

HOUSE DISCUSSION DRAFT RELEASED ON REGULATORY APPROACH FOR IN VITRO CLINICAL TESTS

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House Discussion Draft Released on Regulatory Approach for In Vitro Clinical Tests

Written by Elizabeth Guo - Tuesday, April 4, 2017

On March 20, 2017, Rep. Larry Bucshon (R-IN) and Rep. Diana DeGette (D-CO) released a discussion draft of the Diagnostic Accuracy and Innovation Act (DAIA). DAIA would regulate “in vitro clinical tests,” defined in the discussion draft as a “laboratory test protocol or finished product” intended for clinical use “in the collection, preparation, analysis, or in vitro clinical examination” of human specimens for the purpose of “identifying, screening, measuring, detecting, predicting, monitoring, or assisting in selecting treatment for a disease or other condition.” According to Rep. Bucshon, DAIA is intended to establish a “flexible, risk-based approach” to regulation of IVCTs.

The following are some of the highlights from the discussion draft of DAIA:

Establishes a Regulatory Framework for IVCTs: DAIA would authorize FDA to review the “design, development, validation, production, manufacture, preparation, assembly, and modification” of IVCTs, but would not give FDA authority to regulate “laboratory operations” under the Clinical Laboratory Improvement Amendments (CLIA). DAIA would remove IVCTs from the definition of a device. The draft would create a new Center for In Vitro Clinical Tests within FDA responsible for reviewing and ensuring that IVCTs demonstrate “reasonable assurance of the analytical validity or clinical validity” for their intended use.

Risk Classification of IVCTs: DAIA proposes three risk classifications for IVCTs based on an IVCT's intended use.

- **High-risk IVCTs** are those that would cause “serious or irreversible harm, prolonged disability, or death to a patient or public” based on a clinically significant inaccurate result; have no factors to mitigate the risk of an inaccurate result; and the risk of adverse impact is not remote.
- **Moderate-risk IVCTs** are those that have mitigating factors for an otherwise high-risk test; or would cause non-life threatening injury, medically reversible injury, or a delay in medical treatment based on an inaccurate result, have no factors to mitigate the risk of an inaccurate result, and the risk of adverse impact is not remote.
- **Low-risk IVCTs** are those that have mitigating factors for an otherwise moderate-risk test; have minimal or no harm from an inaccurate result; or the risk to patients is remote.
- **Premarket Review Based on IVCT Risk**
Classification: DAIA would require FDA to approve an IVCT based on the IVCT's level of risk.
- **High-Risk IVCTs:** A sponsor would need to submit an application with evidence to demonstrate with “reasonable assurance” that the IVCT is analytically and clinically valid. FDA is required to approve or disapprove the application within 120 days after submission.
- **Moderate-Risk IVCTs:** A sponsor would need to submit an application with summary evidence to demonstrate with “reasonable assurance” that the IVCT is analytically and clinically

valid. FDA is required to approve or disapprove the application in 75 days after submission. The draft also requires that FDA establish a third-party review process under which third parties may review the IVCT and FDA could agree or disagree with a third-party reviewer's conclusion

- **Low-Risk IVCTs:** A sponsor would need to list the IVCT and its intended use within 10 days after a sponsor offers the test on the market.
- **Special Pathway for Certain IVCTs:** DAIA provides other pathways to market for qualifying IVCTs.
- **Unmet Need IVCTs and Moderate-Risk IVCTs that Offer a Clinically Significant Advantage:** A sponsor would need to submit summary evidence to demonstrate a reasonable assurance of analytical validity and either reasonable assurance of clinical validity or probable clinical validity. FDA must approve unmet need IVCTs within 30 days and moderate-risk IVCTs within 75 days after submission.
- **Rare Disease IVCTs:** A sponsor would need to list the IVCT and its intended use within 10 days after a sponsor offers the test on the market.

Postmarket Requirements: Sponsors of IVCTs would need to maintain records of and report adverse events related to each IVCT. DAIA would give FDA authority to require a manufacturer to correct or remove an IVCT from the market if FDA finds that there is a "reasonable probability" that an IVCT would cause "serious adverse health consequences or death."

As previously reported, the appropriate framework for oversight of LDTs and the question of whether FDA has authority to regulate LDTs has been the subject of significant debate. After FDA abandoned its effort to finalize its draft guidance documents on regulation of LDTs, the agency released a discussion paper on a possible regulatory approach for laboratory developed tests (LDTs) in January of this year. FDA states in its discussion paper that its risk-based approach reflects the agency's review of the public comments submitted on the draft guidance documents. FDA's discussion paper differs in many respects from the draft guidance documents and also from the DAIA.

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