INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Board on Health Sciences Policy

Roundtable on Translating Genomic-Based Research for Health

Refining Processes for the Co-Development of Genome-Based Therapeutics and Companion Diagnostic Tests: A Workshop

Payer / Strategy Perspective

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February 27, 2013 Washington, DC

VER 3 : FINAL DECK

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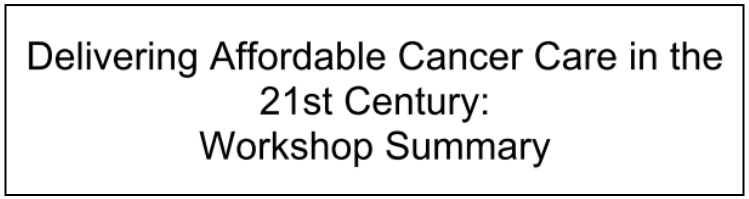
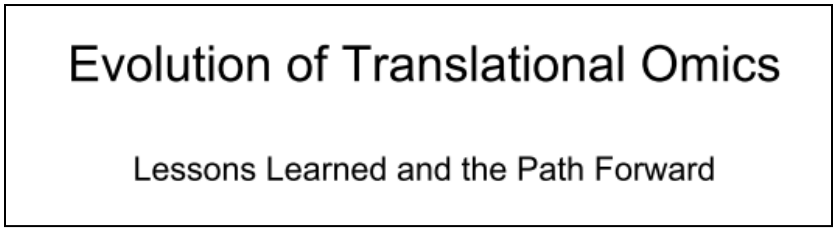
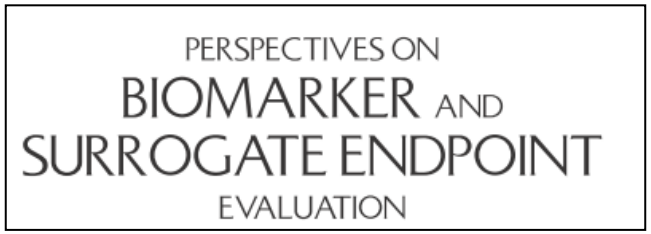
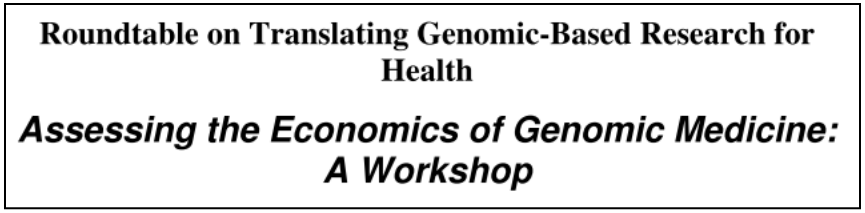

Delivering Affordable Cancer Care in the 21st Century:
Workshop Summary

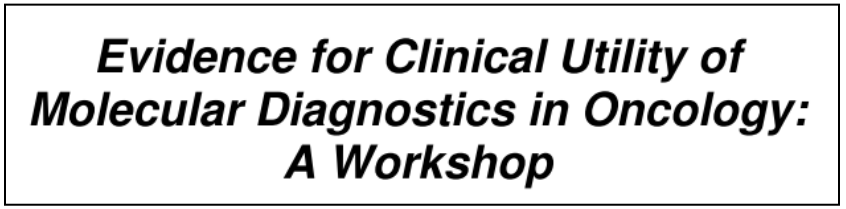

GENOME-BASED DIAGNOSTICS
Clarifying Pathways to Clinical Use
WORKSHOP SUMMARY

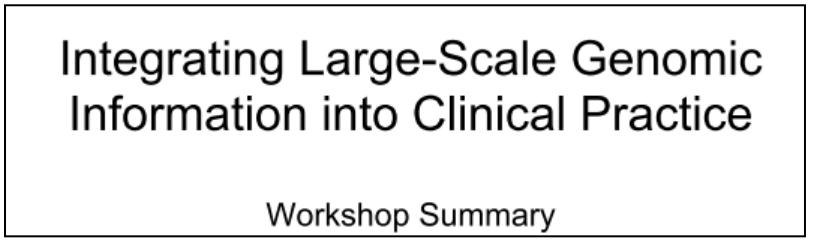

Evolution of Translational Omics
Lessons Learned and the Path Forward

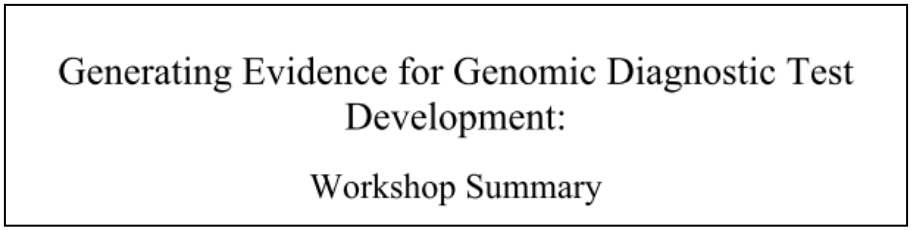

Genome-Based Diagnostics:
Clarifying Pathways to Clinical Use
Workshop Summary


PERSPECTIVES ON
BIOMARKER AND
SURROGATE ENDPOINT
EVALUATION

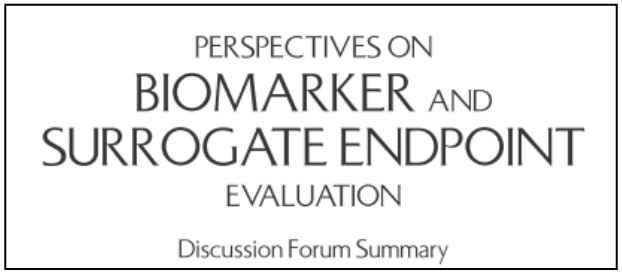

Roundtable on Translating Genomic-Based Research for Health
Assessing the Economics of Genomic Medicine:
A Workshop


Evidence for Clinical Utility of Molecular Diagnostics in Oncology:
A Workshop


Integrating Large-Scale Genomic Information into Clinical Practice
Workshop Summary


Generating Evidence for Genomic Diagnostic Test Development:
Workshop Summary


Genome-Based Therapeutics:
Targeted Drug Discovery and Development


PERSPECTIVES ON
BIOMARKER AND
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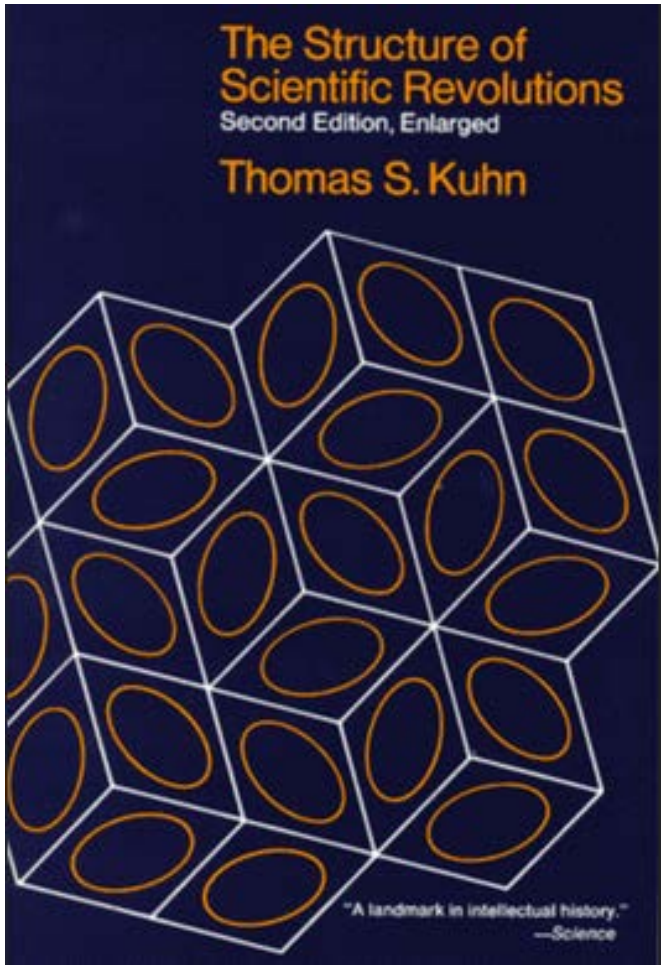
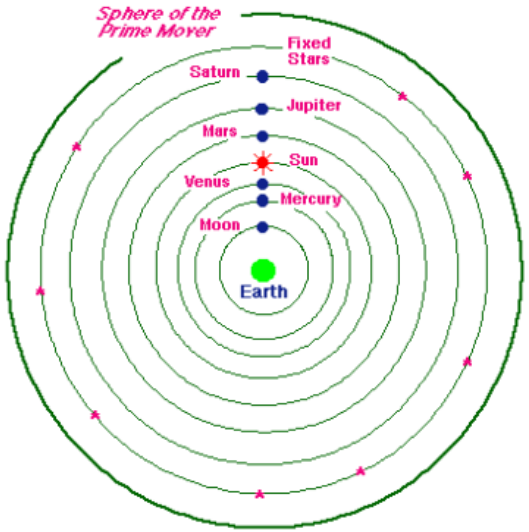
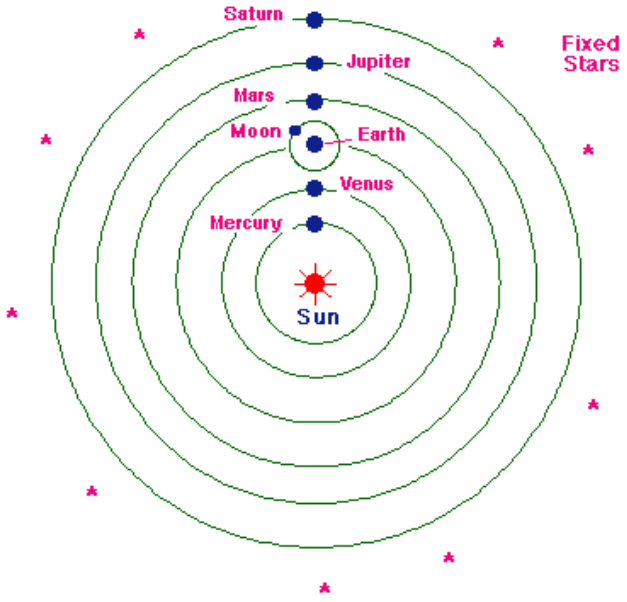
EVALUATION
Discussion Forum Summary





Paradigm Shift



Conflict of Interest

- Foley Hoag, my employer:
  - Supports Coalition for 21st Century Medicine
  - Numerous clients in LDT, IVD, pharma, biotech, association, and patented and non patented spaces, while working frequently with both CMS and FDA agencies.
- My presentation now:
  - Strategy consultant approach from a content knowledge, microeconomics, and business strategy perspective

Genome-Based Diagnostics: Clarifying Pathways to Clinical Use

Workshop Summary

November 15, 2011

Important Points Highlighted by the Individual Speakers

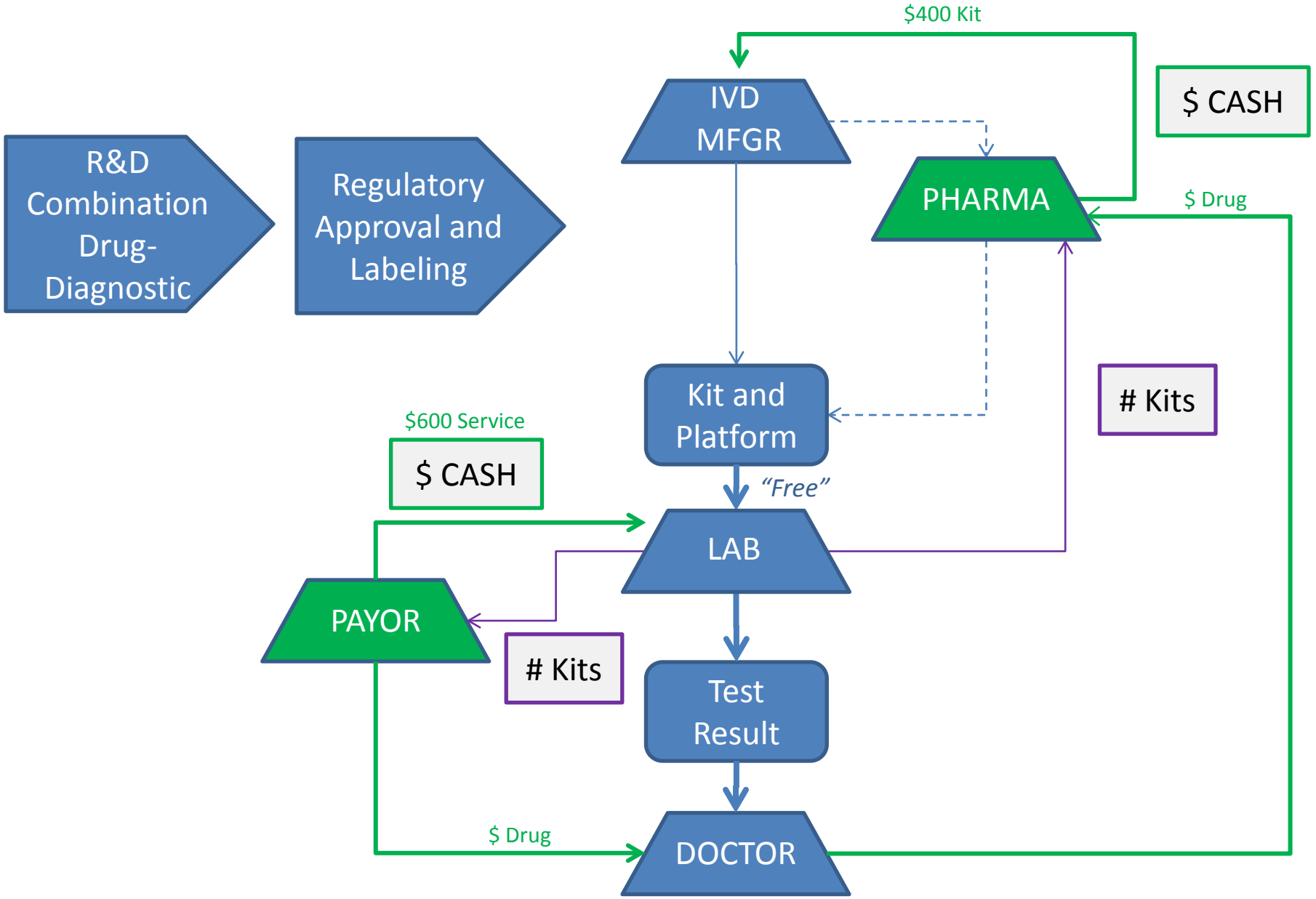
- The undervaluation of tumor biomarkers reduces the use of diagnostic tests as well as incentives to develop evidence about their effectiveness.
- Eliminating the LDT pathway and submitting all genomic tests to a rigorous regulatory process could result in the generation of high-quality evidence regarding the analytical validity and clinical utility of all such tests.
- Venture capital companies are no longer investing in the development of molecular diagnostic tests because of the complexity in and lack of clarity for both regulatory and reimbursement pathways.
- A predictable and efficient pathway, not necessarily an easier one, from regulatory approval to reimbursement could help attract further venture capital investment in this space.
- Standards for molecular diagnostics could help establish widely accepted regulatory and reimbursement pathways that test developers can follow.

While reflecting their own viewpoints, two speakers framed much of the day's discussion. Daniel Hayes, from the University of Michigan Comprehensive Cancer Center, challenged the workshop participants to consider a system in which all genomic diagnostic tests are approved through FDA rather than going through the LDT pathway. Sue Siegel, with the venture capital firm Mohr Davidow, said that venture capital companies are no longer investing in life sciences and health care, including molecular diagnostics, because of a lack of regulatory and reimbursement clarity. Both speakers called for major changes in the regulation of genomic diagnostic tests to ensure that the field continues to move forward.

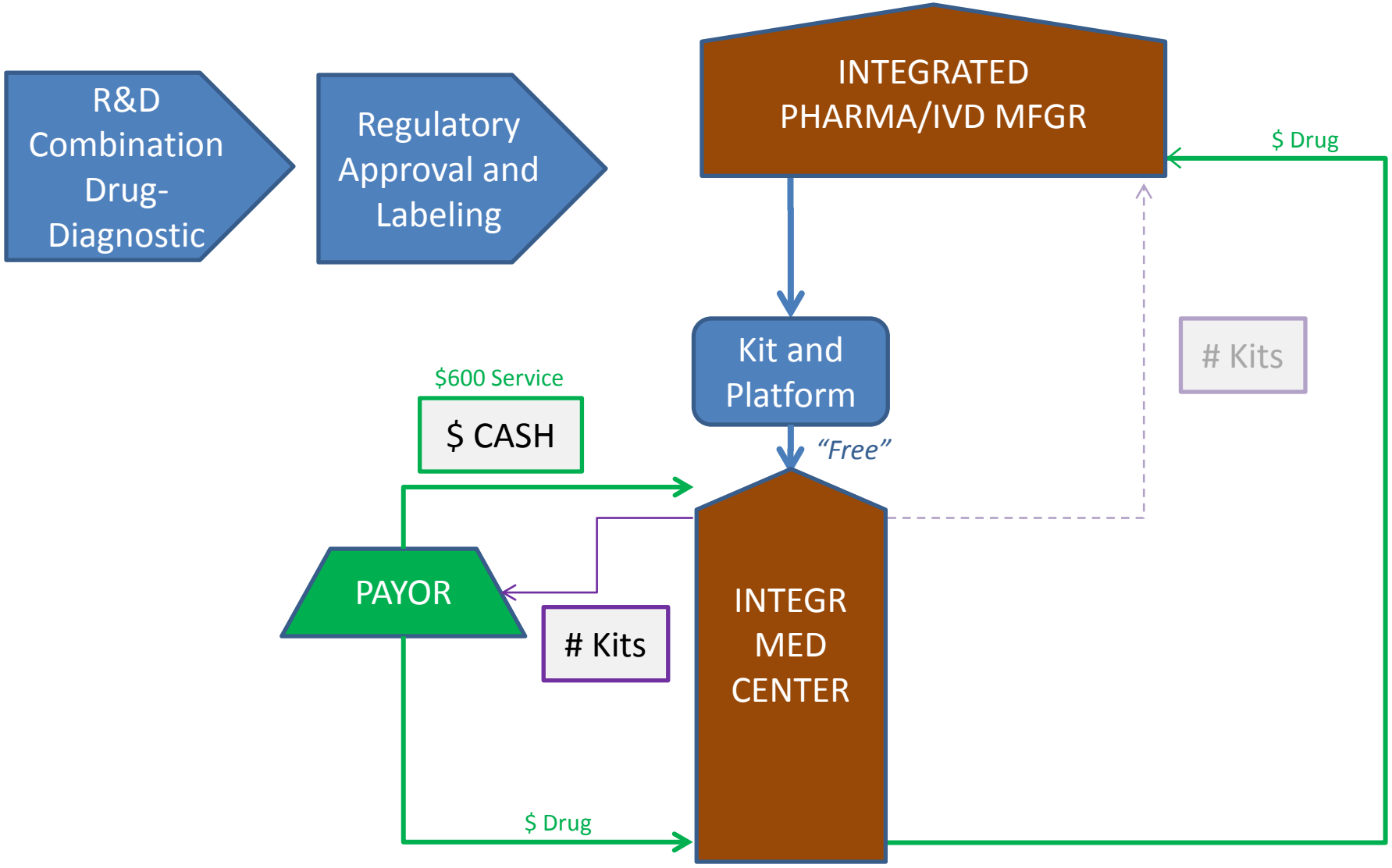
A CONSOLIDATED SYSTEM OF REVIEW AND APPROVAL FOR GENOMIC DIAGNOSTIC TESTS

Similarly:
NCCN Summit,
July 14, 2011
bit.ly/WfzjZN

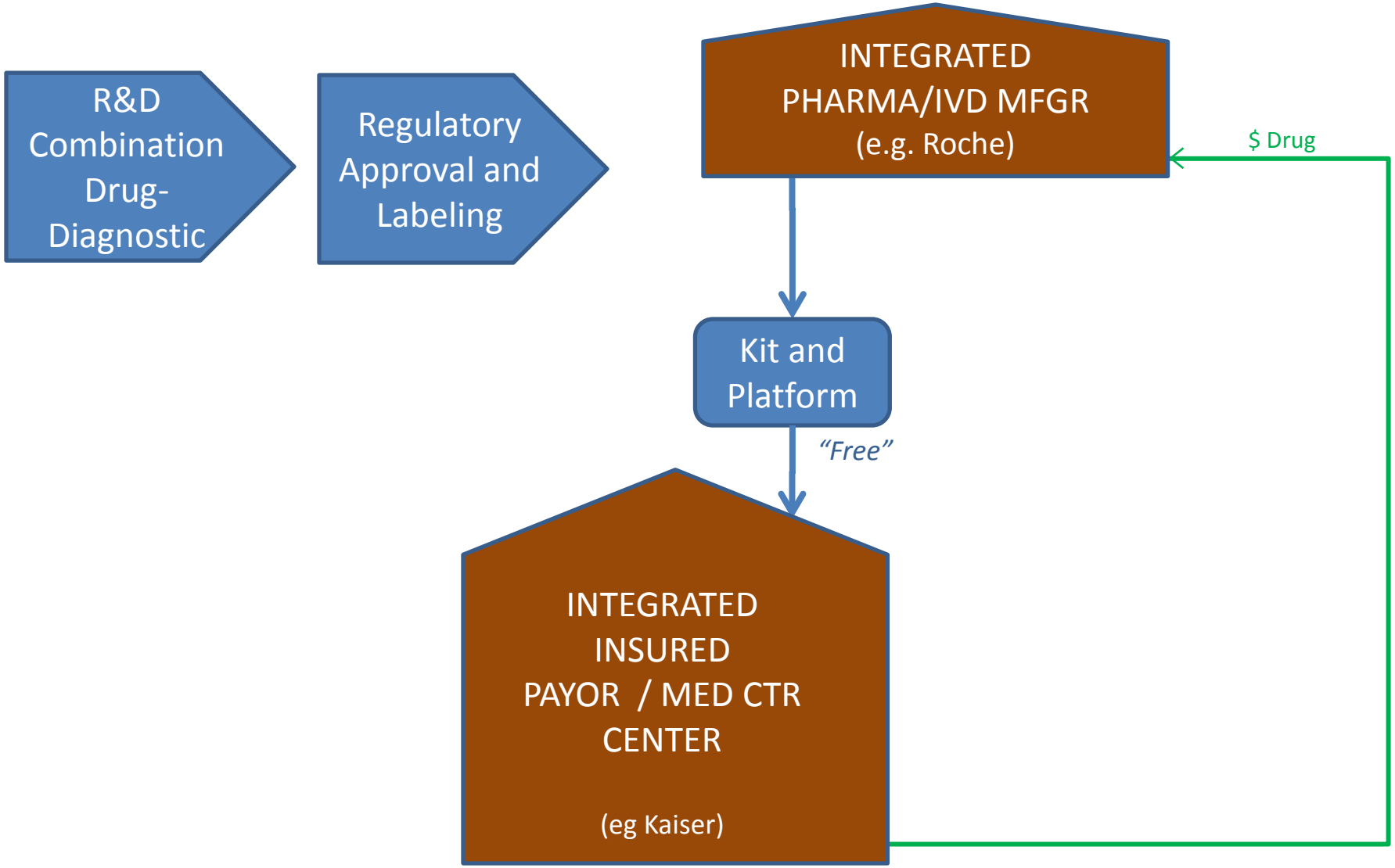
Discussion Model



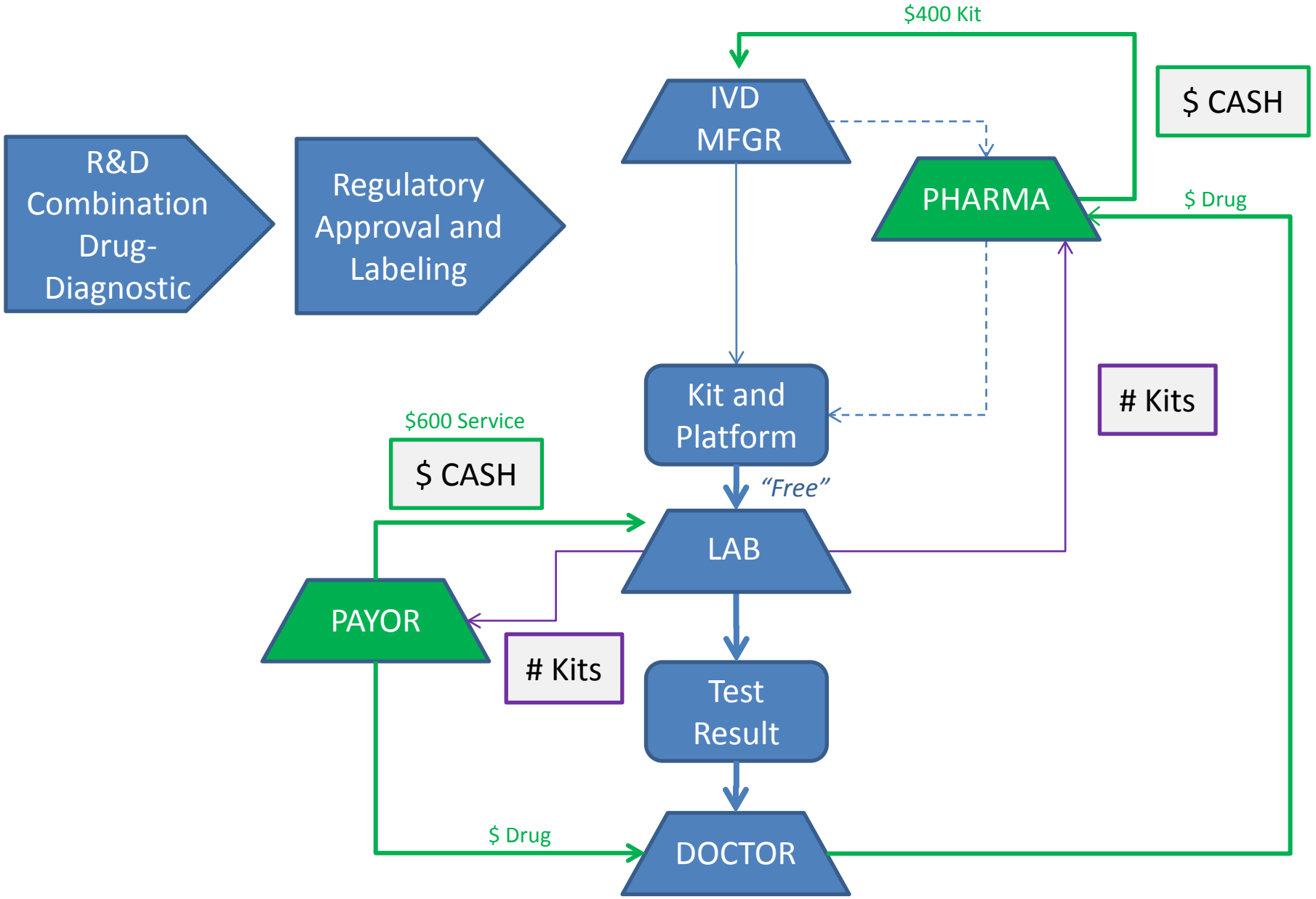
Discussion Model



Discussion Model



Discussion Model

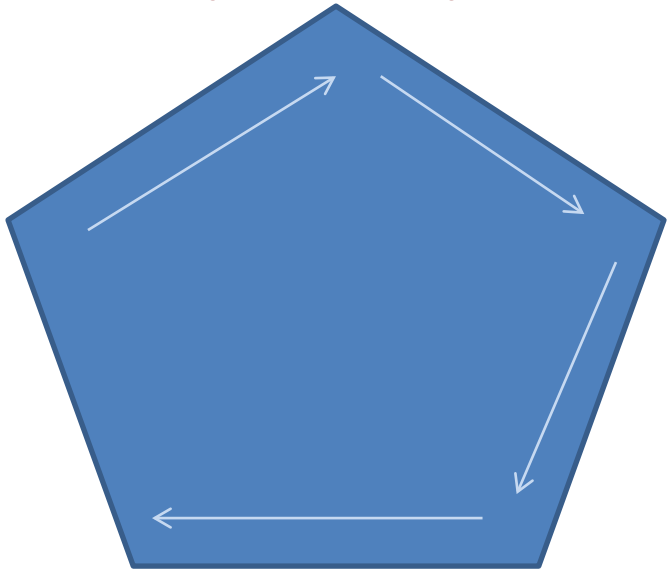


Topic	Issue	Observation
Assuming a goal ***<u>to enforce IVD use</u>***, will this work?	**What prevents the lab from doing any LDT?**	It is only being paid a service fee, inadequate to pay for test (chemicals).
	Can the payor institute this system unilaterally? ***{what is the locus of control? Law? Contract?}***	No. The payor could pay just $600, but the lab requires the IVD to be supplied elsewhere.
	Can the payor and lab collude to provide the LDT?	No, in that, they have only $600 to work with.
	Potential issues with "free goods" being transferred.	See prior "Legal" talk (B Thompson)
Unclear Viability when…	• Already a generic drug - OR - Drug goes generic • Test must be provided to 10 patients per treated patient • A population-limited test is provided but NOT by the drug mfgr	
To enforce IVD use, **are there other methods?**	Yes, at least two: • (1) Through federal action, make LDT illegal • (2) Through CPT reform: Payor requires IVD use by other means, codes, contracts. (No pharma action required) • *If you <u>wanted</u> to enforce IDE, coding reform is vastly less cumbersome and disruptive.*	
Is the **goa**l to enforce an **IVD Monopoly sound?**	• Allows IVD Mfgr to raise price of IVD; pharma & payer have no alternative (no BATNA) • Does not resolve tissue supply problems (eg Lung Ca FNA) • No incentive for competitors to enter, better product • No workaround for major scientific change in timely fashion *(before FDA) (Might not apply then – but, who would decide? Locus of control issue again.)*	
What about **"Super CLIA"** or MOLDX or other HTA?	• Does **<u>not</u>** resolve copycat and ROI problem for IVD MFgr who went through FDA, one of the <u>core</u> issues presented. New locus of control issues. • For <u>some</u> issues (e.g. "correct" discriminatory sensitivity of a Herceptest) LDT model is challenging – the "<u>it's just an analyte</u>" dogma just <u>isn't</u> always that simple at all.	

Five-Way "Dilemma-Addressing" Thought Experiment

LDT Pays Royalty
(ROI Criteria)

FDA Approves IDE Under Stringent Evaluation
("Efficacy" Criteria)



..and LDT May Be Multiplexed
(Tissue Shortage Criteria)

Payer Requires All other Criteria To be met
(Locus of Control Criteria)

Some Indp't Entity Reviews Performance
(Third Party Quality Criteria) *

- This could be FDA but could be outsourced to CAP, USDiagnosticsStandards, Other Institute, etc.
- FDA and payers and society allow as a type of "efficacy v s effectiveness" issue…. "good enough" review for "effectiveness" stringent review for "efficacy."