The VALID Act:

A Proposed Framework for IVD/LDT Regulation in the U.S.

AMDM Annual Meeting ***April 2019***

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- Average Income per year $16,000.00
- Cost of a gallon of Gas $0.59
- The movie “Rocky” with Sylvester Stallone was released
- NASA unveils its first space shuttle, Enterprise
- IBM introduces the first laser printer
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1976

The Problem

- The current U.S. medical device regulatory framework was created over 40 years ago and intended for therapeutic medical devices.
- The same diagnostic test, depending on if it is an IVD or a LDT, is regulated by different federal and state laws.

- **Today's innovative *in vitro* diagnostics (IVDs) require a modern regulatory pathway in order to keep pace with our rapidly advancing global health care system.**

- We must urge the U.S. Congress to pass legislation that:
  1. Regulates all IVDs the same regardless of who develops them;
  2. Is specific to IVDs and not therapeutic devices;
  3. Allows innovative tests to reach people faster while having the flexibility to meet the challenges of tomorrow.

- Development of a modernized, risk-based regulatory framework for IVDs will prevent America from falling behind and ensure U.S. patients have access to the most innovative tests available.

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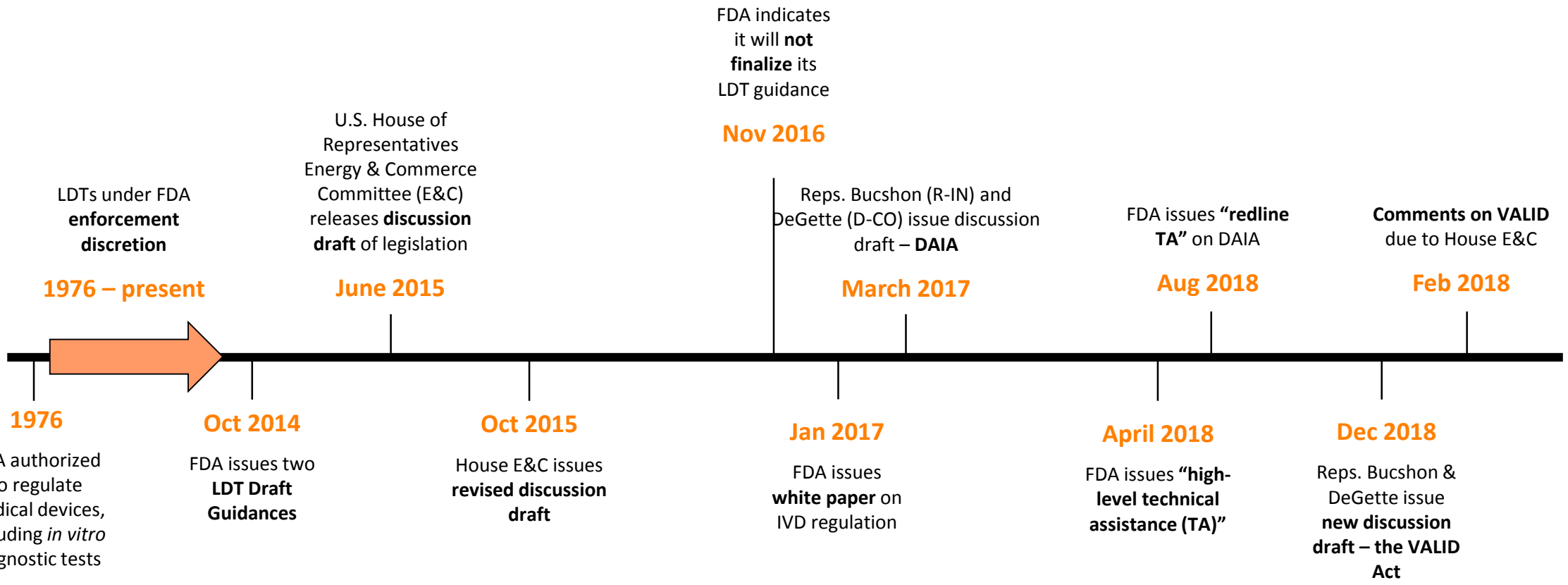
The VALID Act

Verifying Accurate, Leading-edge IVCT Development

- On December 6, 2018, House Energy & Commerce Committee, (Reps. Larry Bucshon (R-IN) and Diana DeGette (D-CO)) released a new discussion draft bill
- Goal is to implement a new, risk-based approach for regulation of both manufactured IVDs and LDTs, collectively known as *in vitro* clinical tests (IVCTs)
- The VALID Act of 2018 adopts key components of the House's previous discussion draft legislation – called the Diagnostic Accuracy and Innovation Act ("DAIA") – and the FDA's August 2018 IVCT regulatory framework proposal.

Background/Timeline
Regulatory Policy and Legislation



Analysis of VALID Act
Policy Provisions - Definitions

- VALID Act is a comprehensive approach for IVD manufacturers and clinical laboratories
- Definitions Requiring Additional Discussion
  - IVCT, analytical validity, clinical validity
  - High risk, low risk
  - First-of-a-kind, cross-referenced
  - Need to clarify test's intended use must be the developer's intended use
  - New terms such as test group

- ❑ Establish a **comprehensive, reasonable, and risk-based framework** for both manufacturers and the lab community
- ❑ Regulate the same activity the same way, regardless of where the test is developed
- ❑ Regulate *in vitro* diagnostics as a standalone category -- separately from medical devices
- ❑ Use analytical validity and clinical validity as the review standard

Analysis of VALID Act
Policy Provisions – Regulation Consistency

- Applies requirements to both IVDs and LDTs
- VALID permits FDA to exempt some "classes" of entities from regulation while requiring other entities developing the same test to comply with the requirements

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Analysis of VALID Act
Policy Provisions - Devices

- VALID carves IVCTs out of the definition of drug and biologic; uses separate regulatory system from devices; however, several provisions still cite device regulations and authorities

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Analysis of VALID Act
Policy Provisions – Review Standard

- Maintains DAIA standard of analytical validity and clinical validity
- Use of “safety” only in relation to specimen collection devices

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Analysis of VALID Act
Policy Provisions - Classification

- VALID moves to a “no classification” system – IVCTs require review, no review, or are eligible for precertification
- “Focus is on where FDA review can add value”
- Premarket review for high-risk tests and possibly low-risk tests, unless specifically exempted by FDA or eligible for precertification
- Creates exemptions for certain IVCTs
  - Including grandfathered LDTs, rare disease, custom, and low-volume tests
- Creates automatic review for certain IVCTS

- ❑ Clear, transparent three-class system, based on the **intended use and risk to patients**
- ❑ Independent analysis of accessories and platforms
- ❑ Streamline modification processes, requiring submission only if modification changes intended use or has a meaningful clinical impact
- ❑ Tailor new systems and processes to IVCTs to promote timely availability and access to innovative tests

Analysis of VALID Act
Policy Provisions - Classification

- Pathway for review needs additional clarity, consistency
  - There appears to be considerable subjectivity in definitions of high and low risk

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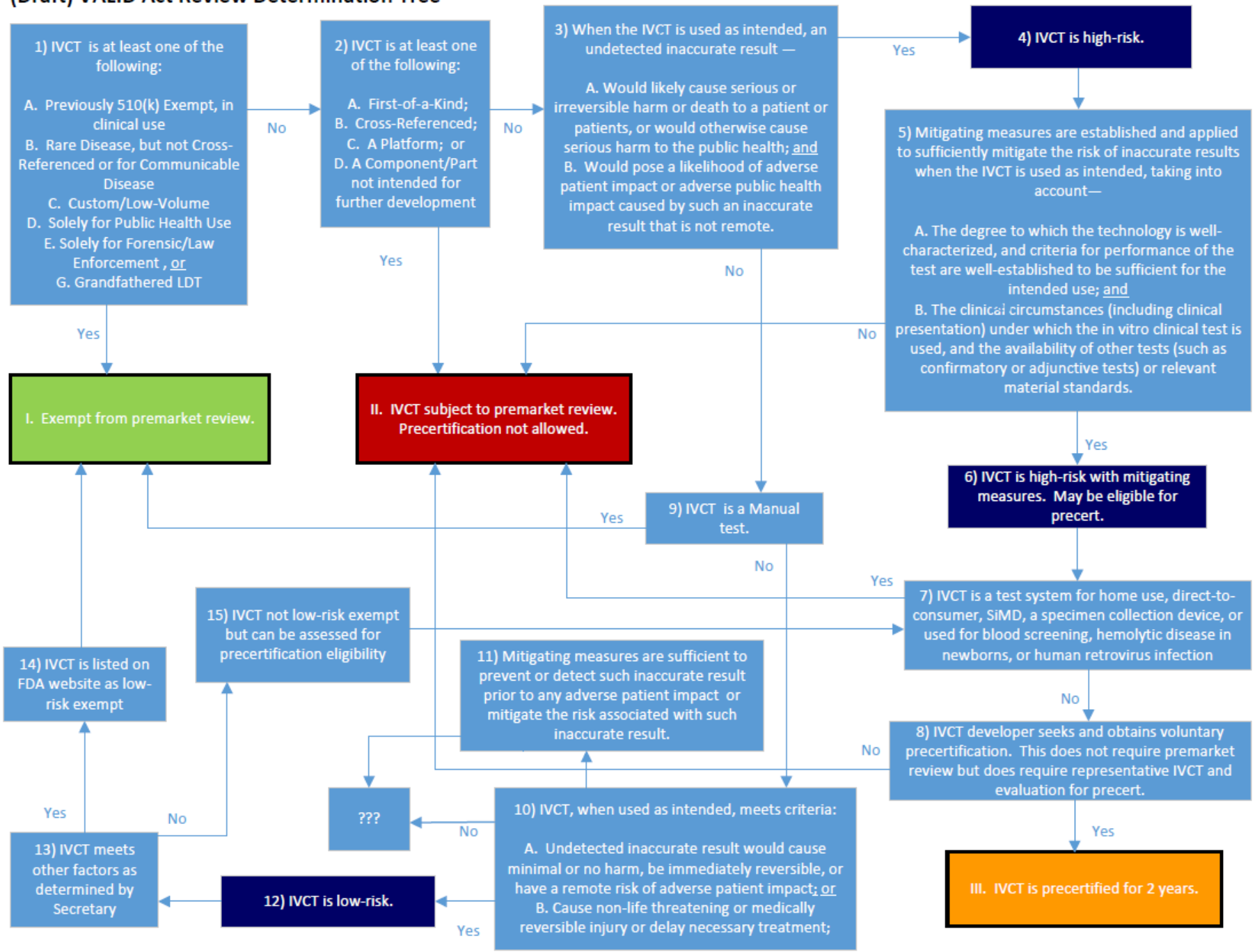
(Draft) VALID Act Review Determination Tree



Analysis of VALID Act
Policy Provisions – Systems Approach

- VALID continues to take a “test systems approach”
- Directly regulates many components and parts, including through premarket requirements
- VALID requires only analytical validity for platforms, but requires they be reviewed by FDA

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Analysis of VALID Act
Policy Provisions

- Incorporates “change protocol” concept
- VALID requires submission of modifications for a much broader scope of changes

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Analysis of VALID Act
Policy Provisions

- VALID may intend for less tailored quality systems than envisioned under DAIA
- Requires prompt reporting of serious adverse events, and quarterly reporting of other individual adverse events and gives FDA broad authority to require post-market studies

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Analysis of VALID Act
Policy Provisions - Grandfathering

- VALID provides for grandfathering of IVCTs on the market at least 90 days before enactment

- **Implement the new framework in a timely manner**, with appropriate provisions for transitions, grandfathering, and user fees

Analysis of VALID Act
Policy Provisions – Transition, User Fees

- Transition timelines not defined
- Imposes existing device regulations on LDTs first introduced during the transition period, with potential application of new IVCT regulations at some indefinite point in the future
- Includes provisions to ensure that IVCTs on the market do not present a public health risk, but allows FDA discretion
  - Immediately subjects existing LDTs, including grandfathered LDTs, to device authorities upon enactment, at FDA's discretion
- User fees not specified

- ❑ **Implement the new framework in a timely manner**, with appropriate provisions for transitions, grandfathering, and user fees

Analysis of VALID Act
New Policy

- “No classification” approach
- Test group elements establishes intended use and triggers modifications
- Comprehensive test information system serves as online database for public and FDA
- VALID does not include a provisional review pathway
  - Has similar special pathways but does not define “breakthrough” pathway
- Goal to engage with stakeholders but appears intended to eliminate Federal Advisory Committee Act (FACA)
- Administrative law protections may be missing
  - Guidance vs rulemaking

- ❑ **No classification**
- ❑ **Test group drives intended use**
- ❑ **Comprehensive test information system**
- ❑ **Special pathways**
- ❑ **Collaborative communities**

Analysis of VALID Act
New Policy

- VALID incorporates FDA proposal for precertification program for IVCTs
  - Precertification shifts focus from product approach to a process or organization
  - Essentially captures tests that could be “moderate risk”
  - Excludes certain IVCTs, such as home use and direct-to-consumer

❑ **Precertification for IVCTs**

Summary

- VALID represents a positive step forward in efforts to pass comprehensive diagnostics reform
- Changes are needed but should be able to be addressed through the stakeholder process
- We need a modern, risk-based regulatory pathway for IVDs that will allow us to address the demands of our global health care system.
- We must work together to urge Congress to pass legislation that:
    1. Regulates all IVDs the same regardless of who develops them;
    2. Is specific to IVDs and not therapeutic devices;
    3. Allows innovative tests to reach people faster while having the flexibility to meet the challenges of tomorrow.
- Only a modernized regulatory framework can provide American patients the access they deserve to the world's most innovative, high-quality IVDs.

Questions