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From: Robert Thompson
To: Moira Hennessey; Tansy Mundon; Wiseman, Ross
Date: Thu, Jun 14, 2007 8:59 AM
Subject: Feedback on Lab testing

Blair Fleming talked to Oscar Howell about our questions. These questions focused on what did EH do after the June 2003 letter about the remaining problems at the EH labs.

Dr. Howell essentially repeated what he told Moira earlier in the day: 1) stopped rotating staff and focused on 2-3 people to improve their technical skills; 2) switched to the semi-automated Ventana system, and 3) concentrated the testing in one area of the facility to reduce risks. Dr. Howell said in response to Dr. Fleming's questions that these improvements were done mainly to address the ER/PR situation. Therefore, the changes were not focused on the other antibodies that were the subject of tests addressed in the letter, or the other types of cancer mentioned in the letter (e.g., prostate). He said that the focus was on ER/PR because there was an index case that converted from negative to positive, which started the ball rolling on everything else, but there was no such index case for other types of tests. However, he notes that the improvements directed toward ER/PR testing would generally cause improvements in other related tests in immunohistochemistry.

These answers give rise to other questions. As the letter pointed out, lab weaknesses related to 5 or 6 tests other than ER/PR, and given the lack of focus on these tests in particular, is it possible that there were unacceptable errors in these other tests that should have been investigated retrospectively? If they had been investigated and an error rate established, then there would be a benchmark for assessing improvements due to the new lab procedures. The significance of this question, and the implication that other cancer patients may not have received appropriate treatment if error rates were high, is dependent on a better understanding of how these tests are used and whether they play as critical a role in treatment decisions as does ER/PR. Dr. Fleming will give us more perspective on this question.

In regard to the other question on whether only breast cancer patients were re-tested for ER/PR, and the possibility that other ER/PR tests for non-breast cancer patients were not retested, Dr. Howell says that ER/PR is not used for other cancers than breast cancer. (When I received that answer I gave Dr. Fleming more details about how we discovered that ER/PR might be used for other than breast cancer, and he will do another follow-up on this question.)

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