



American Cancer Society
Cancer Action Network
825 Brook Street
1-91 Tech Center
Rocky Hill, CT. 06067
(203)-379-4850
www.aescan.org

**Insurance and Real Estate Committee
March 3, 2015
American Cancer Society Cancer Action Network Testimony**

SB 418 (RAISED) AN ACT CONCERNING OFF-LABEL PRESCRIPTION DRUGS.

The American Cancer Society Cancer Action Network (ACS CAN) supports SB 418, An Act Concerning Off Label Prescription Drugs. SB 418 requires insurance companies to provide coverage of off label prescription drugs provided these drugs are recognized for such treatment by compendia and peer reviewed medical literature, as enumerated in the bill.

New uses of older generic medications are sometimes found and there is often medical evidence to support the new use. However the makers of the drugs have not put them through the formal, lengthy, and often costly studies required by the FDA to officially approve the drug for new uses. When a drug is used in a way that is different from that described in the FDA-approved drug label, it's said to be an "off-label" use.

Off-label drug use is common in cancer treatment because:

- Some cancer drugs are found to work against many different kinds of tumors.
- Chemotherapy treatments often combine drugs. These combinations might include one or more drugs not approved for that disease. Also, drug combinations change over time as doctors study different ones to find out which work best.
- Cancer treatment is always changing and improving.
- Oncologists (cancer doctors) and their patients are often faced with problems that have few approved treatment options.
- Oncologists and their patients may be more willing to try off-label drugs than other medical specialties.

Studies have reported that about half of the chemotherapy drugs used are given for conditions not listed on the FDA-approved drug label. In fact, the National Cancer Institute (NCI) has stated, "Frequently the standard of care for a particular type or stage of cancer involves the off-label use of one or more drugs."

Actual off-label use is likely much higher than estimated because chemotherapy is only one aspect of cancer treatment. Studies have yet to look at all the drugs used in cancer treatment, such as anti-nausea drugs and pain medicines.

Off-label use can vary greatly from one doctor to another. It depends on the doctor's

preferences, knowledge, and past patient experiences. Two of the biggest barriers are lack of insurance coverage and lack of information about how to best use the drug beyond what was approved.

The most reliable and easy-to-find source of information available to health professionals, caregivers, and patients is the drug label. But the label can only contain the information that has been approved by the FDA, and it does not mention off-label uses.

The medical literature reports clinical trials, including those that are not part of the FDA approval process. This is the main source of off-label use information, although treatment guidelines may also offer options that include off-label use. Treatment guidelines are based on information from medical literature, including clinical trials, and recommend standard ways to treat certain diseases.

Lack of information on off-label drug use and outcomes may also put patients at a higher risk for medication errors, side effects, and unwanted drug reactions. It is important that the patient and doctor talk about the possible risks of using the drug and weigh them against the possible benefits.

SB 418 removes barriers and provides doctors patients with more options. We urge a Joint Favorable report from this committee.

ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society that supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem.

Bryte Johnson
Government Relations Director
American Cancer Society Cancer Action Network

#####