U.S. PAIN FOUNDATION

U.S. PAIN FOUNDATION POSITION STATEMENT – BIOSIMILARS AND BIOLOGICS

U.S. Pain Foundation agrees that biosimilars are exciting and promising for the future treatment of many conditions. Safely bringing them to market requires adequate study prior to FDA approval, careful dispensing to protect patient safety, and monitoring for potential harm in patients. U.S. Pain Foundation is committed to ensuring speed doesn't supersede safety.

Biologics are medications produced from living cells that have proved remarkable in treating debilitating conditions like rheumatoid arthritis, ulcerative colitis, psoriasis, and even some cancers. Biosimilars are structurally similar to biologics and will be used to treat some of the same illnesses. Unlike generic medicines that have an identical chemical makeup to their brand-name counterparts and are inexpensively duplicated, biosimilars are complex substances created from living organisms. They are sensitive to minor changes in the manufacturing process and have the potential to be less effective or cause more side effects compared with the original biologic.

When focusing on policy surrounding the use of FDA approved biosimilar and interchangeable biologic products, patient safety and transparency are of utmost concerns. Substitution should occur only when the FDA has designated a biologic product as interchangeable. Only in this situation can patients and their physicians be assured that all reasonable efforts have been undertaken to assess the possible adverse effects on a patient, in terms of diminished safety or effectiveness, when one biologic product is substituted for another. We also believe in the power of the patient and physician relationship. The prescribing physician is in the best position to evaluate a patient’s treatment history and options, and thus it is important for the treating physician to be able to designate exactly which product he/she believes should be dispensed to the patient. The prescribing physician, as well as the patient, should also be notified of a substitution.

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By enacting comprehensive biosimilar substitution laws, states can increase access to this new age of medicines and do it in a safe, reliable and consistent way for patients and physicians. It is essential that safeguards be in place to ensure that patients' therapies are not indiscriminately switched because of cost, insurance considerations, or other factors.