Background

When the federal Food and Drug Administration (FDA) approves drugs, it requires pharmaceutical companies to list the approved uses for the drug on the package label. Some drugs and medications are also beneficial in treating symptoms and illnesses that are not listed on the drug’s label. Physicians often prescribe the drug “off-label” for symptoms and/or illnesses not approved by the FDA. Assemblymember Loni Hancock (D-Berkeley) wants to assure that every patient who receives a prescription for an “off-label” drug is also provided full and complete information about the medication so that the patient is able to make an informed health care decision and decline use of the drug if he/she so wishes. In order to assure full disclosure about the drug that is being prescribed, she introduced AB 2856 that will require physicians and surgeons to obtain informed consent from a patient before prescribing, administering, or furnishing off-label use of prescription medications. The bill also specifies what information must be provided to the patient.
What Information Must the Physician Give the Patient?
AB 2856 requires physicians and surgeons to verbally provide the following information to patients about each medication that is prescribed for “off-label” use:

- The medication is being prescribed to treat a symptom or illness that is not approved for that medication by the federal Food and Drug Administration.
- The significant risks of the medication, including the medication's adjuvant (an additive that increases the effectiveness of medical treatment).
- The nature, degree, duration, probability of side effects and the degree to which the side effects of the medication may be controlled.
- A description of the effect of the medication on the human body.
- The dosage that is medically necessary to treat the patient's condition.
- The median age group for which the medication is prescribed.
- Available and appropriate medical alternatives to the medication and the reasons the physician and surgeon recommend the medication instead.
- That there is no consensus among medical experts as to the effectiveness of the medication for its “off-label” use.

Impact of AB 2856 for People with Neurological Conditions

Many neurological diseases are treated with drugs that are used off-label. Generally, these drugs are used to treat symptoms or conditions associated with the disease, but not specifically approved for that disease. *(A list of some of the drugs that are used off-label for various neurological conditions is attached.)*

While the Alliance supports the need and right to be informed of vital information about all drugs and treatments, AB 2856’s requirement to provide all-inclusive information to patients goes too far. Current law requires that physicians explain medical procedures and treatments to patients before administering them. People with neurological conditions have long-term relationships with their physicians and the existing law has proven effective in their ability to obtain necessary information on drug side effects and risks, without compromising the ability to receive medications.

In addition, physicians have raised concern about the amount of time and the extensive information they would be required to provide to patients when writing prescriptions. They contend that providing an extensive explanation of each drug used off-label for a patient, as
required in AB 2856, would necessitate a lengthy office visit, which doctors say is not possible both in terms of time and reimbursement of the cost of the visit. Since doctors may not be willing or able to spend the time to meet the requirements of AB 2856, they may choose not to prescribe the drug. Additionally, there may be cases, such as stroke, where informed consent cannot be obtained and therefore, patients would be ineligible for treatment with a drug used off-label.

The California NeuroAlliance believes that the extensive information required for informed consent contained within AB 2856 would unnecessarily create a barrier in accessing the most effective medications available to treat these life-altering diseases and will undermine the Alliance’s highest priority of quality patient care.