Breast cancer genetic tests without clinical validity should not be offered, researchers say

A group of international researchers is making the case that genetic tests that look for multiple hereditary genes suspected of being linked to breast cancer should not be offered until they are proven to be valid and useful in clinical practice.

Such tests, made by several companies including Myriad Genetics Inc, Ambry Genetics, Invitae and Illumina Inc, cover up to 100 inherited cancer genes, including more than 20 for breast cancer.

In a paper published on Wednesday in the New England Journal of Medicine 17 genetics experts proposed that “a genomic test should not be offered until its clinical validity has been established.”

“It’s been pretty widely assumed that all of these genes on all of these panels have clear clinical validity,” meaning the genes are clearly associated with cancer, said University of Pennsylvania breast cancer expert Dr. Susan Domchek, a study co-author. “The point of this article was to say, we’re not finished with that step yet.”

It comes as the U.S. Food and Drug Administration considers how to regulate lab-developed diagnostic tests, which include most genetic tests. Under guidelines established by the Clinical Laboratory Improvement Amendments (CLIA) of 1988, such tests are not required to prove clinical validity or utility, meaning the information aids patient care.

Several insurance companies have already decided not to pay for the tests.

Earlier this month, the U.S. Centers for Medicare and Medicaid Services issued a draft statement saying large panel tests for BRCA genes that include genes not relevant to the patient “are not reasonable and necessary.”

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion and analysis. Read full, original post: Researchers oppose unvalidated gene panel tests for cancer links