PANCREATIC CANCER ACTION NETWORK®
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October 12, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number FDA-2011-D-0215

The Pancreatic Cancer Action Network is a national nonprofit organization dedicated to working together to advance research, support patients, and create hope for those affected by pancreatic cancer and is guided by a pre-eminent Scientific Advisory Board and Medical Advisory Board. We have reviewed the Draft Guidance for Industry and Food and Drug Administration Staff "In Vitro Companion Diagnostic Devices" and appreciate that the Food and Drug Administration (FDA) has recognized the need for this guidance.

We are pleased that recent scientific developments have advanced the ability of physicians to base certain treatment decisions on objective measures such as a patient's biomarkers or a tumor's genetics. We agree with the FDA that in general, it is ideal for the treatment that depends on the use of an in vitro (IVD) companion diagnostic device or test for safe and effective use to be considered by the FDA at the same time that the in vitro companion diagnostic device or test is reviewed. At the same time, we commend the FDA for recognizing in the draft guidance an appropriate exception in the case of a treatment for a "serious or life-threatening condition for which no satisfactory alternative treatment exists and the benefits from the use of the therapeutic product with an unapproved or uncleared IVD companion diagnostic device are so pronounced as to outweigh the risks from the lack of an approved or cleared IVD companion diagnostic device."

This exception is particularly important to people diagnosed with pancreatic cancer, given that the five-year relative survival rate is just 6%. The FDA has approved only three chemotherapies and targeted therapies for pancreatic adenocarcinoma, none of which has had a meaningful impact on survival rates. Fortunately research into additional therapies is ongoing. Should future pancreatic cancer therapies need to be used in conjunction with an in vitro companion diagnostic device or test that cannot be approved concurrently, the Pancreatic Cancer Action Network would not want the therapy's approval to be automatically delayed, and thus strongly supports this reasonable exception.

Thank you for your consideration of our comments submitted on behalf of the tens of thousands of people diagnosed with pancreatic cancer each year.

Sincerely,

Megan Gordon Don

Megan Gordon Don
Director, Government Affairs and Advocacy