



Testimony presented by Ken Yanagisawa, M.D.

In Insurance and Real Estate Committee

On

March 3, 2015

SB 418 AN ACT CONCERNING OFF-LABEL PRESCRIPTION DRUGS.

Good Afternoon Senator Crisco, Rep. Megna and other distinguished members of the Insurance and Real Estate Committee. I am Ken Yanagisawa, MD, a board certified otolaryngologist practicing in Hamden, Milford, Ansonia and the New Haven area. I am here to represent the thousands of physicians and physicians in training who are in the state medical society and the over 1000 physicians in the medical specialties of Dermatology, Ophthalmology, Otolaryngology and Urology.

On behalf of this group of dedicated physicians, we appreciate the efforts of this committee for bringing this important issue of off label prescription drug coverage up for consideration and would like to request that any bill moving forward include language consistent with the American Medical Associations standards on off label drug coverage specifically with regard to the language addressing medical necessity determinations which should be based on the medical opinion of the physician for his/her patient and that the peer review journals fit the criteria by the AMA criteria for such peer review journals.

Many examples exist and we expect more to be forthcoming as the insurance industry reacts to the economic pressure of the marketplace with regard to the coverage of medications. One that has effected ophthalmology is the use of the dry eye medication, Restasis, a product that has been a godsend for millions of people afflicted by chronic discomfort caused by age related changes in tear production and quality. Restasis works best in the earliest stages of dry eye, often bringing complete relief with just twice a day use, while at the same time forestalling the development of more severe disease. Unfortunately, many insurance companies have taken the stand that it can only be used in the most severe forms of dry eye where it offers little if any benefit. Even worse, they will

not cover the off-label use of Restasis for chronic ocular inflammatory surface disease and allergy in children where it can work wonders as a virtually risk free substitute for steroids which carry the very real risk for developing glaucoma and cataracts.

This is not good medicine. It is medical decision making outside the exam room and severed from the expertise, experience and judgment of physicians. It is medical decision making by non-physicians. It is medical decision making on the basis of economics at the expense of quality health care. No drug company can submit every product it develops to the rigors of FDA testing for every imagined application, let alone those applications and uses that are conceived or serendipitously discovered afterward. Federal law, in recognition of this inevitable fact, permits physicians to use drugs off-label, and thank goodness or we would not be where we are today in healthcare. Medical decision making must remain the domain of physician and patient alone if we are to preserve high quality health care. Economic considerations will always play a role, but they must not dominate the decision making process. Following the well-established and carefully conceived AMA guidelines for off-label use will accomplish that purpose.

Thank you for your consideration