



Community Anti-Drug Coalitions of America

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February 9, 2004

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20850

Re: Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests – Draft Guidance

To Whom It May Concern:

As Chairman and Chief Executive Officer of Community Anti-Drug Coalitions of America (CADCA), I have had years of experience working to help our members make their communities safe, healthy and drug-free. Having been recently apprised of the above mentioned draft guidance for industry and FDA staff, I found it necessary to provide comment on this guidance.

As proposed, this guidance would remove the single most important safeguard available for drug screening tests: bundled GC/MS confirmation. Further, this guidance removes all distinction between a certified technologist and an anxious parent, or between a screening device capable of no better than approximately 95% accuracy and GC/MS testing with accuracy approaching 100%. As proposed, the FDA intends to integrate occasional test settings such as home testing and repetitive test settings such as sports, schools, insurance and rehabilitation centers. I respectfully disagree with this.

I do not feel that cautionary labeling is a viable substitute for GC/MS confirmation. You state “Labeling and other performance controls may help mitigate the risk of inaccurate or unreliable results and may do so at less cost to the manufacturer and consumer.” The result of a false positive test has significant adverse potential costs where school, sports, insurance and employment are concerned. Where mandated, drug screening must be undertaken only when it is both safe and effective. Parents and their children, employers, employees, students, and indeed everyone involved in the screening process, have the right to expect it to be so. I believe that implementation of this guidance will undermine drug screening as a preventative/deterrent methodology, leading to serious consequences where inaccurate results go unconfirmed.

I am in opposition to this guidance as it pertains to the omission of GC/MS testing in Workplace and OTC drug of abuse tests. These tests can and will be performed by individuals inexperienced in diagnostic test performance and interpretation, utilizing screening devices

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which do not offer the accuracy necessary to guarantee both safe and effective application. I believe that implementation of this guidance will undermine drug screening as a preventative/deterrent tool thereby diminishing our efforts to reduce the demand for drugs in America's communities.

Sincerely,

A handwritten signature in black ink, appearing to read "Arthur I. Dean". The signature is stylized with a large initial "A" and a long horizontal stroke extending to the right.

Arthur I. Dean
Major General, U.S. Army, Retired
Chairman and CEO