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October 4, 2000

Docket Management Branch  
HFA-305 Food & Drug Administrative  
Notice of Public Workshop-Dockets-00N-1394  
5630 Fisher Lane, room 1061  
Rockville, MD 20852

Too Whom It May Concern:

I am writing to you about the Public Workshop on Waived Testing. I am a surveyor for the state of Ohio, the Clia Program. I was not able to attend the meeting on August 14-15th. I was involved in a Pilot program for Waived and PpmP Certificate verification of testing.

I would like to share my personnel experience about Waived testing. First, the criteria for manufacturer's to meet the qualification for the Waived Complexity is too lenient. The criteria of simple, accurate as to render likelihood of erroneous results negligible are misleading. The technology must be accurate. There must be no errors. For example, if a urine dip is performed by a consumer and positive results are given. The consumer goes to a physician, who then repeats the test, if, his result is negative. Who is right, if, the patient challenges the physician result. The physician is going to determine user negligible and no reasonable risk of harm, if performed incorrectly. My point is, who is incorrectly performing the test(s). The criteria for manufacturer's must be raised.

I have been in physicians offices where the test are being performed incorrectly. The test kits are expired, no manufacturer's inserts, test kits being used with other manufacturer's reagents, testing staff unaware of time limits for reading tests, incorrectly performing the tests, improper storage of test kits, improper specimen collections and handling and the list goes on. The physician staff, stated, "the training of the testing personnel is insufficient. **The manufacturer's are pushing the product(s) because of the waived status and waived testing is not regulated by an inspector.**" I feel the manufacturer's must provide better training , technical support and easier manufacturer's inserts.

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I have also worked in a hospital lab, which was accredited. I agree whole heartedly with the College of American Pathology, that all testing must have quality control, quality assurance and proficiency testing. On the personnel side, my mother is a diabetic. She did not know, how to use her glucometer. She is a retired teacher. She felt the manufacturer's insert and booklets were very confusing and poorly constructed for home users. My sister, who is a nurse and myself, trained my mother. I explained the correlations between the whole blood results and serum results. Also these glucometer are also technique dependent. A good finger stick is important. These took sometime to make sure she was proficient. There were also some strange results give by the glucometer, in which , the glucometer was check by a laboratory .

My concern is that a product will be released to the consumers that will not have the health benefits that are claimed to be for such devices and we have a Firestone crises on our hands. It is sad in today era of technology we are not proactive. We must have a crises in order to act or provide the best quality of patient care. Patient care must be priority. The price of affecting ones health is priceless.

Sincerely,

A handwritten signature in cursive script that reads "Branetta Bronson-Ross". The signature is written in black ink and is positioned above the printed name.

Branetta Bronson-Ross

HEA 8409

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## State of Ohio

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Return Requested



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