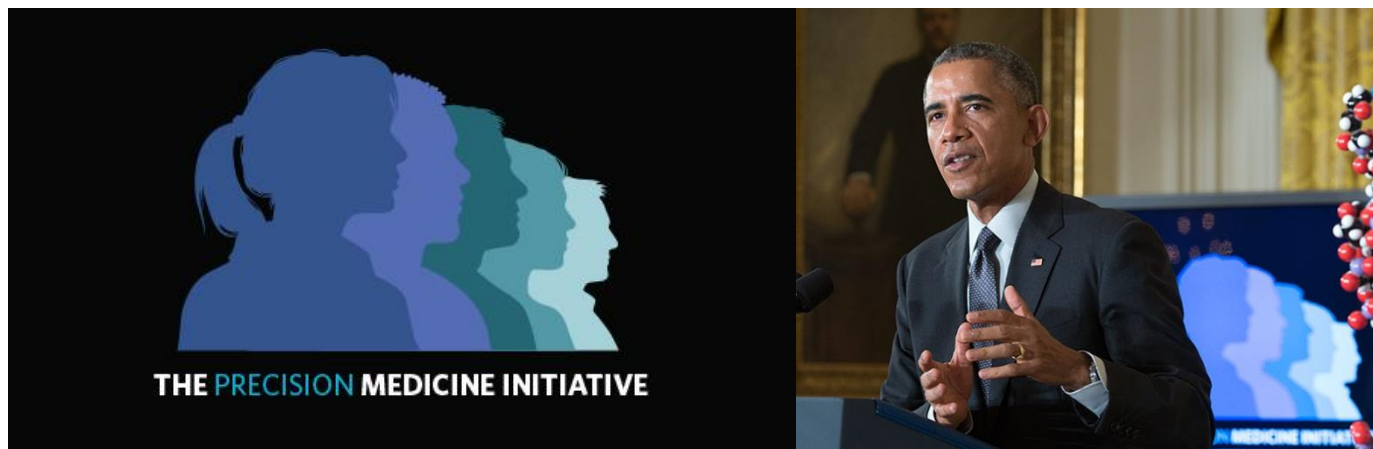




# The President's Precision Medicine Initiative (PMI)

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# The President's Precision Medicine Initiative (PMI)



*To enable a new era of medicine through research and technology that empowers patients, researchers, and providers to work together toward development of individualized treatments.*

# Precision medicine – Tailoring Health Care to Each Patient

- The right treatment
- The right patient
- The right time



# Precision Medicine Initiative: Modernizing FDA Regulation of Genomic Laboratory Tests

- Need to ensure that the information that patients receive from NGS tests is accurate and relevant to their condition (analytically and clinically valid)
- *Differences in data volume and interpretation call for a new regulatory approach* that will ensure that patients and providers are able to make treatment decisions based on accurate test results

# Precision Medicine Initiative: Modernizing FDA Regulation of Genomic Tests

Traditional testing



Next generation



# Workshop Agenda

- Panel 1: Well Patient Tests/Predictive tests
- Panel 2: Acute Disease Tests
- Panel 3: Chronic Disease Tests
- Public Comment