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12TH DISTRICT, NEW YORK

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April 22, 2008

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

Dear Dr. von Eschenbach:

I write to urge FDA to improve the accelerated approval process for drugs and biologics intended to treat patients with rare cancers. Rare cancers such as Sarcoma, which accounts for less than 1% of new cancer cases each year, by their very rarity present specific challenges in designing an appropriate treatment approval process. I draw your attention to one method for improving this process submitted to FDA in an October 26, 2007 Petition by The Alliance Against Alveolar Soft Part Sarcoma (TAAASPS) and the Sarcoma Foundation of America (SFA).

The Petition requests that FDA issue a guidance document for the accelerated approval of drugs and biologics that are intended to treat rare cancers. Some cancers are so rare, they often do not offer ideal sized patient pools and other optimum circumstances for testing and clinical trials. What should be avoided is a taxing approval process that leaves many rare cancer patients without a viable therapeutic treatment option. For each one of these patients, time is of the essence. The Petition addresses these unique challenges, and suggests the guidance document as a way to overcome them.

A guidance document potentially holds the key both to addressing the FDA's legitimate interest in maintaining a safe, viable treatment approval process, and to exhibiting the flexibility necessary to meet the challenge posed by rare cancers. Such a guidance document would also provide a roadmap for companies seeking to develop treatments.

FDA should provide better guidelines for the approval of drugs and biologics intended to treat rare cancers. Such guidelines as those established in the TAAASPS-SFA Petition, afford more opportunities to help patients overcome rare cancers such as Sarcoma.

Sincerely yours,



Nydia M. Velázquez
Member of Congress