# Eisai Inc.

August 17, 2012

Ms. Danielle Holahan
New York Health Benefit Exchange
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

**Via Email: exchange@health.state.ny.us**

**Re: Selection of Benchmark Plan and Essential Health Benefits**

Dear Ms. Holahan:

I am writing to you on behalf of Eisai Inc. (Eisai), to formally submit comments regarding the benchmark plan options and essential health benefits (EHB) as examined by the New York Health Benefit Exchange, and as delineated by the federal *Patient Protection and Affordable Care Act* (ACA). Eisai believes it is essential that any benchmark plan that would ultimately be used to establish the EHB ought to ensure access to the most comprehensive pharmaceutical benefit possible while balancing the need for affordable copayment or cost-sharing requirements. Moreover, any chosen plan should have a benefits package and pharmaceutical benefit that incorporates all-encompassing chronic illness prevention, management, and treatment, including that of obesity and management of overweight patients.

As a research-based bio-pharmaceutical company, Eisai is proud of its *human health care* (*hhc*) mission to give first thought to patients and their families and to increasing the benefits that healthcare provides. Eisai's U.S. commercial presence was established in 1997 with the launch of Aricept® for Alzheimer's disease. Today, Eisai's U.S. portfolio has grown to include a broad spectrum of treatments for gastrointestinal disorders, epilepsy, and prevention of deep vein thrombosis as well as several oncology and supportive care products. Of these, four medicines carry "orphan drug" status, with patient populations of fewer than 200,000 people. These include three oncology treatments, as well as, BANZEL®, an approved medication for the adjunctive treatment of Lennox-Gastaut Syndrome (LGS) in children 4 years and older, and adults.

**Choice in Drug Therapy**

While the ACA includes pharmaceutical coverage as part of the EHB package, there is no guarantee that the coverage will be adequate unless the state chooses a benchmark plan with robust pharmaceutical benefits. While current proposed federal guidelines indicate that they will permit a formulary class to have only one drug in a class, this does not guarantee adequate coverage to patients, particularly those that may require multiple prescription therapies to address their medical needs. While Eisai believes that physicians should always have access to the full portfolio of treatments available to help fight disease in their patients, some conditions are more sensitive than others and should never be restricted in terms of the number of drugs a physician has to choose from. For example, patients with epilepsy frequently need

to take several adjunct medicines, in addition to the originally prescribed treatment, just to gain control of breakthrough seizures. Eisai's prescription drug BANZEL®, is an adjunctive treatment for LGS in children 4 years and older, and adults. LGS is an orphan condition that can be debilitating for those afflicted, sometimes having upward to 100 seizures a day. Having one medication in a drug class such as an anti-seizure medication would not suffice for these patients.

Cancer is another example of a disease that should never be confined to the one drug per therapeutic class standard, as clearly demonstrated by Congress in creating a protective class for cancer drugs under the *Medicare Modernization Act* (MMA) (P.L. 108-173). Potential limitations on the physician and patient's choice of cancer medications within a drug class could seriously jeopardize a patient's survival. Physicians must have access to a thorough portfolio of drugs to treat their patients' medical conditions.

**Treatment and Management of Obesity and Chronic Illness**

According to the Centers for Disease Control, the incidence of obesity in the United States has risen to more than 35%. This means more than one-third of all adults are considered obese (defined as a body mass index (BMI) of 30 or above). Subsequently, approximately 25% of New York adults are considered obese.[1] Obesity is linked to a variety of chronic illnesses, including diabetes, heart disease, stroke, sleep apnea and cancer. These ailments not only jeopardize the lives of patients, but destroy their quality of life, as well as drain valuable health care resources from the state and businesses in the overall economy. In particular, the disease of obesity is costing the country billions of dollars per year. In 2008, approximately $147 billion was spent on obesity and obesity-related care. These estimates are expected to rise along with the growing crisis of obesity.[2]

The State of New York is currently considering options for a benchmark plan, which in turn would establish the confines of what the EHB would be until a review can again be conducted in 2016. Because of the approach that the Centers for Medicare and Medicaid Services (CMS) have taken, benchmark plans should encompass existing state mandated benefits without incurring costs to the state. This will ensure patients are protected in a manner consistent with the minimum standards of New York law when the ACA was passed. However, there are other options that are important to consider.

Many plans offer varying degrees of coverage for weight-related management and treatment services. Approaches that do not include all options, including pharmacotherapy, will be less than sufficient in the current and future climate in which approximately 25% of New York residents are considered obese. Unfortunately, the EHB benefit comparison appears to only compare two weight-related benefits; weight-loss programs, and gym membership. Often plans offer nutritional counseling, but many place limits on counseling, and then make a leap to treat patients who are morbidly obese. Some plans lack coverage for, or place severe restrictions on, anti-obesity drugs to assist people in losing weight before they become morbidly obese. Plans then will often cover bariatric surgery as treatment for what is generally considered the "morbidly obese." "Morbid obesity" would typically be measured as a BMI greater than 40, according to the Agency for Healthcare Quality Research.[3]

[1] http://www.health.ny.gov/prevention/obesity/
[2] Finkelstein E.A., Trogdon J.G., Cohen J.W., Dietz W. (2009) Annual medical spending attributable to obesity: payer- and service-specific estimates. *Health Affairs*. 28: w822-w831.
[3] http://www.ahrq.gov/research/obesity.htm

With the "obesity" measure thresholds beginning with a BMI of 30 or greater, there are few options until "morbidly obese" patients need care, which would deem them eligible for bariatric surgery. Prior to a patient becoming eligible for bariatric surgery, the only intervention that many plans provide are recommendations in changing diet and exercise (i.e., nutrition counseling), with some providing some additional comprehensive counseling. Another option is for coverage of weight-loss management programs, which many, but not all, plans now cover. Unfortunately, no plans in the comparison cover weight loss programs in their benefits. Any chronic disease program for overweight or obese patients that includes prevention, management, and treatment should include all elements of treatment, including possible pharmacotherapies.

The ACA requires coverage of preventive, wellness, and chronic disease management as part of the "essential health benefits," however, the extent of that coverage is uncertain. The inclusion of certain diseases and the term "chronic disease" is not well-defined. Obesity is a chronic illness and should be treated as such. Qualified health plans may have a variety of benefits that could fall within their definition of "management and treatment" of chronic disease. These benefits could exclude pharmacotherapy. Therefore, interpretations of what may include treatment for overweight or obese patients as a disease or a medical illness may vary throughout the time a patient may have the disease. Moreover, plans will likely have differing variations of benefits that fall under this sub-heading depending upon considerations of the actuarial value. Overweight and obese patients require treatment through all stages of their illness to formally manage the condition.

While it has been several years since new pharmacotherapies have been introduced into the market for weight loss, there are new medicines recently approved to help bring hope to patients suffering from obesity. Because the benchmark plan, and in turn the EHB will not be revisited until 2016, it is imperative that New York choose a benchmark plan in 2012 that will encompass all innovative treatments or at least allow coverage for future treatments prior to 2016. Obesity is a current and ongoing crisis, with immediate cost implications that should not be ignored for an additional four years.

Thank you for the opportunity to comment on the benchmark plan and essential health benefits. 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 or at 551-579-2793.

Sincerely,

/s/

Jack Geisser
Associate Director, State Policy