NATIONAL BREAST CANCER COALITION

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Dear Rick,

As always, I hope you are well and safe. First, let me say that we applaud the preliminary steps FDA has taken through its Project Confirm to create a framework for discussion and input related to Accelerated Approvals (AA) for oncology indications. This is a good first step.

We have reviewed the information that has been synthesized through Project Confirm as well as the background data. While all the information is also available elsewhere on the FDA's website, we appreciate the FDA's efforts to make it more readily accessible in this format.

Having said that, we note that there are several additional pieces of information that we believe would further promote the transparency of FDA's AA decisions. For instance, we believe that it is critical to include information about the surrogate endpoint that was used in each AA instance. While this information is currently available through the online database by way of links to the original approval notices, it would be more efficient if it were contained as a separate variable in the synthesized database. Additionally, given that the AA program is intended to support moving drugs to the market earlier for life-threatening conditions where there is an unmet need, we believe you should include a brief description of the unmet need that is being served by each drug approval.

More importantly, for those drugs that are designated as having "verified clinical benefit" and have advanced to regular approval, we believe that it is critical to include more information about the justification. For example, Project Confirm should describe the endpoint in the confirmatory trial that led to the regular approval and the evidence behind it. Further, given that, by the FDA's own analysis (Beaver et al. 2018) many of these conversions are based on the same or different surrogate endpoint as the AA, we believe that it is imperative to include FDA's rationale in those circumstances for converting a drug to regular approval (e.g., what is the evidence at the time of regular approval that validates the surrogate outcome). Again, we are pleased to see FDA taking steps to promote transparency of its AA program and believe that the ongoing public conversation must continue. We also believe that the above-recommended changes will further support systematic examinations of the processes underlying the AA program which at present seems to operate arbitrarily and contrary to its own guiding rules. NBCC would welcome being part of continued discussions to improve this program.

Sincerely,

Fran Visco
President