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The Patient's Voice | since 1996

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January 24, 2011

Nicole Veseley, Pharm.D.

Center for Drug Evaluation and Research

Food and Drug Administration

10903 New Hampshire Avenue

WO31-2417

Silver Spring, MD 20993-0002

Re: **February 8, 2011: Oncologic Drugs Advisory Committee Meeting Announcement**

Dear Ms. Veseley;

The National Patient Advocate Foundation ("NPAF") thanks you for the opportunity to submit comments to the Oncologic Drugs Advisory Committee ("ODAC") regarding updates on new drug applications (NDAs) and biologics license applications (BLAs) approved under 21 CFR 314.500 and 601.40 (subpart H and subpart E). The ability to comment on accelerated approval regulations assures ODAC members receive comments from a multiplicity of respondents, including those representing the patient voice.

NPAF is a non-profit organization dedicated to improving access to healthcare services through both federal and state policy reform. Our mission is to be the voice for patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained case management services from our companion organization, Patient Advocate Foundation (PAF). In fiscal year 2009 (July 1, 2009 – June 30, 2010), PAF resolved 64,188 patient cases and received more than four million additional inquiries from patients nationally.

Assessing potential patient impact in the regulatory decision-making process is of paramount importance to NPAF. In the context of an accelerated oncology product approval process, patient impact necessitates weighing promising oncology product availability as well as protection from products with little to no clinical benefit or unintended negative outcomes. We understand the goal of the February 8th ODAC meeting will be to explore possible ways to improve the planning and conduct of trials to determine clinical benefit in the provision of early availability of oncology products. NPAF encourages ODAC to assure patient oncologic drug availability and safety issues are considered and addressed when defining the optimization of an accelerated approval process. NPAF recommends that ODAC consider the following when defining clinical benefit in providing accelerated availability of oncologic products:

Quality of Life Consider assessment of improved quality of life measures during the trial noting improvement in diminished pain, enhanced mobility, increased freedom from debilitating symptoms of the disease and improvement in overall function that may be restricted due to disease. Each of these areas has been documented in patient surveys measuring patient compliance to protocols.

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Input on Benchmark Design Development of trials with specific benchmarks to identify control of disease with anticipated improved life expectancy. These benchmarks may include measurement of reduced side-effects that accelerate mortality. Historically time to disease-free progression has been an instrument to define successful control of disease. While NPAF supports this standard, additional guidance by the manufacturer is encouraged in the trial design to establish end points that extend life significantly as defined by a broad coalition of healthcare stakeholders including patients, physicians and regulators. NPAF also appreciates that we have conquered disease with small advances across extended timelines and knowledge, that process may be the result moving forward; however, if all stakeholders are committed to increased life expectancy initially, we may improve outcomes.

NPAF further encourages clinical trial admission criteria that assures clinical outcome extrapolation to discrete populations, such as those with limited yet successfully managed underlying chronic illnesses, a broad range of age cohorts and ethnically diverse populations.

Life Expectancy Consideration NPAF encourages focusing on improved life expectancy in the trial design, as this is the patient's ultimate goal. Thus, the patient voice must be heard throughout the fact-finding and deliberation process.

Greater Analysis of Side Effects Side-effects that have proven to be fatal in previous trial designs for significant percentages of the trial population must be considered in the trial design. In oncology, tradition has defined nausea as standard; however acute nausea may be fatal. NPAF would encourage trial designs with a renewed commitment to designing drug trials that minimize the likelihood of death due to acute side-effects. Risk and benefit must be balanced. Renewed attention to protocols that establish a level playing field between the threat of death from disease versus the threat of death from protocol side-effects must be balanced against the projected outcome of long-term life without disease. If the outcomes are minimal, the question becomes is the risk warranted.

We thank you for the opportunity to comment from the patient's perspective on the rules relating to accelerated approval regulations. We would be pleased to respond to any questions about our recommendations that may arise.

Respectfully submitted,



Nancy Davenport-Ennis
Chief Executive Officer and President