Eisai Inc.

September 23, 2016

Mr. Jim Freeburg
Office of Insurance Commissioner
P.O. Box 40255
Olympia, WA 98504

Via Email: rulesc@oic.wa.gov

Re: Draft of Proposed Amendment to the rule regarding Prescription Drug Substitution Processes; Rule 2016-22

Dear Mr. Freeburg:

I am writing to you on behalf of Eisai Inc. (Eisai), to offer comments to the draft of proposed rules revising insurance requirements for prescription drug substitutions. Eisai believes it is critical that these rules provide a standardized review period for all exceptions and a uniform submission form for the "standard exceptions" or "prior authorization" of prescription drugs. Ensuring efficient patient access to needed medicines should be the primary goal of any new regulations.

Eisai believes that physicians should have the ability to use the full portfolio of medical therapies available to them to treat their patients. Prescribers and/or pharmacists should have the right to require the use of a drug when it is deemed medically necessary by the medical professional for their patient.

At Eisai Inc., *human health care* is our goal. We give our first thoughts to patients and their families, and helping to increase the benefits health care provides. As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., we have a passionate commitment to patient care that is the driving force behind our efforts to help address unmet medical needs. We are a fully integrated pharmaceutical business with discovery, clinical, manufacturing and marketing capabilities. Our key areas of focus include oncology and specialty care (Alzheimer's disease, epilepsy and metabolic disorders). To learn more about Eisai Inc., please visit us at www.eisai.com/US.

Prior authorization requests are becoming more complex and many states are revising statutes to standardize the information needed and time frame for review of them. We urge Washington to follow the lead of other states to put patient health in the forefront of decision making. Those states have passed uniform prior authorization laws with decision time frame windows as short as 2-business days, while at least 8 states have passed "real-time" electronic prior authorization decisions. If the shorter time-frame and standardized simplified form can be successfully implemented in states such as Texas, Colorado, Oregon, Massachusetts, and Minnesota*, Eisai believes insurers ought to be able to meet these same requirements in Washington State. This is why Eisai supports changing the draft of the proposed rule to encompass a shortened decision time-frame to 48-hours or 2-business days from the time of the request.

* These are just some of the states that have implemented Uniform Prior Authorization forms.

However, if the rule is not changed, Eisai recognizes it is still a vast improvement over existing regulations.

Patients awaiting new therapies should never be forced to wait more than 48-hours to find out whether they can receive the treatment their physician orders, especially those with life-threatening diseases such as cancer. According to a 2013 article published in the *American Journal of Managed Care*, 93% of the 47 major health plans surveyed regularly use prior authorization on oncology products. The same article points out that more than three-fourths of those payers (encompassing more than 100 million patient lives), "place at least some reliance on 'rigid' PA."[1] Cancer patients should not be made to feel their lives are in the balance because of an administrative procedure. Whether it is for a prior authorization request or a "standard exceptions request" the result is the same, delayed patient access to care.

Furthermore, this 48-hour or 72-hour, whichever is included in the final rule, automatic approval of a prior authorization or "standard" exceptions request" is essential for patients that have epilepsy or take orphan drugs. Eisai has a commitment to patients fighting epilepsy. Approximately 30% of all epilepsy patients still do not have control of their seizures.[2] Epilepsy patients frequently must take multiple medicines in order to control their seizures, so physicians must have flexibility to tailor treatment regimens accordingly, rather than prescribe to the cookie-cutter mandates of a preferred drug list or formulary established by a health insurer that does not always have intimate knowledge of a patient's medical history or needs. Uncontrolled seizures can decrease patients' quality of life, potentially endanger patients' lives, and increase health care costs through increased hospitalizations and doctor's visits.

Thank you for the opportunity to comment on this draft revision of the procedures for prescription drug substitution processes. If you or your staff have any questions or would like to discuss Eisai's comments further please contact me at jack_geisser@eisai.com, at 551-579-2793, or at 202-347-7253.

Sincerely,

Jack Geisser
Associate Director, State Policy

[1] Fox, Lisa A., "Managed Care Restrictions: Barriers to Product Use in Cancer Care." *The American Journal of Managed Care*, January/February 2013, pgs. SP24-SP25.

[2] Ranjani Manjunath, Pierre Emmanuel Paradis, Hélène Parisé, Marie-Hélène Lafeuille, Brian Bowers, Mei Sheng Duh, Patrick Lefebvre, and Edward Faught; "Burden of uncontrolled epilepsy in patients requiring an emergency room visit or hospitalization;" *Neurology* October 30, 2012 79:1908-1916; published ahead of print October 17, 2012