations

Lynch Syndrome



BRCA1/BRCA2



Burden of High-Risk Screening

… Last colonoscopy I had was when I could use my insurance and my parents as a secondary. Can't do $4000 every year. Just not doable.

I'm an under 50 Lynchie and haven't had a colonoscopy yet because I was told it would cost me $3,000-$5,000.

I need support leading up to my colonoscopy every year as I am terrified of the prep.

I'm 40 and I've never been able to get my insurance to cover colonoscopy as preventive, so I pay about $2500 before I hit my deductible.

Burden of High-Risk Screening

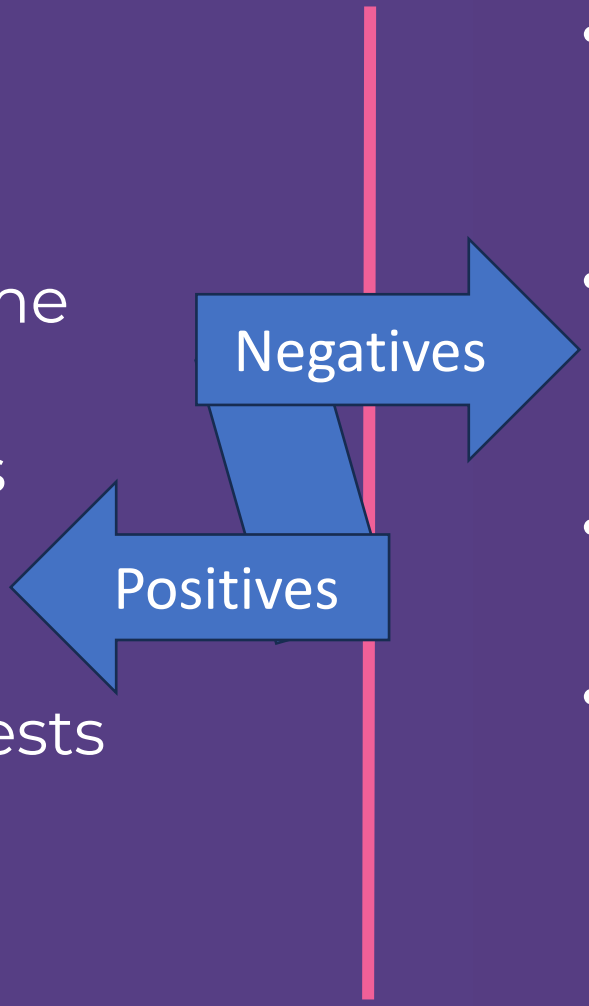
The financial burden of breast MRIs deters me from the additional screenings that are recommended.

Lack of resources in the region plus changes by my provider from one system to another have cut me off from recommended screenings for the past five years.

I live in a services desert. The nearest breast MRI is a 3 ½ hour drive...
ONE WAY.

BalancingTest Benefits vs. Risks, Costs and Limitations

- Lower cost than currently available high-risk screening
- Less preparation time
- Fewer stressful, invasive procedures
- Less travel
- Could reserve more invasive/intensive tests as follow-up for abnormal results



- Clinical validity/utility need to be established, especially for diverse groups & rare cancers.
- People may forego guideline-recommended interventions in favor of a blood test.
- False positives means more invasive procedures.
- Limited dollars for preventive care can exacerbate disparities for high-risk screening.

Media Hype

Blood test that finds 50 types of cancer is accurate enough to be rolled out

Diagnostic tool being piloted by NHS England shows 'impressive results' in spotting tumours in early stages

Nadeem Badshah *and agency*

Fri 25 Jun 2021 01.00 EDT

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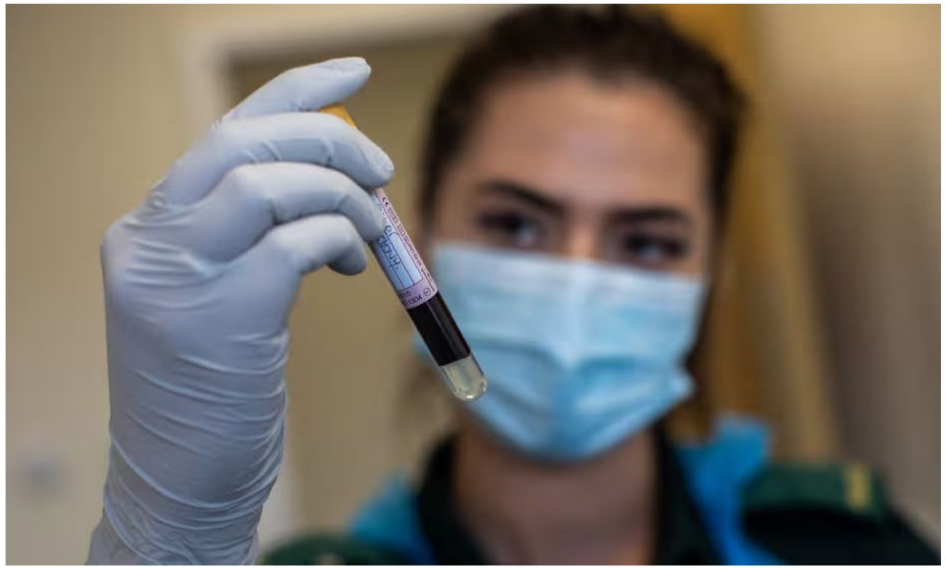
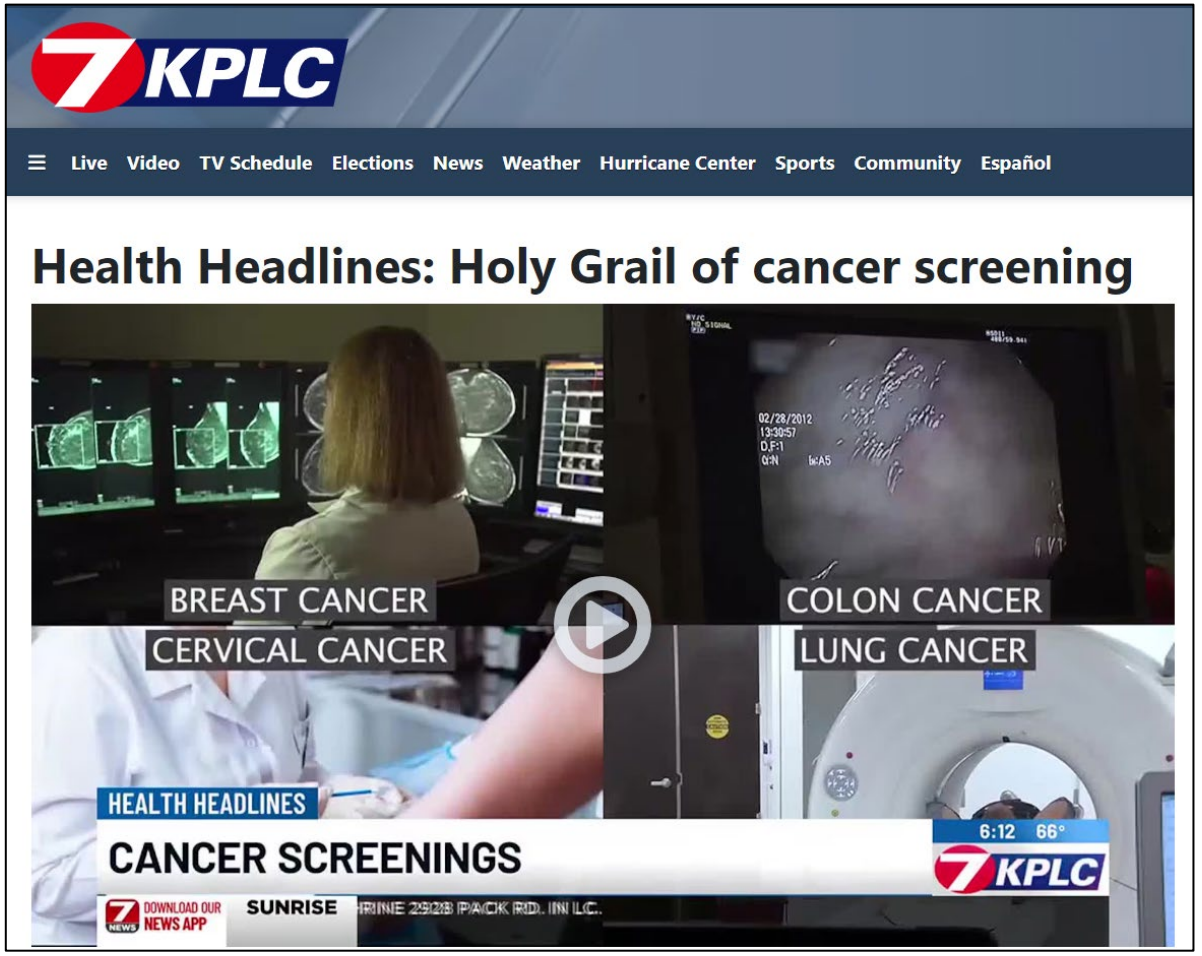


The blood tests are accurate enough to be rolled out as a screening test, scientists say. Photograph: Getty Images

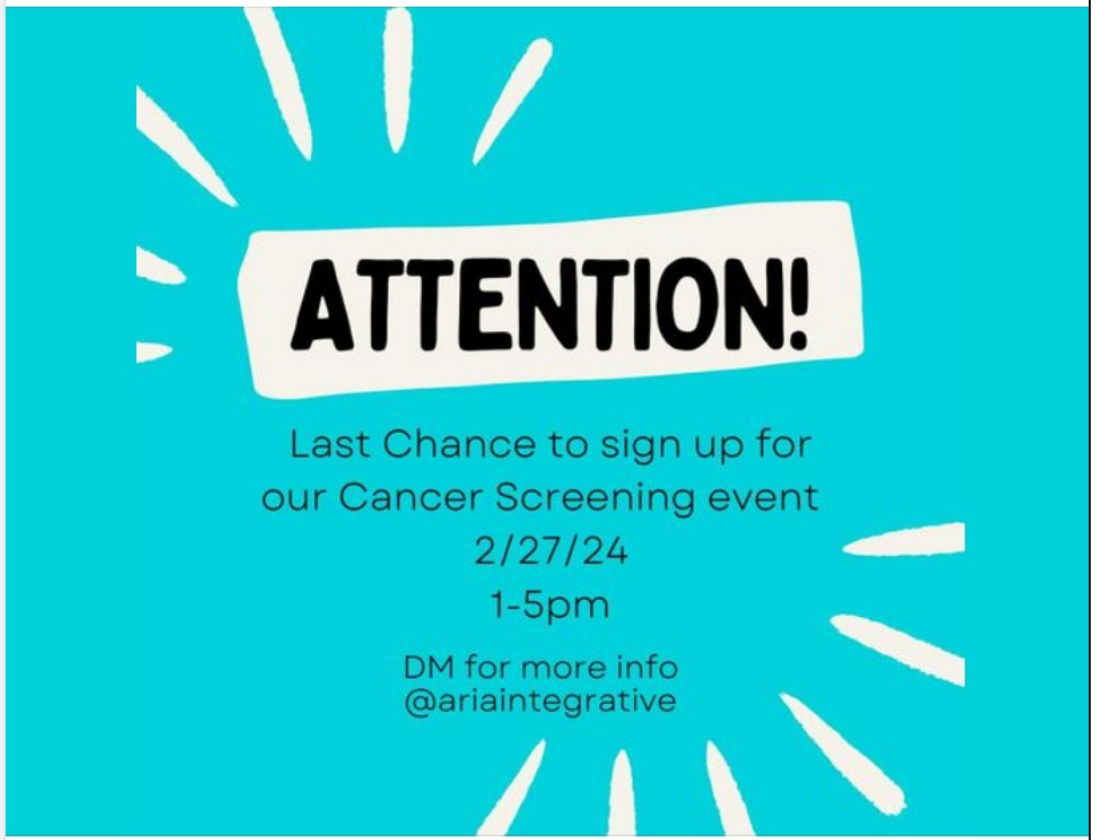


- Nadine Badshaw and Agency, "Blood test that finds 50 types of cancer is accurate enough to be rolled out." *The Guardian*. June 25, 2021.
- Rhonda Kitchens. "Health Headlines: Holy Grail of cancer screening." *WKPLC, Channel 7*. October 15, 2024.

Social Media Amplification

Aria Integrative Medicine
February 26 ·

Cancer Hides and Galleri knows how to find it! Today is the last day to sign up for our Cancer screening event which can detect over 50+ cancers in one blood draw!
#earlycancerdetetion #galleri #ariaintegrative #aimaccess



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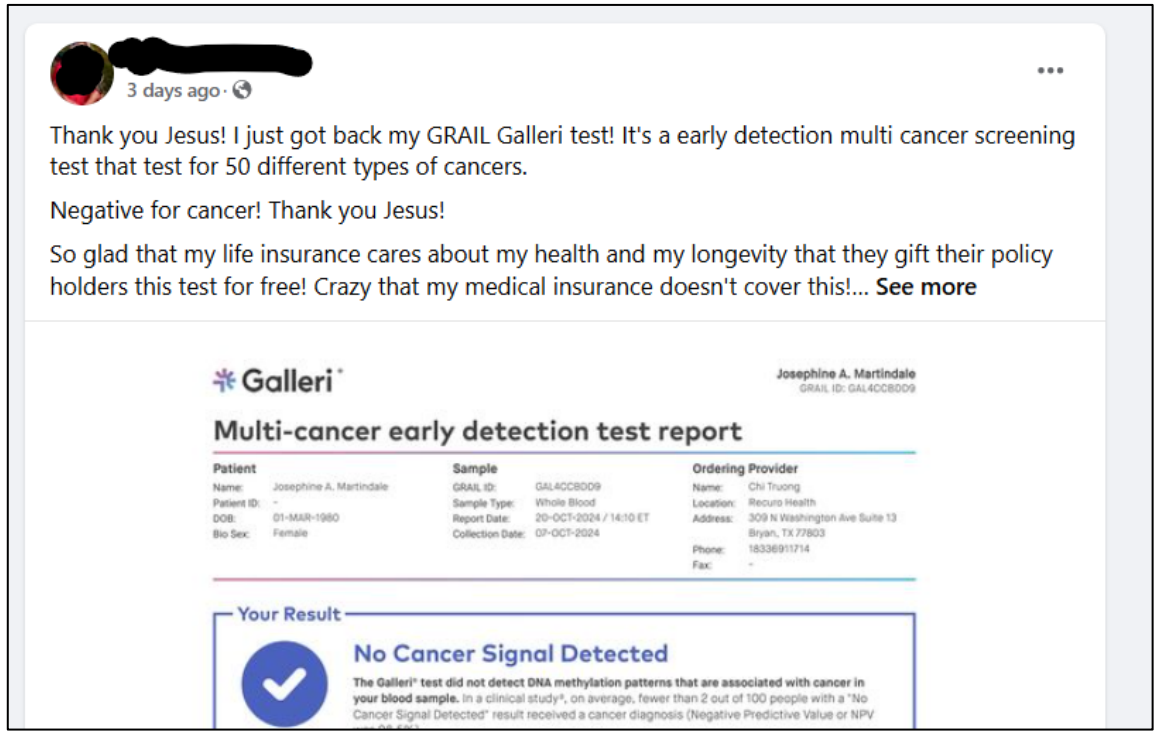
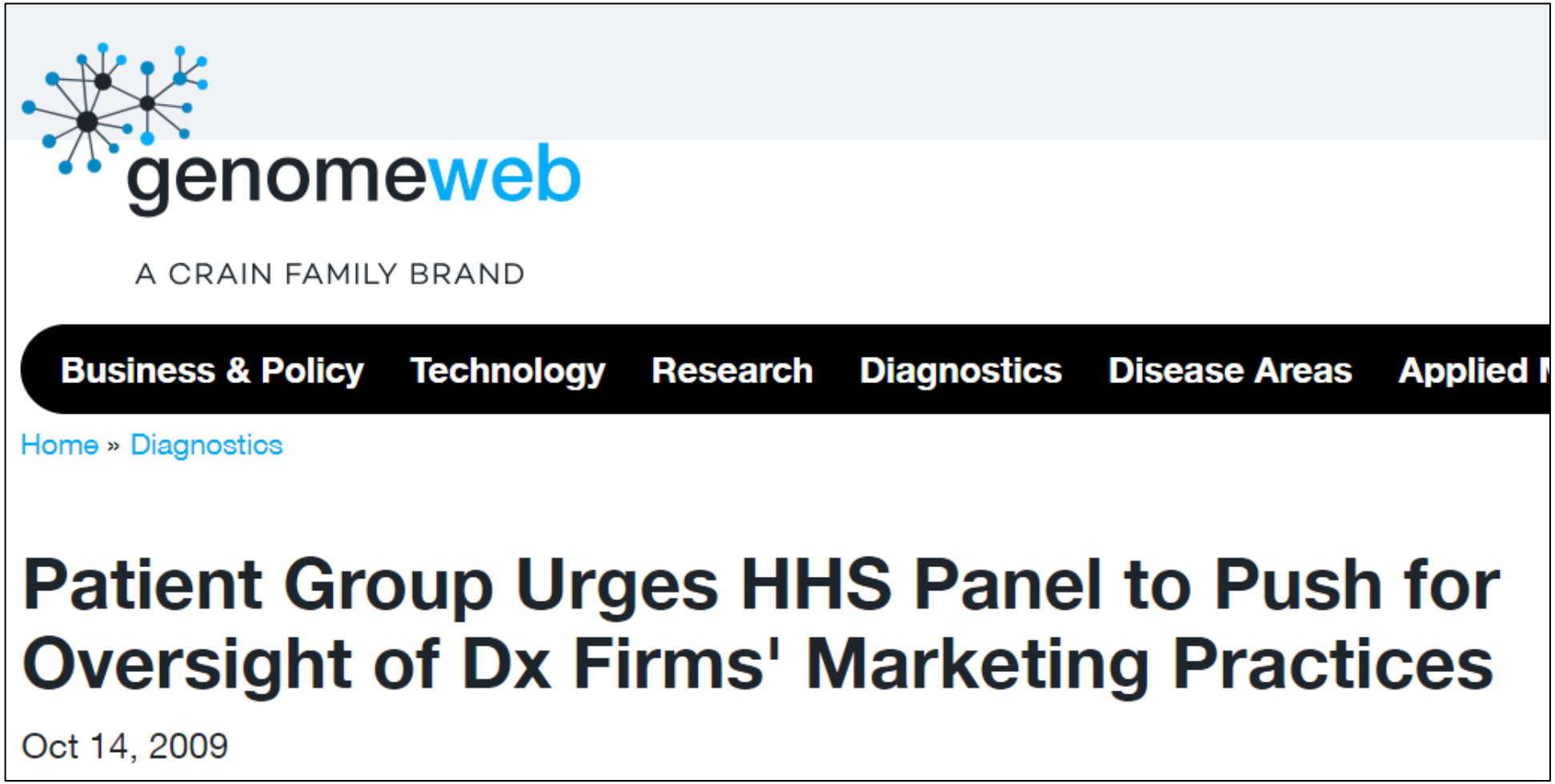


We've Been Here Before



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Patient Group Urges HHS Panel to Push for Oversight of Dx Firms' Marketing Practices

Oct 14, 2009

Turna Ray, "Patient Group Urges HHS Panel to Push for Oversight of Dx Firms' Marketing Practices." Genome Web, Oct 14, 2009.

We've Been Here Before

- **How the laboratories market these tests to doctors and consumers**

People are making medical decisions today based on test results, sometimes in the absence of evidence. Therefore, the information that labs provide about these tests, and how they market them to doctors and consumers are significant matters. In 2009, we provided testimony to the Secretary of Health's Advisory Committee on this topic, and based on that testimony, the FDA implemented a mechanism for health care providers to report adverse events stemming from laboratory tests.

"Regulating the Next Generation of Genetic Tests." FORCE Blog – March 15, 2015

Recommendations

- Require rigorous validation of MCED tests for diverse populations and in high-risk settings prior to commercialization.
- Require transparency about test benefits, risks, limitations and clinical utility in marketing materials to providers and in plain language for patients.
- Promote equitable access to guideline-recommended, risk-based cancer screening and preventive services for people of every risk level.
- Once validated, assure access for marginalized, over-burdened and under-resourced populations.