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February 18, 2013

The Honorable Joseph J. Crisco and Robert W. Megna, Co-Chairs, and Members
Insurance and Real Estate Committee
Room 2800, Legislative Office Building
Hartford, CT 06106

RAISED BILL 857: An Act Concerning the Use of Step Therapy For And Off-Label Prescribing of Prescription Drugs

Senators Crisco, Representative Megna and Members of the Insurance and Real Estate Committee:

The Arthritis Foundation supports most of the provisions in Raised Bill 857, which will protect patients from barriers that certain step therapy provisions present for effective control of chronic, disabling diseases, such as arthritis.

Doctor-diagnosed arthritis affects one-fourth or 654,000 of our state adult population, according to the Centers for Disease Control and Prevention (CDC).¹ CDC also estimates that arthritis affects 3,400 children in our state.²

Step therapy is a practice that insurers use to control costs by requiring patients to fail less expensive treatments before receiving more expensive treatments.

We support the following provisions of the bill:

1. Patients should not be required to fail more than once ever a particular medication. Some commercial insurers require patients to re-fail a therapy after a specific time period, for example, every 180 days.
2. Impose a co-pay higher than the lowest co-pay for the preferred drug in the same class where a patient has failed the preferred drug. Studies show that patient initiation and continuation of drug therapy, especially for the expensive biologic therapies used in inflammatory forms of arthritis, such as rheumatoid arthritis, are affected by co-pays.³

We raise the following concerns for the Committee's considerations about the proposed provisions of Raised Bill 857:

1. The bill does not require that the step therapy provisions follow currently accepted and published medical guidelines for progression of treatment for chronic diseases. For instance, there is nothing to prohibit an insurer from requiring a patient with rheumatoid arthritis from failing aspirin therapy first before proceeding to the recognized first step in treatment. Why this is important is the research has shown that most of the joint damage in rheumatoid arthritis occurs within the first two years after diagnosis. Aspirin does not prevent joint damage, it only provides symptomatic relief of pain and inflammation, but has significant side effects when taken in the large doses required for rheumatoid arthritis.

The American College of Rheumatology (ACR) recommendations for the treatment of rheumatoid arthritis starts with disease-modifying anti-rheumatic drugs, most of which as available in generic form⁴. These agents are given singularly then in combination before adding treatment with the more expensive biologic therapies, for example Enbrel or Humira. In the last several years, we have seen insurers (e.g. CIGNA) require patients to fail two or more self-injectibles before getting access to an

infusible therapy, such as Remicade. Infusible therapies are often chosen when a patient can't inject because of hand deformity or in children where the dose needs to be adjusted for body weight.

The choice of an individual agent is complex and is undertaken with many variables in mind, including the diagnosis, the proximity of the patient to the physician's office, the patient's preference for mode of administration, the patient's ability to be mobile, and the physician's experience.

2. The bill does not protect those stable on a therapy from having to switch to a preferred drug and fail it before getting back on a therapy that meet established criteria for disease control. Since preferred drugs lists can change several times during the year, this puts patients at risk for losing disease control. Our state's Pharmacy and Therapeutics Committee, which is composed of medical experts who oversees the state's preferred drug list for Medicaid and HUSKY, will consider for certain therapies grandfathering those stable on an existing therapy in the interest of maintaining disease control.

The Arthritis Foundation does not have a problem with newly diagnosed patients being required to follow step therapy, so long as the sequence follows best medical practice guidelines and patients are not required to re-fail a therapy.

3. Section 1, Provision B, which permits the use of a therapeutically equivalent generic prior to using a brand-name drug may pose a problem in the near future when FDA issues final regulations for the approval of biosimilars. These are non-brand name versions of the expensive biologic agents, such as Enbrel or Remicade. The problem is that there will be two versions of these agents: those that are exactly the same as a brand-name agent, called interchangeable biologics, and those that are similar to the brand-name agent but have different inert ingredients. We do not know at this time how FDA will differentiate therapeutic equivalency between these two versions of biologic agents.

Thank you for your consideration.

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¹CDC, Division of Adult and Community Health, 2010 (cdc.gov).

²Sacks J, Helmick CG, Luo YH et al. Prevalence of and annual ambulatory health care visits for pediatric arthritis and other rheumatologic conditions in the United States in 2001-2004. *ArthRheum (Arthritis Care and Research)* 57:8 1439-1445 2007

³ Solomon MD, Goldman DP, Joyce GF, Escarce JJ. Cost sharing and the initiation of drug therapy for the chronically ill. *Arch Intern Med* 2009 169:8 740-748.

⁴ Singh JA, Furst DE, Bharat A, et al: 2012 update of the 2008 American College of Rheumatology recommendations for use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *ArthRheum (Arthritis Care and Research)* 2012 64:5 625-639

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