U.S. PAIN FOUNDATION

U.S. PAIN FOUNDATION POSITION STATEMENT – OFF-LABEL PRESCRIBING

U.S. Pain Foundation believes that off-label prescribing should be at the sole discretion of a health care provider, not an insurer. Furthermore, it should be based on clinical, not cost, considerations. Forced off-label prescribing requires patients to try and then fail on prescription medicines that are not approved by the Food and Drug Administration (FDA) for the treatment of their medical condition – before granting access to FDA-approved options.

Requiring patients to try and fail on one or more medications not indicated for treating a particular medical condition can jeopardize patient health and well-being by: (1) prolonging suffering when access to appropriate care is delayed, and (2) subjecting patients to unintended consequences associated with exposure to medications that may not have been well studied for use in treating a particular medical condition and / or in specific patient populations.

For example, patients suffering from extremely painful conditions such as neuropathy and fibromyalgia are being required to try, and fail, on medications not approved by the FDA for these conditions, before they will be covered for approved drugs. Under these protocols, a patient must first pay for, take, and fail on one, sometimes more, medications both not recommended by their health care provider and not indicated for their condition. After suffering through the health and financial pains of the failure process, they can then obtain coverage for the medication recommended by their health care provider and indicated by the FDA for their condition.

The decision to prescribe off- label requires extensive medical training, clinical experience, and direct knowledge of a patient's medical history, all which is best understood by a patient's own healthcare provider.