

**Draft Guidance for Industry and FDA Staff -  
Commercially Distributed In Vitro Diagnostic  
Products Labeled for Research Use Only or  
Investigational Use Only: Frequently Asked Questions**



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# Summary of FDA Guidance Document

*Due to the circumstances related to RUOs, the FDA released a guidance with recommendations on how to label these tests for their intended purposes*

## OVERVIEW OF FDA GUIDANCE DOCUMENT

*FDA recently released a guidance document<sup>‡</sup> reminding manufacturers of the requirements applicable to RUO and IUO IVDs. The aim is to control the clinical diagnostic use of IVDs to prevent misinformed clinical decisions that may lead to adverse patient health consequences. The document is not legally enforceable; however, they represent suggestions on labeling and marketing these tests by the FDA.*



### GUIDANCE ON RUO/IUO LABELING

- Appropriate RUO labeling refers to IVD use for research intended to evaluate the test itself or in non-clinical laboratory research. These tests are inappropriate for use in diagnostic procedures.
- Appropriate IUO labeling refers to the use of IVDs in an investigation, but it is not to be used for clinical diagnosis without confirmation from another established product or procedure.

### GUIDANCE ON RUO/IUO MARKETING

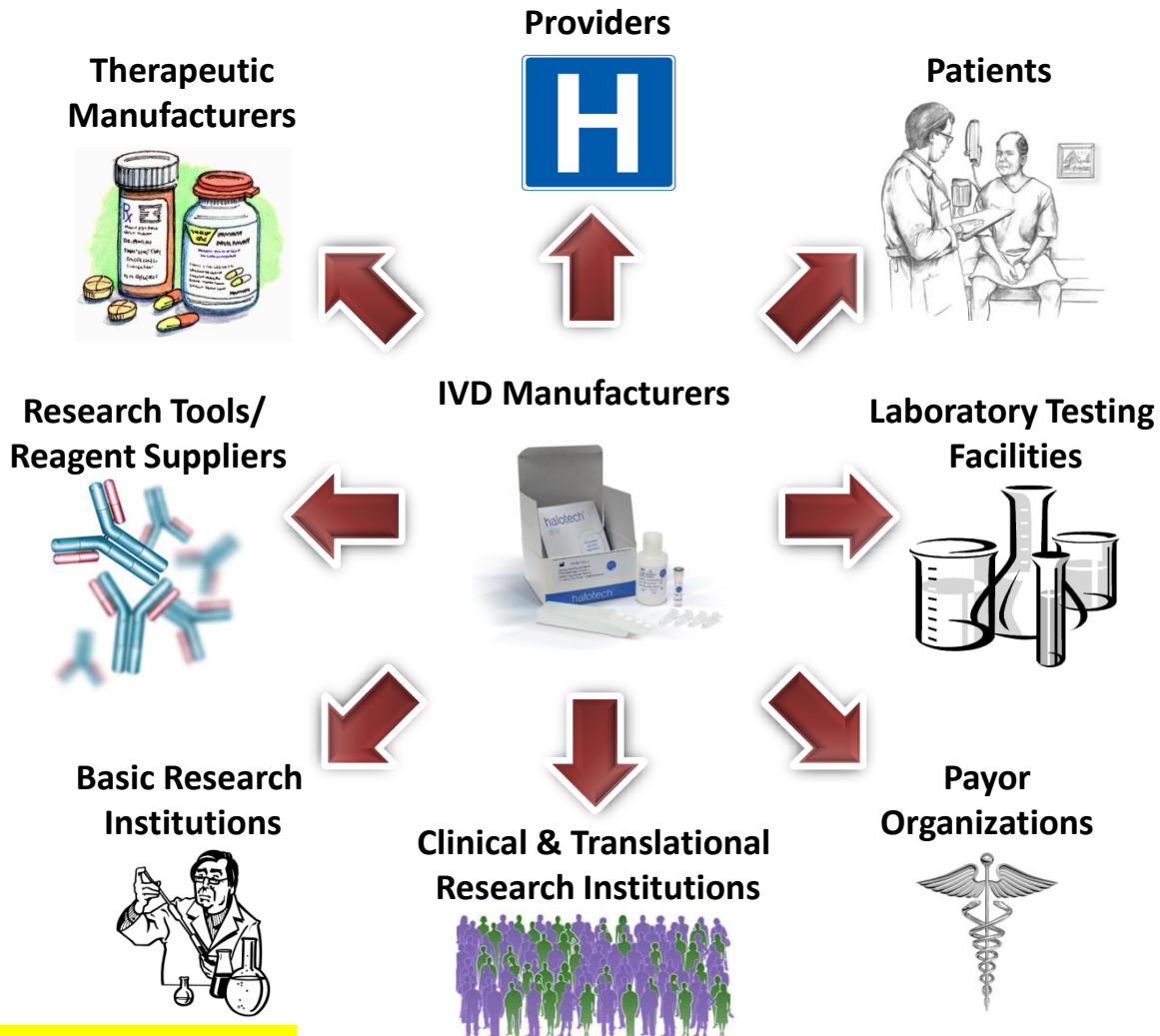
- Advertising, promotion, support or sales of RUO IVD for use in clinical investigation, clinical diagnostic use, or for LDT development meant for clinical diagnosis conflicts with the intended use of an IVD labeled RUO
- Advertising, promotion, support, or sales of IUO IVD for use in non-investigational diagnosis, or use that is inconsistent with an exempt investigation conflicts with the intended use of an IVD labeled IUO

Notes: RUO- Research Use Only; IUO – Investigational Use Only; <sup>‡</sup>Draft guidance released on June 1<sup>st</sup>, 2011 titled “Draft Guidance for Industry and FDA Staff - Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions.”

# Stakeholders Involved with RUO & IUO IVDs

RUO and IUO IVDs are used by several stakeholders in various capacities

## KEY STAKEHOLDERS INVOLVED WITH RUOs / IUOs



## KEY TAKEAWAYS

- The use of RUOs and IUO involve several stakeholders during and after test development
- These tests are used in a variety of settings for multiple purposes, including:
  - Basic research
  - Clinical research trials
  - Development of lab tests
  - Use in therapeutic manufacturing and development
  - Use in the provider setting
- How these tests are regulated going forward will impact these stakeholders, some more dramatically than others

FIGURE # 2

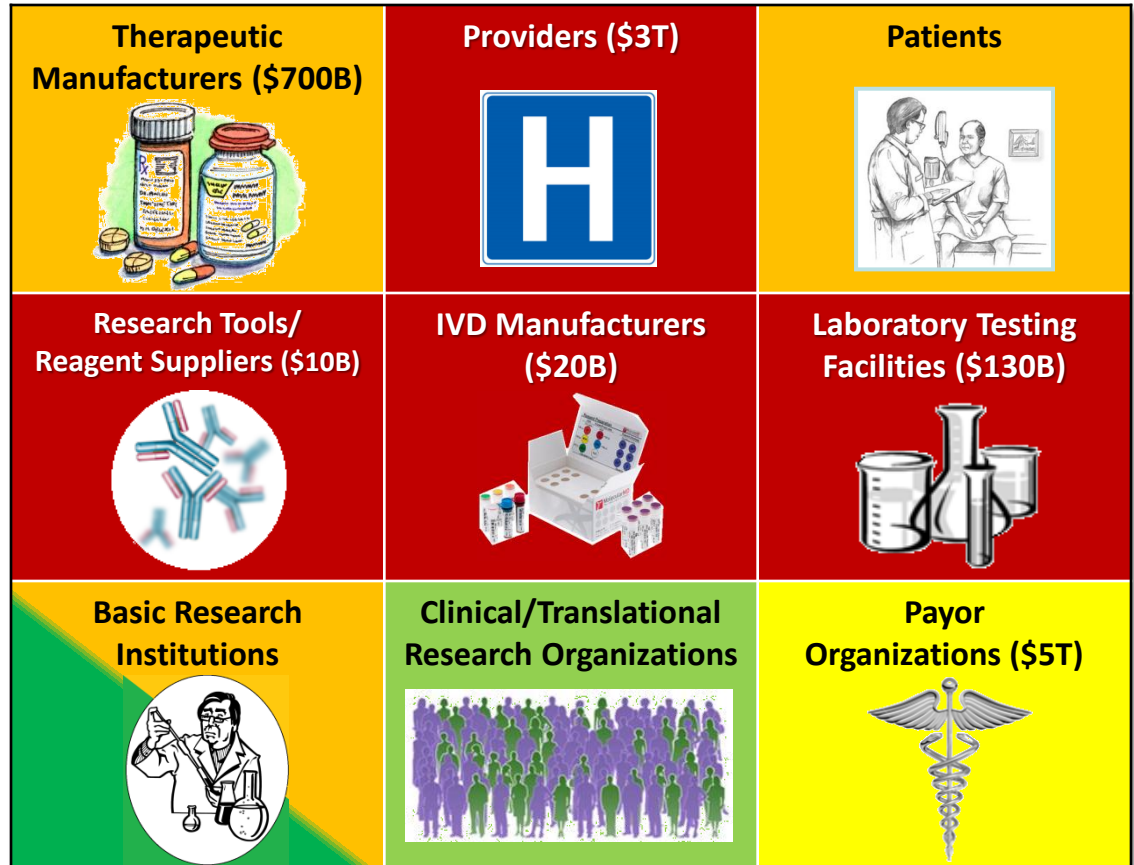
# Sectors Impacted by the FDA Draft Guidance

Because of the FDA guidance with recommendations on how to label and market these reagents/test for their intended purposes

## DIAGNOSTIC COMPANIES AND MANUFACTURERS

Examples, not a complete list...

- Abbott Diagnostics, Inc.
- Affymetrix, Inc
- Agilent, Inc.
- BD, Inc.
- Gen-Probe, Inc.
- Genomic Health, Inc.
- Illumina, Inc.
- LIFE Technologies, Inc.
- Luminex, Inc.
- Promega, Inc.
- Qiagen, Inc.
- Thermo-Fisher, Inc.
- Roche Diagnostics, Inc.



LEVEL OF IMPACT: LOW

HIGH

FIGURE # 3

Notes: (\$) in chart represents respective market size

Source: Scientia analysis

# Clinical Care Will Be Impacted by the Guidance

*Because of the broad impact on laboratory developed tests and manufacturers*

## PHYSICIANS / LABORATORIANS / PATIENTS

Question: Is this an encroachment on the practice of medicine by the FDA?

One concern about this guidance from the FDA is that it targets manufacturers of reagents, rather than test manufacturers directly, according to CAP Board Member Paul Valenstein, MD, a practicing pathologist in Michigan.

The draft guidance makes reagent manufacturers responsible for evaluating and monitoring the activities of their customers. Dr. Valenstein believes this is ill-advised, adding that in the pharmaceutical world, drug companies are not held accountable for off-label use of medications by individual physicians, provided that the companies do not promote off-label use.

Finally, Dr. Valenstein believes that removing IUO and RUO reagents from Laboratory Developed Tests (LDTs) will have a negative impact on patient care. “There are IUO and RUO reagents that are essential components of generally accepted LDTs and for which no reasonable FDA-cleared substitute is available,” he said. “Medical care will be disrupted if IUOs and RUOs cannot be used in properly-validated LDTs.”

# Understanding the Implications to Your Business

*Crafting appropriate strategies and solutions to navigate through them*

ScientiaAdvisors



***Scientia understands the market dynamics and where you play in the enterprise***



***Scientia can help you understand the potential impact, risks, and opportunities***



***... and help you develop strategic business solutions to manage change.***