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July 25, 2001

Margaret M Dutzel,
Associate Commissioner for Policy
Dockets Management Branch (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01N-0197
Clinical Development Programs for Drugs, Biological Products, and Devices for the Treatment of Ankylosing Spondylitis (AS) and Related Disorders; Request for Assistance

Dear Ms Dutzel,

I am interested in taking part in critical appraisals related to guidance development for ankylosing spondylitis. As a statistician, I was involved in the development of the ACR20, for improvement in rheumatoid arthritis, and currently serve on the Arthritis Advisory Committee of the FDA. I recently completed some work on the development of improvement criteria in ankylosing spondylitis, that will be published soon in the journal Arthritis and Rheumatism. The paper is 'Ankylosing Spondylitis Assessment Group Preliminary Definition of Short-term Improvement in Ankylosing Spondylitis' Anderson JJ, Baron G, van der Heijde D, Felson DT, Dougados M. Arthritis Rheum (2001) 44: 1876-1886.

I believe that the criteria developed in that paper could be very useful, but that they are limited to short-term improvement. For more general purposes, including a disease-modifying claim, proposed criteria should also require improvement in spinal mobility. Further development and validation of responsive measures that truly represent spinal mobility may be needed, however, before this can be a reality.

Sincerely,

Jennifer Anderson, PhD
Research Professor of Medicine and Public Health
(Epidemiology and Biostatistics)
Boston University School of Medicine

01N-0197

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