THE ENDOCRINE SOCIETY

4350 EAST WEST HIGHWAY, SUITE 500 ■ BETHESDA, MARYLAND ■ 20814-4426 ■ TELEPHONE 301.941.0200 ■ FAX 301.941.0259 ■ www.endo-society.org

TESTIMONY OF
**RICHARD A. DICKEY, M.D.**
**ENDOCRINOLOGIST**

**CLINICAL AFFAIRS COMMITTEE**
**THE ENDOCRINE SOCIETY**

REGARDING
**LEVOTHYROXINE BIOEQUIVALENCE**

**BEFORE THE**
**FOOD AND DRUG ADMINISTRATION**
**ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE**

**March 13, 2003**

# TESTIMONY OF RICHARD A. DICKEY
# THE ENDOCRINE SOCIETY

Good afternoon:

My name is Richard Dickey and I am a newly retired physician. I practiced endocrinology for over 30 years, and still practice as a volunteer at a local indigent clinic. I also continue to teach at Wake Forest University School of Medicine.

I am pleased to testify before you today on behalf of The Endocrine Society, where I serve on the Clinical Affairs Committee.

The Endocrine Society, founded in 1916, consists of over 11,000 physicians and scientists dedicated to research and patient care in the field of endocrinology. Our clinician members are involved in the daily treatment of patients with hormone disorders including thyroid disease. We publish four peer-reviewed journals: *Endocrinology*, *Endocrine Reviews*, *The Journal of Clinical Endocrinology and Metabolism*, and *Molecular Endocrinology*.

I have no current affiliation (financial or other) with the manufacturer of any levothyroxine product. The Endocrine Society receives financial support in the form of unrestricted educational grants from several manufacturers of thyroid drugs, including: Abbott, King, and Watson.

It is our dedication to the treatment of patients with thyroid disorders that brings us to this hearing today. In the interest of time, I will not go into the manner by which the FDA tests for bioequivalence, as you have heard from leading thyroid experts today on that matter. Instead, I will focus my comments on the issue of direct patient care. Testing for bioequivalence is important and we support the FDA in their diligence. However, when testing hormone-based drugs, bioequivalence data needs to be supplemented by therapeutic data.

Bioequivalence does not equal therapeutic equivalence. Bioequivalence testing does not currently include a mechanism for factoring in a baseline correction for endogenous hormone production in the patients tested, and therefore, therapeutic differences can be missed. These differences are clinically significant when treating patients with thyroid disorders such as thyroid cancer and hypothyroidism.

Endocrinologists are trained and experienced in caring for patients with complicated thyroid disorders and, regardless of bioequivalence data, realize that levothyroxine products are not interchangeable. Our concern is that without any supplemental information, physicians without the same level of specialty training in endocrinology may assume that bioequivalence does equal therapeutic equivalence. In the patient, the consequences of important differences in bioequivalence and therapeutic equivalence between products become obvious over time, as demonstrated in the health of the patient. The differences can even result in serious complications, complications that could have been avoided.

In conclusion, I would like to again point out that our participation today was in the interest of the patient. For your information, a disclosure statement regarding those clinicians involved in the review of this issue and the development of this testimony, as well as financial relationships to the manufacturers of thyroid products, is included in our written testimony provided to each of you.

I would like to officially offer The Endocrine Society's assistance if we can be of any future service to this committee or related committee(s) of the FDA.

Thank you.

Disclosure:
The Clinical Affairs Committee of The Endocrine Society reviewed the issue of levothyroxine bioequivalence and assisted in the development of this testimony. Committee members with a dual commitment (conflict of interest) did not participate in the discussion. Richard Dickey has no current affiliation (financial or other) with the manufacturer of any levothyroxine product.

The Endocrine Society receives financial support in the form of unrestricted educational grants from several manufacturers of thyroid drugs, including: Abbott, King, and Watson.