CLIAC SPEECH 09/10/2008

Ms Passment
~~Dr. Turner~~ and committee members Good afternoon.

My Name is Ray Ozmon.

I am a consumer and come before you in the best interest of public safety and patient care.

If the General Public knew that 5000 to 35 thousand patients each year could harmed they would ask our government to form a task force to protect them from such chaos. Well such a disorder does exist in the US and it is know as "Waived Testing is growing more problematic every day. We know the vector. It is the FDA. This CLIAC committee has the power to correct this situation. This CLIAC Committee has a mandate from Congress to advise the FDA on waived testing.

I am a practicing medical technologist and have spent the last ten years as a technical consultant to the staffs of the physician office trying to make the bad situation with waived testing acceptable. I know the potential users of this equipments very well, I have real time, ground level understanding of the challenges to the staffs of the Physicians Office. They have a great deal of problems with the 111 analytes presently approved waived medical devices much less trying to work and/or troubshooting more complex equipment such as CBC and Differential counters.

Public law 100-578 Clinical Laboratory Improvements of 1988, was signed into law because of the reported high incidence of laboratory errors in the clinical laboratories. The law defined waived tests that employ methodologies that are so simple and accurate to render the likelihood of erroneous results neglible or would pose no reasonable risk if the test were performed incorrectly. Let me repeat no reasonable risk if the test were performed incorrectly.

Waived test category means that it is Waived of all normal clinical laboratory quality assurance requirements. There are no personnel standards. Minimal and no quality practices required. No external proficiency testing required and minimal inspection from an outside agency. Quality control is NOT required by the FDA on the most waived tests. Let me repeat that. Quality control is NOT required on most FDA approved Waived tests. Now, the FDA wants you to approve Automated Hematology Devices as Waived tests.

This CLIAC committee and the American public can count on the FDA approving Hematology equipment if you do not specifically say no to the FDA on Waiver for Hematology equipment. I do not have the time to list all of the objection I have with this proposal.

This is a money issue not a medical issue.

Hematology instrumentation is not new technology and any physician who would desire hematology equipment does not need to have this instrumentation waived to use them.

There are three things that will happen if you do not say no to the FDA on this issue. (1) You will increase the shareholder stock values in the hematology manufacturing companies.(2) you will be approving increases in unnecessary laboratory errors in the physician offices.
(3)The present owner of hematology equipment will opt out of the inspection processes and proficiency testing.

CMS/CDC studies in 1999 -2003 raised a number of quality concerns in the waived test arena for the potential for poor quality outcomes. These studies determined that this quality deficit was most likely the result of the high level of staff turn over and inadequate training. These studies were done before the recent avalanche of new waived approved medical devices. They went on to say that, 77% of the then 175,000 labs have no direct oversight.

What is needed badly in the physician offices an alternate test sites is oversight and training of personnel. This is the biggest problem that has been identified by CLIA in their surveys of physician offices and nursing homes.

What is needed is more education, training and more training and education.

I am not a Luddite. I support new technology that would be in the best interest of the public, but not at the expense of quality assurance. I am not anti-technology and support enabling the physician community access to these emerging technologies when they can be shown to provide quality, real time information

What I would hope is that this CLIAC committee would recommend today is that they convene a forum to study the problems and solution with the waived testing.
Ask the FDA not to approve any more waived tests until this committee can meet with the FDA,CDC, Devices Manufactures and the public to make laboratory testing safer for the general public and the health of our nation.

By your silence on this issue you will have approved Hematology Instrumentation as waived.
The decision is yours.
Thank you.

Ray Ozmon
4420 7th Ave NW
Naples, Fl
34119
239-455-7618