

September 7, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20850

To Whom It May Concern:

The following comments are in reference to the Notice of Public Workshop published in the Federal Register on July 21, 2000 (Volume 65, number 141) regarding Medical Devices and CLIA Waiver Criteria. These comments are being submitted on behalf of MEDTOX Scientific, Inc., MEDTOX Laboratories, Inc., and MEDTOX Diagnostics, Inc.

MEDTOX commends the FDA for its effort in gathering additional information from stakeholders in order to effectively implement its new responsibilities regarding CLIA waiver test decisions.

As background MEDTOX Scientific, Inc., headquartered in St Paul, Minnesota, is a provider of high quality laboratory testing and on-site/ point-of-care testing devices. MEDTOX Diagnostics, Inc., FDA establishment registration number 1050155, develops and manufactures diagnostic devices for quick and economical on-site / point-of-care analysis for drugs of abuse, therapeutic drugs, and agricultural toxins. MEDTOX Laboratories, Inc. is a SAMHSA certified, College of American Pathologist, Forensic Urine Drug Testing accredited laboratory providing employment drug testing and is a high complexity CLIA accredited, College of American Pathologist, Laboratory Accreditation Program accredited laboratory providing esoteric toxicology and occupational health testing services to companies, hospitals, and laboratories nationwide. MEDTOX Laboratories, Inc. maintains all applicable federal, state, and local licenses and permits for both forensic toxicology and clinical laboratory testing. As a provider of laboratory testing services and a manufacturer of on-site / point-of-care devices, MEDTOX is truly a stakeholder and is grateful for the opportunity to comment. Our comments are as follows:

MEDTOX agrees that waived test systems must be simple, easy to use laboratory tests and procedures. For a qualitative test the test system should have the following characteristics:

- Use only direct unprocessed specimens
- Require no specimen manipulation or device assembly before performing the test
- Contain no procedural steps beyond adding sample to a reagent impregnated device
- Require no specimen or device manipulation during the procedure
- Require a well-defined endpoint limited to a negative or non-negative result
- Contain fail-safe mechanism that renders no result or identifies an invalid result when the test system malfunctions

For test systems meeting this level of simplicity, criteria for accuracy requirements should not go beyond the 510(k) requirements. The clinical usefulness of these tests is primarily information only. The lack of complexity of a one-step test with a negative or non-negative endpoint, in itself, yields negligible risk of error or harm to the patient. No additional data beyond the scope of the FDA 510(k) submission should be required to demonstrate equivalent results when either lay users or laboratory professionals perform the test.

Test systems that are quantitative or go beyond the definition of simple for a qualitative test (42 CFR part 493, September 13, 1995, section 493.7 (b)(2)(i)) may require additional data to substantiate that untrained users performing the test can achieve accurate results with no significant differences when compared to trained users.

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The need for a second confirmatory test should not have an impact on the waiver process. There is no oversight or mechanism in place to ensure the confirmation test is performed. The need for a confirmatory test should be at the discretion of the clinician.

MEDTOX agrees with the current practice that any test system cleared by the FDA for home use be automatically waived under CLIA. We also support the January 31, 2000 change allowing manufacturers to submit pre-market applications for products and requests for complexity categorization under CLIA to one agency, the FDA. Our recommendation is to eliminate redundancy in the pre-market submission process and CLIA categorization process and rely on the 510 (k) for safety, effectiveness, accuracy, and reliability and if the test system meets CLIA criteria for simple and easy, categorize as waived. Again, as the test system becomes more complex, more steps, more user intervention and the clinical usefulness is more than information only, additional criteria may be required or it may not be appropriate to be a waived test. The number of FDA 510(k) cleared one-step assays waiting to be categorized as waived may or may not be significant, however, several one-step devices in this group meet the criteria of simple, accurate, and low risk and should be waived and moved from the "pool" of test systems awaiting categorization.

This concludes our comments. We appreciated the opportunity we had to participate in the public workshop August 14th and 15th, and to subsequently submit comments for consideration. If any additional information or clarification is required, please contact me at spuskas@medtox.com or 651-636-7466.

Sincerely,



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