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114TH CONGRESS
1ST SESSION

H. R. 2443

To amend the Federal Food, Drug, and Cosmetic Act with respect to CLIA waiver study design guidance for in vitro diagnostics.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 2015

Mr. GUTHRIE introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to CLIA waiver study design guidance for in vitro diagnostics.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN VITRO DIAGNOSTICS.

(a) DRAFT REVISED GUIDANCE.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall publish a draft guidance that—

(1) revises section V ''Demonstrating Insignificant Risk of an Erroneous Result—'Accuracy' '' of

the guidance entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices'' and dated January 30, 2008; and

(2) includes guidance on the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services shall finalize the draft guidance published under subsection (a) not later than 12 months after the comment period for such draft guidance closes.

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