

Attention: Louise Magruder HFZ-480

FDA: Panel Hematology and Pathology Device Panel

Concerning: October 22nd and 23rd Meeting on Digital Pathology

Date: October 16, 2009

I am a Board certified physician specializing in anatomic and clinical pathology. I have subspecialty boards in cytopathology and medical microbiology. I am writing in strong support of the significant value whole slide scanned digital imaging already brings to diagnostic medicine and the rapidly developing applications for marked improvement in quality, standardization, and better patient outcomes. I state up front my pathology group is a participant in the Project Pink Study utilizing whole slide scanning for diagnosis of breast cancer.

I have an MD and a PhD from Duke University where I also completed my postgraduate training and fellowship. I have used light and fluorescence microscopes for both clinical and research purposes. I have also used digitized microscopic slides for clinical and research work. In my opinion digitized slides are not equivalent to traditional microscopy, rather they are superior. The use of whole slide digitized microscopic slides in both anatomic and clinical pathology is not new. What are new are the significant improved applications and rapid adoption of whole slide scanned slides in a wide variety of settings for varying reasons.

I was Director of Pathology and Laboratory Medicine for 26 years until Jan 2009 of a complex and large laboratory that provided diagnostic services to one of the largest integrated multihospital healthcare systems in our country. I was and still am an active practicing pathologist performing surgical pathology, cytopathology, and laboratory medicine. Within our system we have a large accredited cancer center and numerous other diagnostic services. We participate in daily educational activities including tumor boards and cancer clinics. We have used digitized microscope slides for years. Also in providing onsite pathology services at several of our hospitals we have use digitized slides for diagnostic help in difficult cases and in circumstances where the expert pathologist was located at a distant site.

The use of digitized microscopic slides for diagnostic purposes is not new and institutions around the world have used it for years. What are new as I mentioned above is faster scanning, higher quality images, and new applications. Just like the computers we used in 2000 were fine the ones we have in 2009 are better. It is important to remember that the microscopes we now use in many ways have not changed in well over a hundred years. They are monocular and binocular with a wide range of objectives and ocular pieces. It is often assumed, incorrectly, that these microscopes, which are used daily around the world, provide the best possible results and lowest risk for patients having diagnostic material examined. In fact from personal observation of microscopes used in scores of laboratories in both the USA and around the world in both clinical and research settings, the knowledge of how to ensure quality outcomes by ensuring the microscopes are properly setup,

aligned, and cleaned is less than adequate. So the microscope tool which we use today is in my opinion a poor substitute for the chance to improve our ability to provide a safer, more standardized and less riskier diagnostic tool for consistent Pathology diagnoses. An analogy from another medical specialty may be apt: just because one is “comfortable” with the long developed use of a knife to perform the surgery does not mean a new technology such as robotics is not better, safer, and produces improved patient outcomes.

One of my primary professional interests is the recognized need, particularly in this age of targeted therapies, to standardize pathologists’ ability to provide consistent, less subjective, diagnoses with added applications to gain more information from the material we examine. In addition there is an increasing shortage of pathologists in non-urban areas and even more of a shortage of pathologists with special expertise, which makes this goal harder to accomplish. This is particularly true in other countries and one of the powerful forces stimulating rapid adoption of whole slide scanned slides. The ability to use whole slide scanned digitized slides already enhances patients and pathologist’s access to assure the right diagnosis and increasingly the right treatment.

There is also the reality of how medical students, pathology training and maintenance of competence for pathologists is done today. Medical students no longer use microscopes in the vast percentage of schools for education in histology, cytology and pathology. They use digitized images, many whole slide scanned. Also when one takes the Board examination in Pathology a not insignificant portion utilizes digitized slides to determine diagnostic abilities. Almost all post-graduate education in Pathology uses digitized slides. The three major Pathology Organizations: CAP/ASCP/and USCAP all use essentially 100 percent digitized slides in their educational courses. In the USA as well as other countries, online CME courses and proficiency testing are widespread and of course use digitized slides.

I want to comment on three more pertinent issues: the misuse of terms primary and secondary or consultative diagnoses, the widespread use of whole slide scanned tissue and cells in basic and clinical research, and finally the reality of its current use as a primary diagnostic tool in the USA and around the world. **The primary diagnosis is the one that results in action being taken by the physician to treat or manage the patient.** This can result from the first person to examine the slide or by “the consultant” or secondary examiner. The whole reason to get a second opinion is because one is unsure of the diagnosis. To separate out and say the first person to examine a slide is limited to a traditional microscope but the second or consultant who actually makes the diagnosis can use either a traditional microscope or digitized images seems hard to justify if ones assumptions are that the traditional microscope is superior.

Next, contract research organizations (CROs) operations use digitized slides, as do clinical groups like the Pediatric Oncology Group to make diagnostic decisions that may result in patients being placed in specific research clinical trials or being treated with certain therapies. Thus to separate out clinical from research

diagnostic activities is in many cases irrelevant as far as individual patients are concerned.

Finally the reality is whole slide scanned digitized images are used daily around the world in diagnostic activities that result in direct patient treatment and/or management. The examples are too numerous to list but I will provide one I just saw within the month. I was at Walter Reed Medical Center and was present when a physician who just returned after six months duty in Iraq as a pathologist gave a lecture on how excellent high quality pathology services were provided in a war zone. One pathologist with many diagnostic challenges. However she had an "OLD" whole slide-scanning device that permitted her to send slides directly and quickly to experts at Walter Reed for diagnosis. The patient could then be managed as rapidly as though they had the expert diagnostic pathologist at their side. She described no incorrect diagnoses, after slides sent and reviewed in the traditional manner.

Thank you for the opportunity to give my personal perspectives on the topic you are deliberating. It is an exciting time for pathologists.

Jared N. Schwartz MD PhD

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