

Stakeholder: Patient Problems with CDx

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Patients are 'clinical start' users
(not 'end users')

Response to Proposed Solutions

- **C21CM:** Agree with clinical utility and evidence standards
- **ACLA:** Not sure it gets to the critical issues
- **AdvaMed:** Agree with risk based approach
- **CAP:** Not sure is presents a reasonable biz dev pathway, results repository is good – transparency; but what incentive?
- **Individual:** Solves distal problem, but not the value of diagnostics
- **ASCO:** Understanding, certainty and coordination

Patient Experience

- Provider doesn't have clear sense of what is useful
 - Over-treatment
 - Inapp treatment
 - Lack of treatment
- Lack of clarity over what is covered by insurance and battles ensue
- Inappropriate patient demand, appropriate demand

Real Problems

- Reward to understand disease is low – how to incentivize this?
- Who will be the enforcer of outcomes – or even utility?? In other industries, consumer is more empowered to do this.
- All stakeholders (including patients) make decisions that are disconnected from the consequences: this is a moral hazard

We are sick, we are payers, we are regulators, we are innovators

Solutions

- This is an interim problem – once we understand disease, there is no need for CDx (Kalydeco)
- Learning healthcare system – patients reporting back - collect data for outcomes
- Transparency on performance of tests, data sharing on what has worked in the clinic – lost time and money
- All stakeholders need to contribute to a new paradigm that everyone is afraid of – because there will be new value chains and new metrics tied to outcomes. Not biz as usual.

“Proponents of science as a foundation for healthcare have not come together to form a grassroots movement, and until this happens, all of us will have to live with a system built on pseudoscience, greed, myths, lies, fraud and looking the other way.”

Otis Brawley

How We Do Harm: A Doctor Breaks Ranks About
Being Sick In America