

February 10, 2013

Colorado House of Representatives
House Health Committee

Dear Committee members:

As background to the importance of the biosimilar bill under consideration, I'd like to summarize briefly how anti-tumor necrosis factor (anti-TNF) agents have revolutionized care for patients with rheumatoid arthritis. The first biosimilars that will be available in the field of rheumatology will be in this particular class of biologic drugs.

Rheumatoid arthritis is an autoimmune disease that causes a multi-joint inflammatory arthritis which, particularly if not treated aggressively or early enough, can cause permanent joint damage resulting in deformity and functional disability. Apart from what it does to an affected individual's joints, rheumatoid arthritis is a systemic disease that not infrequently attacks other organ systems, such as the lungs, eyes, nervous system, and cardiovascular system. As a result, mortality in this disease has been shown to be similar to that of Hodgkins lymphoma. More than 30 years ago very limited treatment was available. The treatment "pyramid" of the 1960's and 70's consisted of supportive care and treatment with NSAIDs (i.e. aspirin, ibuprofen and the like) for long periods of time before more aggressive interventions were entertained. Such options then were very limited. Eventually, methotrexate, a chemotherapy agent in higher doses than used in rheumatologic diseases, became a standard therapy shown to have true disease modifying effects (slowing/preventing joint damage), particularly when used very early in the disease. However, for patients who couldn't tolerate this agent, or in whom it wasn't effective, other immunosuppressive agents with greater potential for toxicity were required. The year 1998 ushered in a new era of biologic therapy with the first of the anti-TNF agents, etanercept (Enbrel), becoming FDA approved for use. The anti-TNF's provided nothing short of a paradigm shift in rheumatoid arthritis treatment. Studies then and since have demonstrated that combination treatment of MTX with an anti-TNF is significantly more effective than our prior standard of MTX alone. Most importantly, these agents have been shown to prevent joint damage and improve quality of life to a greater degree than prior standard therapy. Thus, with the availability of anti-TNFs (a biologic), our treatment armamentarium became one in which we can not only have a higher chance of alleviating pain and suffering in this devastating disease, but one in which we have a much higher likelihood of keeping our patients functional and in the workplace.

Although use of biologic therapy has made rheumatology immensely more rewarding to practice, biologics have also made our specialty tremendously more costly (the least expensive of the anti-TNFs cost \$20,000-25,000 a year). Not surprisingly, and to the frustration of treating physicians, their cost has limited availability to many patients in need of what's become the new standard of care. Obviously the hope of many rheumatologists is that having the option of biosimilar agents will broaden these

important agents' availability and allow us to have an even greater impact in treatment of rheumatoid arthritis and other diseases for which these drugs have indications; thus, the importance of the bill under consideration. Without this bill, or something similar, the state of Colorado will not have the option of providing lower cost biologic therapy. Having read the bill's provisions, I am in agreement with the conditions in which a pharmacist can substitute an interchangeable biosimilar, i.e. when the physician doesn't designate "do not substitute" on the prescription. I also agree with the provision that the patient be notified of the substitution at the time the prescription is dispensed, just like they are when a generic is substituted for a nonbiologic prescription, and I also agree with the importance for a treating physician to be notified in a timely fashion of such a substitution. In the coming era of biosimilars, documentation of a biosimilar substitution at the pharmacy AND in the physician's record is needed in order to track and document dispensing of these agents since adverse effects and/or efficacy, could prove to be unique compared to "branded" agents. For completeness sake, details about the substitution, including name of the manufacturer (since there will likely be more than one), should be part of the physician's and pharmacist's record. Lastly, because some adverse effects can be delayed, a time frame of 5 years for maintaining record of a biosimilar substitution seems to me conservative and reasonable. In summary, my opinion is that this bill's provisions are thoughtful and reasonably designed to ensure improved access to an important form of treatment and to ensure patient safety.

Finally, because biologics have revolutionized the treatment of rheumatologist diseases, I am very invested in their successful development and have partnered with Amgen and Abbott to speak on this topic at conferences.

Sincerely,

Robert T. Spencer, M.D.
Colorado Arthritis Center, P.C.
Clinical Associate Professor of Medicine
University of Colorado Denver, School of Medicine