



AMERICAN  
THYROID  
ASSOCIATION

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2003-2004

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Clark T. Sawin, M.D.  
Washington, D.C.

October 28, 2003

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Los Angeles, California

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Worcester, Massachusetts

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Paul W. Ladenson, M.D.  
Baltimore, Maryland

Dockets Management Branch, HFA-305  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

**Directors**

Peter A. Singer, M.D.  
Los Angeles, California

To whom it may concern:

Jeffrey R. Garber, M.D.  
Boston, Massachusetts

Stephanie L. Lee, M.D., Ph.D.  
Boston, Massachusetts

Please add the attached letter to the docket 2003P-0387

John C. Morris, III, M.D.  
Rochester, Minnesota

Rebecca S. Bahn, M.D.  
Rochester, Minnesota

Donald L. St. Germain, M.D.  
Lebanon, New Hampshire

Steven I. Sherman, M.D.  
Houston, Texas

Sincerely,

Bryan R. Haugen, M.D.  
Denver, Colorado

Sandra M. McLachlan, Ph.D.  
Los Angeles, California

Barbara R. Smith, CAE

**Executive Director**

Barbara R. Smith, CAE

Executive Director

**Headquarters Office**

American Thyroid Association  
6066 Leesburg Pike, Suite 650  
Falls Church, Virginia 22041  
Phone: 703 998-8890  
Fax: 703 998-8893  
E-mail: bsmith@thyroid.org  
Web: www.thyroid.org

2003P-0387

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Phone: 703 998-8890  
Fax: 703 998-8893  
E-mail: [bsmith@thyroid.org](mailto:bsmith@thyroid.org)  
Web: [www.thyroid.org](http://www.thyroid.org)

October 1, 2003

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Docket 2003 P-0387

Janet Woodcock, M.D.  
Director, Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane, HFD-240  
Rockville, MD 20857

Dear Dr. Woodcock:

I am writing on behalf of Dr. Peter Singer, Immediate Past President of the American Thyroid Association; Dr. E. Chester Ridgway, President of the Endocrine Society; and Dr. Donald Bergman, President of the American Association of Clinical Endocrinologists. We thank you for the thoughtful manner in which you and your staff recently listened to the concerns of our societies, physician members, and patients regarding dose precision and bioequivalence standards for levothyroxine sodium formulations.

We are heartened by the commitment that you made to plan and hold a workshop of sufficient depth and duration to address all of the relevant issues: bioequivalence testing baseline correction, optimal test subjects, and acceptable confidence limits; and TSH as a pharmacodynamic measure. We also support your interest in designing a crossover chronic thyroxine therapy trial with serum TSH as an outcome. We agree with you that a properly designed and executed study could address the fundamental concerns that physicians and their patients have about optimizing the safety and effectiveness of thyroxine therapy. We offer our assistance in designing, implementing, and interpreting the results of such a study.

Because of the concerns that we all share regarding thyroxine dose precision and limitations in the current bioequivalence standard, we ask that 1) FDA suspend approval of new formulations until these matters are resolved, and 2) FDA not make a final decision regarding equivalence testing until it has received further input from experts at the workshop that you proposed.

As you requested, we will send to you a draft agenda and list of potential contributors to the workshop program that you have proposed.

Dr. Janet Woodcock  
October 1, 2003  
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Although I am no longer Secretary of the American Thyroid Association, I have become president-elect and our new president, Dr. Clark Sawin, has asked me to remain the primary point of contact between the three societies and FDA. We look forward to hearing from you.

Sincerely,



Paul W. Ladenson, M.D.  
President-Elect, American Thyroid Association

PWL:sr

xc: Dr. Peter Singer, Past President, American Thyroid Association  
Dr. Clark Sawin, President, American Thyroid Association  
Dr. Gregory Brent, Secretary, American Thyroid Association  
Dr. E. Chester Ridgway, President, Endocrine Society  
Dr. Donald Bergman, President, American Association of Clinical Endocrinologists  
Ms. Barbara Smith, Executive Director, American Thyroid Association  
Mr. Scott Hunt, Executive Director, Endocrine Society  
Mr. Donald Jones, Executive Director, American Association of Clinical  
Endocrinologists