



## American Academy of Family Physicians

2021 Massachusetts Avenue, N.W., Washington, DC 20036-1011

October 16, 2000

The Honorable Jane Henney, MD  
 Commissioner  
 Food and Drug Administration  
 Dockets Management Branch (HFA-305)  
 5630 Fishers Lane, Rm. 1061  
 Rockville, MD 20850

Dear Dr. Henney:

The American Academy of Family Physicians, the national specialty medical specialty organization representing 89,400 family physicians, residents and medical students, appreciates the opportunity to comment on the Food and Drug Administration's (FDA) review of criteria used to determine waived test status.

The Academy strongly opposes further restrictions on the waiver category. While the AAFP signed onto an August 11 letter to the agency, along with fifteen other medical specialty organizations, stating this position, we wish to offer the following additional comments.

### Background

It should come as no surprise that the least restrictive testing categories under the Clinical Laboratory Improvement Amendments (CLIA) - waived and provider performed microscopy procedures (PPMP) - have proliferated among laboratories in the country since the passage of this law. Of the 171,000 labs registered under CLIA, 74% have waived or PPMP certificates. While physicians struggled initially under the restrictive regulations of the moderate/high complexity category, many ultimately scaled back their labs. In contrast to the moderate/high complexity requirements, the waived and PPMP categories allowed physicians to provide high quality patient care, yet escape the burdensome requirements and costs of the more restrictive category. Developing more stringent criteria for waived tests would serve to only decrease the opportunity for physicians to successfully diagnose, prescribe, treat and educate their patients in a single office visit. It would also increase the likelihood that patients who have to be tested in a lab will fail to do so, particularly in rural areas, and at risk to their health status.

### New Technologies

In addition, since the passage of CLIA, many new test systems have been developed and subsequently classified as waived, allowing physicians to offer new technologies to patients in their offices. Manufacturers have met the demands of physicians for simple yet accurate test systems while incorporating the very latest technology into these tests. It is neither fair nor economically wise to belatedly change the rules for waived test criteria once the system has been in place and working well. This is particularly true in the absence of outcome data showing harm to patients. Instead of adding additional waiver criteria, we think that the

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FDA should encourage manufacturers to continue researching and developing additional innovative test systems that are appropriate for physicians' offices.

**Need for Education**

Finally, rather than produce more stringent regulations for the waived test criteria, we urge the FDA to design procedures that educate the laboratories and their personnel on the importance of following precisely the manufacturers' instructions. Part of this education should be to investigate educational opportunities that exist already in the marketplace, or to encourage the development of voluntary external quality assurance programs. For example, our organization offers an education program that was designed specifically for the waived or PPMP laboratory, and which includes the opportunity for continuing medical education credit (CME). Assisting laboratories to become better educated on proper testing rather than adding additional regulations should be the primary goal of the FDA.

Thank you for the opportunity to provide comments on this important issue.

Sincerely,



Bruce Bagley, MD  
Board Chair