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Docket FDA-2015-N-0647, submitted to
<http://www.regulations.gov/#!docketDetail;D=FDA-2015-N-0647>

These comments are submitted on behalf of Fight Colorectal Cancer, a non-profit, nonpartisan advocacy organization that is committed to the fight against colon and rectal cancer. They address issues raised at the March 24th “Complexities in Personalized Medicine: Harmonizing Companion Diagnostics Across a Class of Targeted Therapies” workshop.

Fight Colorectal Cancer (FightCRC) is the leading colorectal cancer advocacy organization in Washington, DC, empowering survivors to raise their voices, training advocates around the country, and educating lawmakers and pushing them for better policies. We offer support for patients, family members and caregivers, and we serve as a resource for colorectal cancer advocates, policymakers, medical professionals, and healthcare providers. Additionally, we do everything we can to both increase and improve research—at all stages of development and for all stages of cancer.

FightCRC believes in fully disclosing conflicts of interest. We have worked with and received unrestricted funding from many companies that have an interest in genetic testing around colorectal cancer, including Quest Diagnostics, Myriad, Genentech, Bristol Myers Squibb, Amgen, Genomic Health and Foundation Health. None of these companies, nor any of our other corporate supporters has influenced our comments on this issue.

First, we thank the conveners of the meeting for a chance to discuss this important issue publicly, with all stakeholders at the table. In addition, we applaud the Working Group who authored “A Blueprint Proposal for Companion Diagnostic Comparability” for taking the first step towards resolving this issue. While this meeting is specific to PD / PDL drugs, the issue of multiple tests for similar drugs is becoming more common. We need to find a way to keep it simple for the end-users – the treating oncologist and the patient.

Second, we are concerned that the Blueprint does not appear to address patient outcomes. As we’ve seen in the larger discussion around LDTs, analytic validity and clinical validity can be very different. We would like to understand how the Blueprint will compare both analytical and clinical outcomes. At the same time, if the Working Group feels that comparing clinical outcomes is not necessary, we would them to explain why.

Third, we support the comments raised by Dr. Rimm at the workshop where he urged the companies involved to move away from IHC, towards a more quantitative form of testing. Qualitative tests increase the chance of false-positive or false-negative readings, to the detriment of the patient. We hope the Working Group addresses this issue.

Lastly, we reviewed the letter sent in by Dr. Rimm and his colleagues. We feel that this letter raised several excellent points, and would like to see the Working Group response.

Thank you again for inviting us to be part of this important discussion. We look forward to the next steps.

Sincerely,

Anjee Davis

President
Fight Colorectal Cancer

cc: Nancy Roach, Chair, Board of Directors
Jane Perlmutter, Gemini Group
Jeff Allen, Friends of Cancer Research