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July 30, 2004

Lester M. Crawford, D.V.M., Ph.D.  
Acting FDA Commissioner  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Dear Dr. Crawford:

The United States Bone and Joint Decade (USBJD) welcomes the opportunity to comment on the Food and Drug Administration's Critical Path Initiative (Docket No. 2004-N-0181), which seeks to identify existing hurdles in medical product design and development.

The USBJD, a coalition of more than 85 patient and professional health care organizations, more than 80 medical schools and colleges of medicine, all 50 states, and industry, comprises part of the worldwide movement to improve patient care, to promote research and to advance understanding and treatment of musculoskeletal conditions during the International Bone and Joint Decade. The worldwide Bone and Joint Decade is an international collaborative movement sanctioned by the United Nations/World Health Organization and focused on improving the quality of life for people affected by musculoskeletal disorders. President Bush proclaimed the National Bone and Joint Decade 2002-2011 in March 2002.

Millions of Americans are affected by a musculoskeletal disorder (one in three) including those afflicted with arthritis, osteoporosis, childhood diseases, and trauma. The USBJD believes that it is very much in the interests of patients that new medical products and technologies be brought to market as swiftly as possible, as long as the process to review and approve new products ensures the safety of patients is a primary consideration. It is our opinion that there is probably much room for improvement and would support a review to identify problematic areas in the regulatory process.

You have requested input on identification of the most pressing scientific and/or technical hurdles causing major delays and other problems in the development process. The USBJD network comprises almost all disciplines concerned with musculoskeletal disorders, and therefore believes that each of the specialist groups will provide you with the most complete appraisal as pertaining to the drugs, products, and biologic developments in their area of expertise. However, the USBJD would add that with the rapidly increasing aging of our population, the burdens on the health system to provide treatment will increase. The USBJD believes this is a highly opportune time to be undertaking the proposed review.

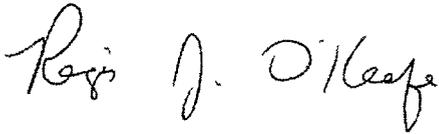
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Musculoskeletal conditions are debilitating, an important cause of morbidity, and lead to economic loss as well as loss of quality of life. They can also contribute to complications that can and do lead to loss of life. It is currently estimated that musculoskeletal disease costs \$300 billion annually to the United States. Worldwide, by the year 2020, there will be double the number of people over the age of 50 compared to 1990. With the cost of musculoskeletal conditions rising at an alarming rate, it can only be in the interests of the nation to study means to expedite the approval of new technologies and treatments for the benefit of lowering the future burden of disease.

Sincerely,

A handwritten signature in cursive script that reads "Regis J. O'Keefe". The signature is written in black ink and is positioned below the word "Sincerely,".

Regis O'Keefe, MD, PhD  
President