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June 23, 2011

Dr. Janet Woodcock

Director

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

White Oak Complex, Building 51

10903 New Hampshire Avenue

Silver Spring, MD 20993

Re: Issue Clinical Study Endpoints

Dear Dr. Woodcock:

Thank you for the opportunity to forward our comments to you addressing our concerns relative to the process to be employed by FDA when a drug has been approved through the accelerated approval process, and then presents with adverse events when used in the national market place.

NPAF is a non-profit organization dedicated to improving patient access to healthcare services through both federal and state policy reform. Its

mission is to be the voice for patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. NPAF has a fifteen year history of serving as the trusted patient voice. 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 2010, PAF resolved 82,963 cases nationally and provided information to almost 4 million online contacts.

As a national non-profit patient organization serving those with serious illnesses, this procedural issue is of great importance to the patient community as the accelerated approval process provides timely access to life-saving medications. The definition of both the statutory and regulatory standard to withdraw accelerated approval of drugs will have significant precedential effect on all drug acceleration approvals going forward. NPAF encourages FDA to consider a statutory and regulatory standard that balances the ability to provide patient access to safe and effective drugs with the importance of preserving the physician-patient relationship in agreeing

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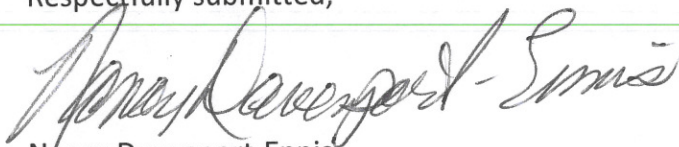
to a drug therapy. This procedural issue is particularly sensitive as it concerns the withdrawal of a medication that some in the patient community believe to be effective.

Additionally, NPAF encourages a descriptor of the FDA process of manufacturers filing their Non-Disclosure Agreement in which they express their mutually agreed to pre-determined endpoint with the FDA. NPAF supports transparency of this process with the understanding that the mutually agreed to end points remain constant through the drug approval process and into utilization in the national marketplace.

With patient safety as a primary responsibility of the FDA, NPAF supports FDA intervention to address safety, purity and efficiency issues. At the same time, those issues would likely represent process issues. NPAF's commends our support of the FDA in its rate to approve new drugs for those we serve through the accelerated approval process.

In preserving access to new therapies, our nation is advantaged through a process of transparency that maintains industry and FDA collaborations to serve the consumer

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Nancy Davenport-Ennis". The signature is written in a cursive style and is positioned above the printed name and title.

Nancy Davenport-Ennis
President and Chief Executive Officer

Cc: Dr. Rick Padzur