NATIONAL BREAST CANCER COALITION

The Hon. Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

June 14, 2023

Dear Dr. Califf,

The National Breast Cancer Coalition (NBCC) read with interest reports in the media concerning comments you made recently at the BIO International Convention, as reported in *Stat News* and *Endpoints News*. Specifically, we want to applaud your commitment to a US drug development system that works and advances drugs that provide meaningful outcomes for patients. NBCC does not believe the current drug approval system supports that goal. While we recognize that the FDA does not regulate drug prices, we agree that drug prices must reflect the value they provide to patients.

NBCC believes that drugs must be approved based on clinically meaningful outcomes rather than unvalidated surrogate endpoints and that we need more drugs that save or meaningfully improve patients' lives, not simply more drugs.

As you know, NBCC has worked with the FDA for many years. NBCC-educated advocates have participated as Oncologic Drug Advisory Committee members, and our representatives have testified at select drug approval hearings, among other interactions. We have been fortunate, over the years, to develop collaborative relationships with FDA senior staff, several of whom have been faculty members for our Clinical Trials Project LEAD® science course for advocates.

Over the years, we have made our position clear on the need for high-level evidence of clinical benefit for drug approval. NBCC recently submitted comments on the draft FDA Guidance on Accelerated Approval Trial Design for Oncology Drugs. Our chief concern with the draft guidance is that it perpetuates the use of a surrogate endpoint, progression-free survival, as a measure of clinical benefit. It also fails to advance the inclusion of trained patient advocates in the design and conduct of clinical trials.

We believe policymakers must consider reforms to the accelerated approval pathway to ensure the drugs ultimately approved through this mechanism improve how patients feel, function, and/or survive. The FDA should impose strict timelines for the initiation of confirmatory trials and require clinically meaningful endpoints (i.e., overall survival and/or

quality of life). Additionally, the FDA should have the authority to quickly withdraw an accelerated approval if a confirmatory trial has not been timely initiated or completed or if the trial fails to confirm clinical benefit.

Having worked on several pivotal trials as informed advocates, we appreciate the importance of a strong FDA with high drug and device development, testing, and approval standards. We are especially supportive of the FDA's resolve in the face of pressure from interests that desire to speed up the approval process at the potential expense of rigor and safety. We will remain strong supporters of an efficient, well-run, and robust FDA that will benefit all Americans and preserve the highest level of public health while employing the latest and best technology and science. If the media reports of your comments are correct, we hope to strengthen our collaboration with you and the FDA to help achieve our mission to end breast cancer.

We look forward to continuing to work with the FDA and other relevant policymakers on these critical issues. .

Sincerely,

Fran Visco
President, National Breast Cancer Coalition