



December 22, 2011

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20933

**Re: *Center for Drug Evaluation and Research, Approach to Addressing Drug Shortage; Public Workshop; Request for Comments [Docket No. FDA-2011-N-0690]***

Dear Dr. Woodcock:

The American College of Rheumatology, representing over 8500 rheumatologists and health professionals, welcomes the opportunity to comment on the FDA's Center for Drug Evaluation and Research's approach to addressing drug shortages. The ACR appreciates the FDA's efforts to manage the increasing prevalence of drug shortages and in particular the recent broadening of reporting requirements for manufacturers in relation to supply disruptions. The ACR encourages the FDA to take additional steps that will address the issues causing drug shortages to occur, as well as steps that could sustain supplies in the face of disruptions.

### **Causes and impact of drug shortages**

As you well know, rheumatologists treat patients with arthritis and other rheumatic and musculoskeletal diseases. These conditions can be painful, debilitating, life threatening and costly. Recently, several drugs prescribed by rheumatologists such as leflunomide tablets, injectable methotrexate, and methylprednisolone tablets, have been in short supply, forcing patients to struggle in searching for the medications necessary to their treatment or in many cases interrupt treatment programs.

Injectable methotrexate shortages in particular are critical because methotrexate is the foundation of rheumatoid arthritis therapy and is frequently used as an important maintenance therapy in vasculitis and other rheumatic diseases. Many patients who cannot tolerate oral methotrexate due to nausea or diarrhea, or who do not absorb methotrexate well, are treated successfully with injectable methotrexate at a fraction of the cost of biologic therapies.

The causes for the shortages vary from manufacturing delays and raw material deficiencies to sterility problems and increased demand. Regardless of the reason for the shortage, drug shortages cause arthritis patients to experience additional pain and immobility, add to suffering and uncertainty as they work with insurance companies to have possible replacement medications

approved, and increase rheumatologists' time and expense as they attempt to identify acceptable and available substitutes.

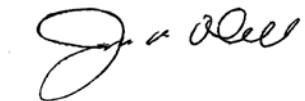
**Strategies for preventing or mitigating drug shortages**

The recent drug shortage problem has been especially difficult for rheumatologists and their patients, as many shortages involve low-margin, injectable generic drugs that have been in use in everyday practice for many years. We recommend the FDA take steps to identify ways in which redundancies in the supply chain for these and other critical drugs could be stimulated so that the impacts of any disruptions are moderated. The ACR would support efforts to incentivize manufacturers to produce certain drugs found in short supply.

Unfortunately, rheumatologists are often not notified about a shortage before their patients experience it. Empowering physicians and pharmacists with advance knowledge of shortages will allow them to better prepare patients and help them to adapt treatment strategies. The ACR supports the FDA's recent expansion of requirements for manufacturers to report disruptions of critical drug production, adding to the circumstances in which drug makers must report a problem and requiring six months' warning for any disruptions, whether temporary or permanent. In addition to identifying ways to stimulate supply redundancies in targeted areas, we encourage the FDA to consider new ways to continue to enhance communication between the agency and drug manufacturers, and to identify strategies for improving communication between the pharmaceutical supply chain and providers.

The ACR stands ready to assist you on these and other issues affecting the rheumatology community. If we can be of assistance to you in any way, please contact Adam Cooper, ACR Director of Government Affairs at [acooper@rheumatology.org](mailto:acooper@rheumatology.org) or (404) 633-3777.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jim R. O'Dell".

Jim R. O'Dell, MD  
President, American College of Rheumatology