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COMMITTEE ON
APPROPRIATIONS

TIM RYAN
CONGRESS OF THE UNITED STATES
17TH DISTRICT, OHIO

November 4, 2008

Commissioner Andrew C. von Eschenbach, M.D.
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

I am writing in strong support of the Citizen Petition submitted by The Alliance Against Alveolar Soft Part Sarcoma ("TAAASPS") and the Sarcoma Foundation of America ("SFA") (FDA docket number 2007P-0420). The TAAASPS and SFA Citizen Petition requests that FDA issue a guidance document for the accelerated approval of drugs and biologics that are intended to treat rare cancers. I believe the Citizen Petition merits the Agency's careful consideration and FDA should move forward to issue the requested guidance document.

The Citizen Petition asks the Agency to provide guidelines for the approval of any drug or biological product that is intended to treat a rare cancer, but for which large size studies may not be feasible due to the rarity of the cancer or ethical constraints in conducting such studies. Rare cancers affect a small percentage of the U.S. population. Because of the rarity of the cancer, clinical trials, especially those requiring the sponsor to demonstrate a survival benefit, are often difficult to conduct and complete. However, under the Agency's current approval process, such studies are usually necessary to the approval of the product. As a result, drug companies typically avoid the risk of development, and many people affected by rare cancers are left without a viable therapeutic treatment option. By providing a guidance document concerning the realistic pathway to approval of treatments for rare cancers, FDA can pave the way for companies to continue to develop and seek approval of products intended to treat rare cancers, and to ensure that these products reach patients who desperately need them.

I urge the Agency to act on the Citizen Petition's request and provide needed guidelines for the approval of drug and biologics intended to treat rare cancers. These guidelines can help preserve and promote public health by making products available to persons suffering from a rare cancer.

Sincerely,

A handwritten signature in black ink that reads "Tim Ryan".

Tim Ryan
Member of Congress

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