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Reforming IVD Regulations:
Necessary or Nuisance?

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DISCLOSURE: Views are my own opinion, but…

- Employee/Advocate for Cepheid, and…
- Member of AdvaMed Dx Task Force
- Member of DTWG
- Member APHL
- Member of AMP, ASM, ACMG
- Former employee of FDA
- Former employee of LOC/CRS
- Am a healthcare consumer
- Have been a caregiver

Observations

- A Lot of devil in details
- Many higher concepts aligned
- Need to agree on terms and definitions; speak same language
- WE NEED YOUR HELP
- Stakeholders need to be active participants: listen, communicate, consider alternatives
- What is equitable, rational, efficient regulation?
- What's the best system for patients?

Tatanka!

Why Regulatory Reform (LDT)?

Necessary

- Regulations are antiquated
- Diagnostics ≠ devices
- It does not make sense to compare to predicates
- System does not adapt well to rapidly evolving technology
- Submission requirements for modifications to tests can be burdensome and costly.
- No efficient or timely mechanism to reclassify tests
- Biforcated regulatory path for the same thing doesn't make sense.

Nuisance

- Existing regulations work
- Already compare to known specimens, reference standards, reference methods
- Need flexibility to modify assays as new scientific information becomes available
- Already subject to multiple regulations, inspections
- Medical services outside of FDA authority
- Developed and performed under supervision of qualified laboratory director

Diagnostic Test Working Group

- Coalition of a few manufacturers and laboratories met end of 2014 and developed a proposal for fundamental regulatory reform
- Began sharing publically in mid-February
- Early March began outreach with AdvaMed, ACLA, E&C and FDA
- Group expanded late March; more aggressive outreach to other stakeholders through April
- In constant contact with FDA, and other stakeholders on clarifying language
- Legislative language expected sometime in June
- Legislative vehicle?
  - 21st Century Cures (2015?)
  - MDUFA (2016)

DTWG Proposal in a nutshell

- **Proposal applies to all IVCT**
- **Allocates responsibility (like activities):**
  - **Test design/development/procedure – FDA**
  - **Laboratory operations – CMS**
  - **Interpretation/consultation – states**
- **Classification: high, moderate, low risk proposed by developer; FDA 60 day option to reject**
- **IVCT moves high-low risk as becomes established**
- **Standard for review: "reasonable assurance of analytical and clinical validity" established through "competent and reliable evidence"**

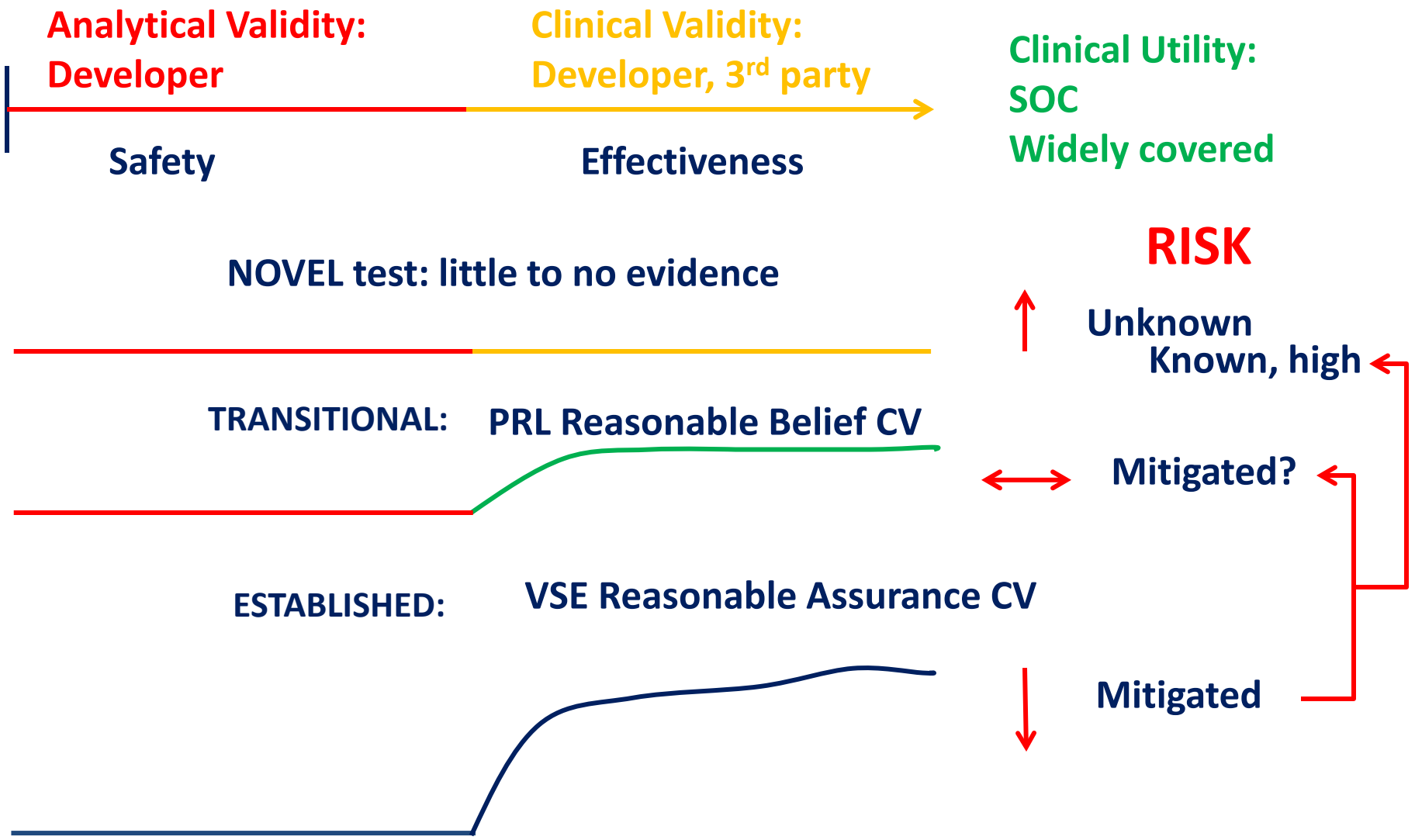
DTWG Proposal in a nutshell

- Special pathways for rare disease, emergency use and unmet needs tests
- Post-market QS and recalls similar to current paradigm, AER tailored to tests
- Instrument platforms Low Risk
- Incentive vouchers for development innovative IVCT
- 3-4 year transition to new system

Big Bucket Issues

- Definitions, e.g., “well-established”
- What is the diagnostic?
- Standard for review: S&E vs A&C V
- Risk Classification process: levels of evidence
- Submissions: what evidence
- Modifications
- QSR/CLIA for production
- New Center for Diagnostics?

FDA: WTF? (What to file)?



Risk Classification: criteria

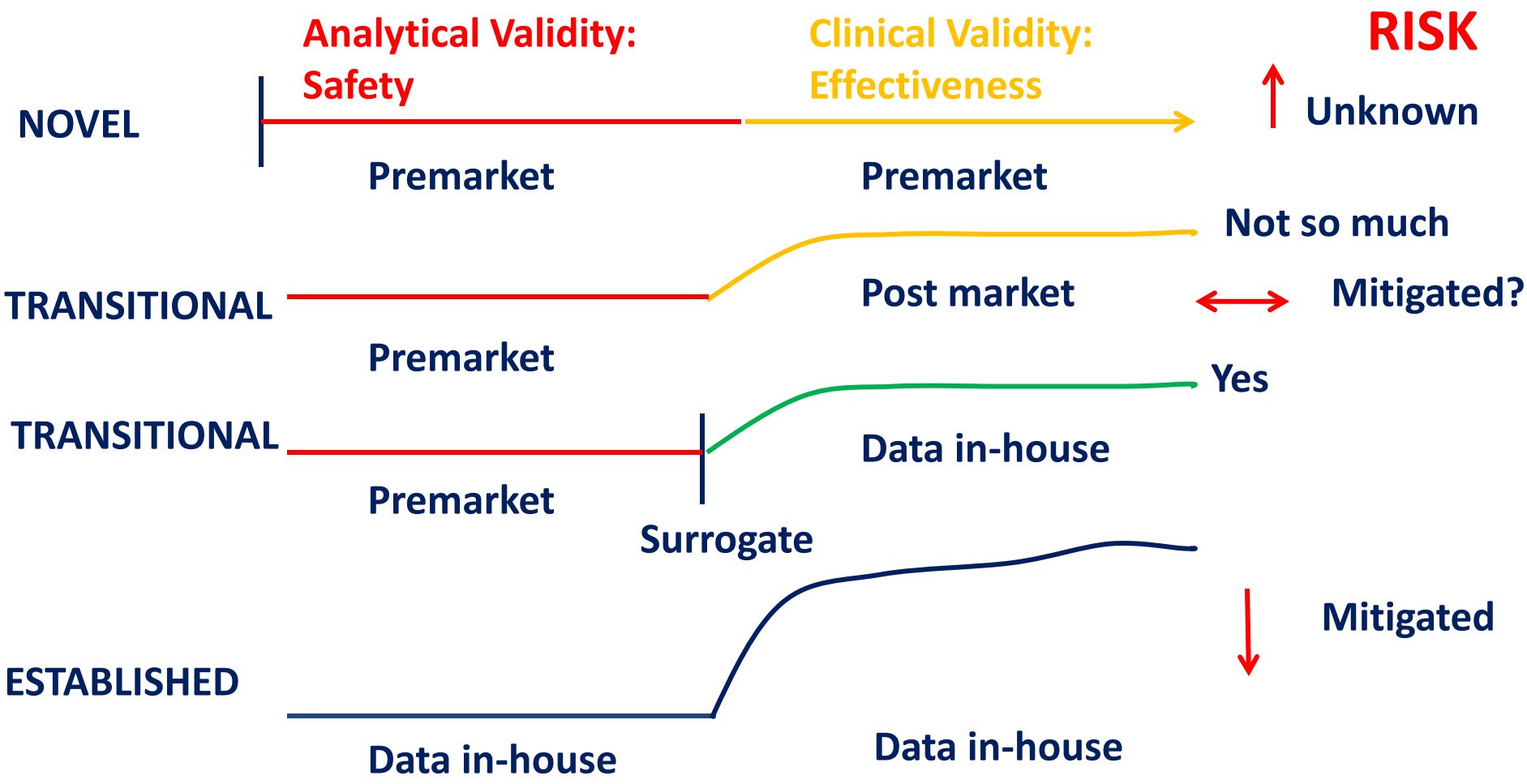
Advamed/Cepheid LDT comment:

- Clinical Use
- Novelty of Analyte
- Novelty of Platform
- Experience of user

DTWG

- Sole determinant
- Clinical use well-characterized
- Technology well-characterized
- Public/patient outcome if wrong result

FDA: W²TF? What/When to file?



How is this different than status quo?

- Recognizes diagnostics as fundamentally different from devices
  - Provides information; are not therapeutic/interventional
  - Medical professional applies the intervention
- New Center?
- No arbitrary classification
  - Use existing evidence to identify data gaps as a means to submission
- No more predicate device
- Give FDA more flexibility for adapting to new evolving technologies and modifications (while protecting developers)
  - Balance pre- post-market submissions and in-house data
- Recognizes that laboratory operations are different from manufacturing operations
- Binding (guidances are not)

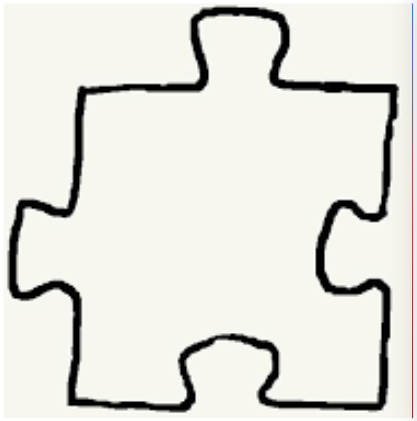
Stakeholders: Call to Action

Manufacturers

Laboratories

Feds (FDA, CMS)

Providers, Patients

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