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June 20, 2008

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

Dear Dr. von Eschenbach:

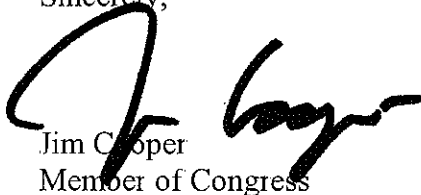
I write to urge the FDA to improve the accelerated approval process for drugs and biologics intended to treat patients with rare cancers. Rare cancers such as Sarcoma, which accounts for less than one percent of new cancer cases each year, present specific challenges in designing an appropriate treatment approval process. One method for improving this process was submitted to the 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 the FDA issue a guidance document for the accelerated approval of drugs and biologics that are intended to treat rare cancers. Under the Agency's current approval process, necessary studies are often hard to complete as the rarity of the cancers do not offer ideal sized patient pools and other optimum circumstances for testing and clinical trials. 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.

While it is critical that any approval process is safe and thorough, it must also afford a flexibility to meet the challenges posed by rare diseases. A guidance document has the potential to both address these interests and provide a roadmap for companies seeking to develop needed treatment.

I urge the FDA to provide better guidelines for the approval of drugs and biologics intended to treat rare cancers, thus affording more opportunities to help patients overcome these devastating diseases.

Sincerely,



Jim Cooper  
Member of Congress