**Switching of Name-Brand thyroid Hormone to a Generic Preparation**

We have consistently had difficulty with the switching of name-brand thyroid hormone to generic preparation by pharmacies as well as refusal to pay for name-brand thyroid hormone by insurance companies. The following are reasons why we insist that our patients use name-brand thyroid hormone, as opposed to generic levothyroxine preparation:

A pharmacovigilance study conducted by The American Association of Clinical Endocrinologists (AACE), The Endocrine Society (TES), and the American Thyroid Association (ATA) in 2007 resulted in reporting of 160 adverse events related to switching sources of levothyroxine, 85% of which were attributed to the pharmacies. This number of adverse events is 3 times higher than the number of reported events in 1997, prompting the FDA to require all levothyroxine products be approved under a new drug application.

Currently, the FDA determines bioequivalence of a medication by employing Area Under the Curve (AUC) and maximum concentration (Cmax) determinations in normal subjects with normal thyroid function. Studies of bioequivalence reported in Thyroid 2004;14:191-2004 by Blakesley V, et al, show that in a finely tuned hormonal feedback system such as the thyroid, the FDA’s methodology may lead to the conclusion that preparations that differ by as much as 33% are equivalent. “Correcting” for baseline values may reduce the difference detected to less than 25%, but still greater than 12.5%. This means that your dose of thyroid hormone could be too much, or not enough to normalize your thyroid studies. As a result of the inadequate studies that the FDA uses to determine bioequivalence, AACE, TES and the ATA all recommend that patients should be maintained on the same “name-brand” levothyroxine product. The significant variability in bioequivalence of the multiple generic levothyroxine preparations may result in a significant impact in the clinical setting, especially among the elderly with cardiac disease or pregnancy.

In following “current best practice” and keeping with current recommendations by the AACE, TES and the ATA, we currently insist that our patients be allowed to use name-brand thyroid hormone rather than a generic preparation. We do not approve of potential “switching” of a patient’s levothyroxine preparations to which ever manufactured levothyroxine product happens to be cheapest for the insurance company or the pharmacy at that time. Avoidance of potential for clinical adverse reactions associated with the highly variable preparations of generic levothyroxine far outweighs their cost-saving potential.