



**AMERICAN COLLEGE  
OF RHEUMATOLOGY**  
EDUCATION • TREATMENT • RESEARCH

Specialists in Arthritis Care & Research

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March 24, 2010

Richard H. Roberts, M.D., Ph.D.  
President  
URL Pharma, Inc.  
1100 Orthodox Street  
Philadelphia, PA 19124

Re: Your Correspondence of February 16, 2010 and March 16, 2010

Dear Dr. Roberts:

Thank you for your letter of February 16, 2010 as amplified by your letter of March 16, 2010 and in particular your company's enhancement of the parameters of its Patient Assistance Program. I also want to thank you for your exegesis on the distinction between a generic and an unapproved drug. However, I have some concerns about the referenced letters.

I seriously doubt, as your letter of February 16, 2010 states, that members of the American College of Rheumatology have been attempting to prevent the Food and Drug Administration from removing as you phrase it, "illegal unapproved colchicine products from the market due to concerns for price-based patient access." In fact, it is incredulous to suggest that individual rheumatologists would have that level of influence over a federal agency. In any event, ACR is not aware of any of its members attempting to undertake such actions. Nor have I, or the ACR staff, encouraged any ACR members to attempt to influence the FDA in that manner.

As you know, it is not your company nor individual members of the ACR, but, rather the FDA, that determines whether an unapproved drug is to be removed from the marketplace. The ACR does not, has not and will not insinuate itself into the manufacturers' marketplace, nor as you continue to request, promote the use of your company's product nor support your company's litigation against other manufacturers. The ACR's primary objective is and will continue to be advancing rheumatology to assist physicians treating patients with rheumatic disease. The ACR is not in the practice of marketing treatments.

The ACR has expressed its concerns to the Director of the Center for Drug Evaluation and Research of the FDA over the current market prices of approved oral colchicine. As suggested by the FDA, the ACR is reaching out to manufacturers of unapproved colchicines to encourage them to apply to the FDA and become engaged in the FDA regulatory approval process.

The ACR is very appreciative of your company's efforts to enhance its Patient Assistance Program. The Patient Assistance Program is posted on the ACR website and will be acknowledged in a future article. The ACR, however, is not appreciative of the hostile, if not threatening, undercurrent of your letters nor your request that ACR in effect become the proponent of your company's product.

Sincerely,

A handwritten signature in black ink, appearing to read "Stanley B. Cohen", with a long horizontal flourish extending to the right.

Stanley B. Cohen, M.D.  
President