



Societies Hold Workshop With FDA About Levothyroxine Bioequivalence; FDA Continues With Questionable Policies

As the one-year anniversary of the Food and Drug Administration's (FDA) approval of three generic levothyroxine products as being bioequivalent to branded products passed this June, the ATA, The Endocrine Society, and the American Association of Clinical Endocrinologists (AACE) continue to voice serious concerns about FDA standards for determining the equivalence of thyroxine formulations.

On May 23, the three societies, in cooperation with the FDA, held a "Joint

Public Meeting on Equivalence of Levothyroxine Sodium Products" in Washington, D.C. The program, which included representatives of the societies, the FDA, the public, and industry, examined clinical and bioequivalence issues for levothyroxine, approaches for comparing levothyroxine products, and next steps.

Despite the data and other compelling information presented by the societies,

continued on page 10

ATA Finalizing Thyroid Nodules and Differentiated Thyroid Cancer Guidelines

The ATA Guidelines Task Force is currently finalizing practice guidelines for the management of thyroid nodules and differentiated thyroid cancer. The guidelines cover the diagnosis and treatment of thyroid nodules, the initial diagnosis and therapy of differentiated thyroid



ATA Guidelines Task Force at a recent meeting: Ernest Mazzaferri, Susan Mandel (seated), Gerard Doherty, David Cooper (seated), Richard Kloos, Stephanie Lee, Bryan Haugen, and Steve Sherman. Not pictured are Bryan McIver and Michael Tuttle.

cancer, including recommendations for surgery and radioiodine therapy, as well as long-term follow-up of the disease.

"These new guidelines will help physicians not well-versed in thyroid cancer to better manage their patients," said David

continued on page 11

President's Message



The growing strength, effectiveness, and influence of the ATA is being felt around the

country and the world. Our spring thyroid cancer meeting was widely appreciated by our members, clinicians, and scientists interested in the field; patients and their families; and the media and public at-large.

Our leadership in raising doubts about the wisdom of

continued on page 15

IN THIS ISSUE

Secretary's Report
Page 2

ATA Research Grants
Page 3

New ATA Web Sites
Page 4

Editor's Corner
Page 5

Patient Donor Brochure
Page 5

Council Meeting Highlights
Page 7

Candidates for ATA Election
Pages 8-9

ATA Spring Meeting
Pages 12-14

**13th International
Thyroid Congress**
Page 15

Important ATA Member Notices

- See ATA candidates for president-elect and directors on pages 8-9.
- ATA Membership Meeting — Wednesday, Nov. 2, 2005, 7:00 a.m., during the 13th International Thyroid Conference in Buenos Aires, Argentina.



The Frontiers in Thyroid Cancer meeting in Baltimore surpassed expectations in every category. The program began with a personal greeting, handwritten by Chief Justice William Rehnquist and read by President Paul Ladenson, followed by an outstanding keynote address by oncology researcher Bert Vogelstein. The outstanding scientific program, assembled by Program Chairs Jim Fagin and Steve Sherman, brought great content and stimulating discussion with interactions that frequently spilled over into the corridors.

The inaugural "fellows track," under the direction of Mike McDermott and Stephanie Fish, allowed fellows to attend the core meeting but also special programs, including case presentations, career planning, and special experience in thyroid ultrasound. This program was a spectacular success, generating a great deal of enthusiasm from fellows and the participating faculty.

The ATA and the American Association of Clinical Endocrinologists co-sponsored a highly successful advanced ultrasound course at the meeting. More than 40 registered for this special hands-on workshop, organized by Dan Duick and Jack Baskin. The focus of this sold-out event was on the role of ultrasound and ultrasound-guided procedures in the diagnosis and surveillance of thyroid cancer patients.

Chip Ridgway again organized and directed a highly successful one day fellows conference before the start of the thyroid cancer meeting. The content of the Frontiers in Thyroid Cancer program will be available by streaming video with CME questions developed by the Education Committee, chaired by Yehuda Handelsman. Also unveiled at the meeting were a number of initiatives being developed to better integrate and publicize clinical thyroid research, including the Roadmap for Thyroid Discovery, conceived by Paul Ladenson and designed by Matthew Kim; the Thyroid Clinical Trials web site developed by Matt Ringel, and the pharmacovigilance web site being launched in the near future.

The media impact of the meeting is still being felt with summaries in *Internal Medicine News*, *Endocrine Today*, and recent articles in *The New York Times* and *The Washington Post*. Lay involvement with the ATA continues to expand as ThyCa: Thyroid Cancer Survivors Association, Inc. held a concurrent meeting for thyroid cancer patients and their

families, a thyroid patient forum was held, and a meeting of the ATA Alliance for Thyroid Patient Education.

The ATA thyroid history program in honor of Clark Sawin and supported by the generous endowment of Leslie Sawin, has been launched. The Clark T. Sawin Historical Lecture was included in the Thyroid Cancer Frontiers program and will be a regular feature of our annual meeting program. Rita Hays has agreed to chair the History and Archives Committee and is taking a lead role in carrying forth this initiative.

We have responded to the decision of the FDA to approve generic levothyroxine as equivalent to branded products on a number of fronts. A one-day conference jointly sponsored by the FDA, ATA, The Endocrine Society, and AACE was held on May 23 in Washington, DC. The program, including representatives of the FDA and the societies, examined approaches for determining thyroxine bioequivalence and the impact of the new FDA policy. Paul Ladenson and the ATA took the lead in developing this program. A series of outstanding

The ATA has responded
in a timely and accurate
fashion to a number
of public health issues.

presentations were made from the society representatives. The FDA agreed to explore partnerships to publicize guidelines for substitutions among preparation and to discuss design of a definitive pharmacodynamic clinical study. The pharmacovigilance program, under the direction of Elliot Levy and Bryan Haugen, is ready and will provide much needed information on the clinical consequences of switching among thyroxine preparations. We continue to provide information to a large number of media outlets on the topic of thyroxine preparation equivalence. A recent story in *Prevention* magazine, with references to the ATA, featured the potential variations in generic substitutes and the impact on the patient.

Our thyroid cancer guideline task force, under the direction of David Cooper, has worked very hard to develop guidelines that are now under review. An extensive literature review was carried out by members. David and his committee, along with our professional staff, have made rapid progress on this initiative.

Our journal, *Thyroid*, made the transition to electronic manuscript submission and review on March 1, 2005. Terry Davies and his staff, along with our publisher Mary Ann Liebert, have put in a great deal of effort to accomplish this

continued on page 11



AMERICAN
THYROID
ASSOCIATION
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ATA Signal

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Four Investigators Receive ATA Research Grants

Four new research projects in thyroid function and disease are being supported by the 2005 ATA Research Grant Program.

The ATA is committed to supporting research that will hopefully translate into

In its third year of offering a research grant in thyroid cancer, ThyCa: Thyroid Cancer Survivors Association, Inc. has generously funded an additional research proposal, thereby giving two investigators

“The generosity of members, patients, industry, and other donors has enabled the ATA to award thyroid research grants of more than \$800,000 since the Research Fund was established.”

better ways to diagnose and treat thyroid disease,” said Jim Fagin, MD, Chair of the Research Committee. “The generosity of members, patients, industry, and other donors has enabled the ATA to award thyroid research grants of more than \$800,000 since the Research Fund was established.”

The 2005 ATA research grant recipients are —

- **Heike Heuer, PhD**, of the Institute of Molecular Biotechnology in Jena, Germany, for his research proposal *Generation and Analysis of Mice Deficient in the Thyroid Hormone Transporter MCT8*, and
- **Bin Xu, PhD**, of the University of Michigan, Ann Arbor, for his research proposal *Mechanism of Regulating Gene Expression by Thyroid Hormone Receptors Through RNA Binding Pathways*

They will each receive a \$25,000 grant funded by the ATA, renewable for a second year after review of status report.

ATA 2004 research grant recipients who are in the second year of their awards are **Orsolya Dohan, MD**, of the Albert Einstein College of Medicine in the Bronx, New York, for her research proposal *Regulation of the Sodium/Iodide Symporter (NIS) by Iodide*, and **Raymond S. Douglas, MD, PhD**, of Harbor-UCLA Research and Education Institute in Torrance, Calif., for his research proposal *Fibroblast Immune Activation in Graves' Disease*.

the opportunity to uncover important information to combat thyroid cancer.

Erich M. Sturgis, MD, of the University of Texas M.D. Anderson Cancer Center in Houston, has been awarded one of the grants for his thyroid cancer research proposal, *Radiation Response Genotype & Risk of Papillary Thyroid Cancer: A Case-Control Study*. **Matthias Schott, MD**, of the Heinrich–Heine University of Duesseldorf in Duesseldorf, Germany, has been awarded the other grant for his medullary thyroid cancer research proposal, *Induction of Cytotoxic Immunity in Medullary Thyroid Carcinoma by Dendritic Cell Vaccination*.

Beginning this year, ATA ThyCa Research Grant recipients will receive a \$25,000 grant renewable for a second year pending status reports.

ATA and ThyCa research awards are targeted to fund new investigators to obtain preliminary data that can lead to further work and funding from additional sources, such as the National Institutes of Health.

“The grant recipients received their awards in July to enable them to begin their research immediately,” explained Dr. Fagin. “It is anticipated that their findings will be presented at future ATA meetings, lead to high impact publications, and provide advances that will increase our understanding of thyroid diseases in a way that will benefit patients.”

Membership Renewal and Dues

Beginning in October, ATA members can pay their dues online at www.thyroid.org.

New ATA Web Sites To Be Launched

The ATA is currently developing three important web initiatives to provide valuable information and resources to patients and medical professionals about thyroid disease.

Thyroid Clinical Trials Web Site

This first-of-its-kind web site (www.thyroidtrials.org) is dedicated to providing listings and information on all current thyroid clinical trials. The web site's goal is to be the primary source of accurate Internet information for thyroid clinical trials for health care providers and patients.

"On behalf of the ATA Website Advisory Group, I am very pleased by this exciting and key addition to our web site," said Matthew D. Ringel, MD, Chair of the Advisory Group, "The addition of clinical trials information and a clinical trial search engine on the ATA web site is designed to enhance the ability of patients and physicians to quickly learn about thyroid disease-related clinical trials."

Our sister societies in the United States and worldwide will be invited to link to the site for broader exposure. The clinical trials site will be launched in September and reassessed in early 2006.

Pharmacovigilance Web Site

The ATA has developed a Thyroid Pharmacovigilance web site (www.thyroidpharmacovigilance.org) to collect information about possible adverse events or product availability problems related to thyroid hormone medications from physicians and other health care providers. The recent FDA decision to allow substitution among certain levothyroxine products has resulted in confusion among patients, pharmacists, and doctors. In some patients, changes between thyroxine formulations could theoretically be associated with adverse clinical outcomes.

"Patients are now being frequently switched between levothyroxine preparations based on FDA rulings and financial pressures," said Bryan Haugen, MD, Co-chair of the ATA's Pharmacovigilance Task Force along with Elliott Levy, MD.

Levothyroxine (LT₄) is the most commonly used medication for thyroid disease and the primary focus of this project, although data on other thyroid hormone replacement products will also be gathered.

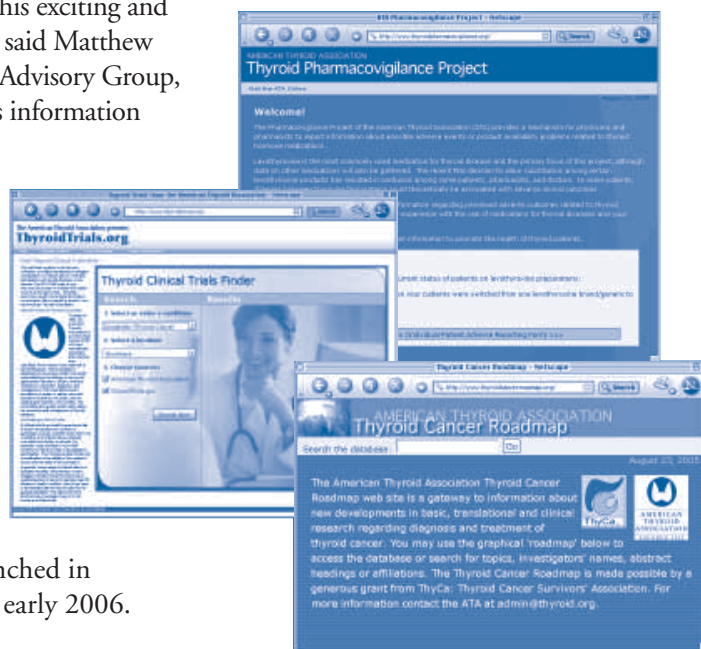
Thyroid Cancer Roadmap Web Site

The Thyroid Cancer Roadmap web site (www.thyroidcancerroadmap.org) will provide information about new developments in basic, translational, and clinical research regarding the diagnosis and treatment of thyroid cancer for professionals and patients.

"This web site will provide patients and investigators with direct access to updated information about a range of research initiatives focused on the diagnosis, evaluation, and treatment of different types of thyroid cancer," said Matthew I. Kim, MD, Assistant Professor of Medicine in the Division of Endocrinology and Metabolism at Johns Hopkins University School of Medicine and a consultant to the ATA for this project.

The new web site will include descriptions of research studies as well as links to institutional web sites, clinical trial web sites, abstracts of current publications listed in PubMed, and pdf files of materials available in the public domain.

There are future plans to link this web site with the clinical trials web site. The web site is co-sponsored by ThyCa: Thyroid Cancer Survivors' Association, Inc., and the link will reside on its web site as well.



www.thyroidtrials.org

www.thyroidpharmacovigilance.org

www.thyroidcancerroadmap.org

Editor's Corner: What's new in thyroidology?



Rebecca S. Bahn, MD, ATA Signal Editor *Is there anything promising on the horizon for treatment of patients with anaplastic thyroid carcinoma?*

While anaplastic (undifferentiated) thyroid cancer is rare, it accounts for more than half of all deaths from thyroid malignancy. Currently available treatment options, including surgical debulking, radiation, and chemotherapy, provide limited benefit as reflected in median survival of between three to nine months.

What is known about the biology of this aggressive cancer, and how might this information help our patients? Several lines of evidence suggest that anaplastic carcinomas evolve from preexisting, well-differentiated papillary or follicular thyroid cancers. Specific genetic point mutations have been identified in both anaplastic and well-differentiated carcinomas, including activating mutations in BRAF and RAS. In contrast, other mutations, including CTNNB1 (b-catenin) and inactivating mutations in *p53*, are unique to anaplastic carcinomas. These mutations appear, therefore, to be involved in tumor dedifferentiation and, as such, may be attractive candidates for novel gene therapy. Indeed, results of *in vitro* studies of anaplastic cancer cell lines are promising in this regard.

In a recent study published in the *Journal of Clinical Endocrinology and Metabolism*, Rosanna Sorrentino and colleagues in Naples, Italy, and the United Kingdom identified the protein Aurora B as being important in the progression of anaplastic thyroid carcinoma¹. The serine/

threonine protein kinases of *aurora* family genes are regulators of mitotic cell division that exhibit unique tissue and cell cycle expression profiles. Overexpression of Aurora B has been documented in several human cancers and leads to chromosomal instability and cell aneuploidy. Sorrentino *et al.* showed that anaplastic thyroid carcinoma cell lines and surgical tissue samples from patients with this tumor express especially high levels of Aurora B. Furthermore, they demonstrated that inhibition of this protein in cultured carcinoma cells resulted in slower tumor growth following their injection into athymic mice.

As noted in the accompanying editorial by Yuri Nikiforov², the development of inhibitors of protein kinases as potential anti-tumor therapy is under active investigation, bolstered by the success of the protein kinase inhibitor Gleevec (imatinib) in the treatment of chronic myelogenous leukemia. Although yet to be tested clinically, several specific Aurora kinase inhibitors have recently been developed. While much remains to be learned regarding their action, Sorrentino's recent findings suggest that these agents may prove effective in slowing the proliferation of anaplastic thyroid cancer cells. If so, the door will be opened to clinical trials of these or related compounds in patients with this lethal thyroid malignancy.

1. Sorrentino R, Libertini S, Pallante PL, et al. *J Clin Endocrinol Metab* 90:928-935, 2005.
2. Nikiforov YE. *J Clin Endocrinol Metab* 90:1243-1245, 2005.

Enlist Your Patients to Raise Funds for Thyroid Research and Education



**Brochure
Now
Available!**

One of the ATA's high priorities is to expand our resources to fund new research and educate patients about thyroid diseases. To achieve this goal, the ATA Development Committee is proactively reaching out to thyroid patients and their families to support these efforts by creating a donor brochure.

This new ATA brochure describes ways that patients and their loved ones can contribute to efforts to prevent, diagnose, treat, and potentially cure thyroid-related diseases. It also

highlights how past and ongoing research has positively affected how we live today.

In addition to this, the brochure provides information about the patient resources available on the ATA web site, as well as through our toll-free phone line and alliances with patient support organizations.

The ATA recently mailed 25 copies of the new brochure to all members in clinical practice. We encourage you to hand them out to your patients, place them in your waiting room, or distribute them in any other way you believe is effective. Please contact the ATA office at 703-998-8890 or admin@thyroid.org to receive more copies of this brochure. And thank you for your generous support of this important ATA endeavor.

ATA Welcomes New Members for 2005

Active

Cumali Aktolun, MD
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Kyu Bo Lee, MD, PhD
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Patrizio Caturegli, MD
Kenneth Ain, MD
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Stephanie Lee, MD, PhD
Bellur Prabhakar, PhD
Virginia Sarapura, MD

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Alain TAYLON, MD
John Tourtelot, MD
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Takashi Uruno, MD
Bin Xu, MD
Farhad Zangeneh, MD

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Upcoming Meetings

American Society for Bone and Mineral Research Annual Meeting

September 23–27, 2005
Nashville, Tenn.

13th International Thyroid Congress

October 30–November 4, 2005
Buenos Aires, Argentina

International Society for Clinical Densitometry Annual Meeting

February 1–4, 2006
San Diego, Calif.

2006 AAAS Annual Meeting

February 16–20, 2006
St. Louis, Mo.

ATA 2006 Spring Symposium Thyroid Health and the Environment: Threats and Effects

March 24, 2006
Washington, DC

AACE 15th Annual Meeting and Clinical Congress

April 26–30, 2006
Chicago

ENDO 2006

June 24–27, 2006
Boston

American Thyroid Association 77th Annual Meeting

October 12–15, 2006
Phoenix, Ariz.

**For more information,
visit www.thyroid.org**

ATA Executive Council Highlights

Baltimore Marriott Waterfront Hotel

At the ATA Executive Council meeting on April 14, 2005, during the ATA spring meeting, *Frontiers in Thyroid Cancer*, a variety of issues were discussed and committee reports provided, covering clinical, public health, legislative, and regulatory issues.

The Council recognized ATA staff for their hard work in organizing the spring meeting and administering the special awards and research grants. In addition, special recognition was given to Greg Brent for initiating the inclusion of the ATA fellows track at the meeting, which was a great success, as well as to Drs. Michael McDermott and Stephanie Fish for the track's outstanding organization and course direction.

The Council discussed the following projects, issues, and committee initiatives:

- ▶ As president-elect, Ernest Mazzaferri will begin to focus on patients and public participation as “Friends of the ATA” — a lay group that will have special access to online features and an affiliation with the ATA. In 2006, the National Thyroid Advisory Board will be formed to coordinate and enhance lay support at a higher level.
- ▶ The ATA thyroid history program in honor of Clark Sawin — and supported by the generous endowment of Leslie Sawin — continues to take shape. The Clark T. Sawin Historical Lecture was a memorable part of the spring meeting program — as delivered by Greg Brent — and will be a regular feature at each Annual Meeting.
- ▶ The ATA journal, *Thyroid*, made the transition to electronic manuscript submission and review on March 1, 2005. Terry Davies and his staff, along with our publisher Mary Ann Liebert, worked hard to accomplish this important step. *Clinical Thyroidology* has been secured with one-year funding from King Pharmaceuticals.
- ▶ The winter Council meeting was held at the site for the 2006 ATA Annual Meeting — the Sheraton Wild Horse Pass Resort and Spa in Phoenix. Strategic planning next steps were outlined and prioritized to make the ATA vision a reality. These plans are available online in the members only section of www.thyroid.org.
- ▶ The Council approved a reduction in dues for Associate members transitioning to Active membership status to half of full dues for the first two years and will not require an additional letter of sponsorship; however, meeting attendance and an updated curriculum vitae and personal statement will be required.
- ▶ Dues renewal continues to be a challenge and an automated credit card deduction strategy was discussed. Sign up would be available online for initiating automated monthly withdrawals. Members would be able to opt-in or opt-out of the service at any time. Donation opportunities will continue to be made available.
- ▶ The History and Archives Committee is looking for funding to interview pathophysiology awardees and transcribe the oral history. The committee will request photos of senior members and plans to develop six oral histories, for which funding will also be sought. The audiotapes of Clark Sawin's vignettes will be posted online.
- ▶ The Education Committee will perform a needs assessment and consider a teaching slide repository to expand professional education available on the web site.
- ▶ The Council endorsed the International Thyroid Hormone Resistance Conference and will offer to partner in logistical support.
- ▶ The Council discussed the importance of the transparency of any conflicts of interest of officers and Council members and mandated a summary list to be published annually in the Annual Meeting program book.
- ▶ The Laboratory Services Committee has developed a paper about cytopathology standards that is under review.
- ▶ The Council voted to broaden the range of the international asset allocation in the endowment investment policy from “0 to 7.5 percent” to “0 to 10 percent” and adjust the reporting methods for the financial funds to distinguish the endowment from operations.
- ▶ The Public Health Committee continues to monitor Health and Human Services reporting on KI, prenatal iodine use in pregnancy, the National Academy of Sciences perchlorate statement, and the coordination of a response about generic levothyroxine.
- ▶ The Clinical Affairs Committee has many initiatives in progress, including the Pharmacovigilance Task Force; best practices for physicians, patients, and pharmacists for web site posting and dissemination to pharmacists; guidelines scheduled for review, including thyroid dysfunction, thyroid function testing (under purview of Lab Services), hyperthyroidism, and hypothyroidism; and planned flow sheets and templates for physicians on the care of thyroid cancer patients, surgical findings, and ultrasound results.

Make Your Voice Heard!

Cast Your Vote for ATA's President-elect and Directors

This year's ATA election process marks four years of holding competitive elections. ATA members will once again vote to select the president-elect and new directors for the ATA Council. The ATA Nominating Committee, chaired by Susan A. Sherman, brings forth the slate of candidates, which are then approved by the ATA Council.

Candidates for president-elect are Rebecca Bahn and David Cooper. The candidates for two director positions are

Alan Farwell, Michael McDermott, Matthew Ringel, and Mary Samuels.

Active ATA members will receive a ballot in early September and are asked to return it by October 15. Results of the vote will be announced at the ATA Membership Meeting being held Wednesday, Nov. 2, 2005, at 7:00 a.m. during the 13th International Thyroid Conference in Buenos Aires, Argentina.

ATA President-elect

One-year term of office (2005–2006), followed by one-year term as president (2006–2007)

Vote for One (1)



Rebecca S. Bahn, MD

Candidate for President-elect

Rebecca S. Bahn, MD, is Professor of Medicine at the Mayo Clinic College of Medicine and a consultant in the Division of Endocrinology, Metabolism and Nutrition at the Mayo Clinic in Rochester, Minn. She also

currently serves as Head of the Office for the Advancement of Scholarship and Mentoring in the Department of Medicine.

Dr. Bahn is a member of the Executive Council of the ATA and Editor of the *ATA Signal*. She is an Associate Editor of *Endocrinology* and serves on the Editorial Board of *Thyroid*. Dr. Bahn was the basic science chair of the ATA Program Committee for the 2003 Annual Meeting and was a member of the Program Committee for the 12th International Thyroid Congress in Kyoto. She has served on the ATA Nominating, Education, and Membership committees and is an active member of Women in Thyroidology. She also served as chair of the Thyroid Research Advisory Council and was a regular member of the NIH Endocrinology Study Section from 1998–2002.

Her research efforts are devoted to the study of Graves' disease and thyroid ophthalmopathy, and her clinical practice is focused primarily on the treatment of patients with these conditions.

Dr. Bahn received her medical degree from Mayo Clinic College of Medicine and completed her internal medicine residency, fellowship training in endocrinology, and an NIH-sponsored research training fellowship at the same institution.

"The ATA has a rich tradition of which we can all be proud. I believe that the future growth and vitality of the association will depend heavily upon our ability to attract, mentor, and retain new, young, and highly qualified physicians and scientists who are truly representative of the national and international endocrine communities. In addition, I would like to see us increase our interactions and forge stronger links with other scientific disciplines and organizations whose input will facilitate the translation of scientific discovery into effective therapies for patients with thyroid disease."



David S. Cooper, MD

Candidate for President-elect

David S. Cooper, MD, is the Director of the Division of Endocrinology at Sinai Hospital of Baltimore and is Professor of Medicine at the Johns Hopkins University School of Medicine.

He serves as Editor-In-Chief for Endocrinology for *Up-to-Date*, as a Contributing Editor of the *Journal of the American Medical Association*, and as the Deputy Editor of the *Journal of Clinical Endocrinology and Metabolism*. He also serves on the ABIM Subspecialty Board for Endocrinology, Metabolism, and Diabetes.

A member of the ATA for 25 years, Dr. Cooper is the immediate past treasurer of the ATA, has served on the ATA Council, and has chaired the Public Health, Publications, and Clinical Affairs Committees. He is also chair of the ATA task force that is developing new evidence-based guidelines for the management of thyroid nodules and thyroid cancer. He is the recipient of the ATA's 2005 Distinguished Service Award.

A graduate of Johns Hopkins University and Tufts University School of Medicine, Dr. Cooper completed his internal medicine residency at Barnes Hospital/Washington University and his fellowship training in endocrinology at Massachusetts General Hospital.

"My vision for the ATA is that it be the world's preeminent voice for thyroidology and clinical thyroidologists. I also want to extend and enhance the relationship that the ATA has established with thyroid-focused patient groups."

ATA Executive Council Director

Four-year term of office (2005–2009); Vote for Two (2)



Alan P. Farwell, MD

Candidate for Director

Alan P. Farwell, MD, is Associate Professor of Medicine and Director of the Endocrine Clinic at the University of Massachusetts Medical School. He is an active clinician, teacher, and basic science

researcher. His research focus is on hormonal regulation of brain development and non-genomic actions of thyroid hormone.

Dr. Farwell has been a member of the ATA since 1990, serving on ATA committees continuously since 1997. He is currently serving a one-year appointed term on the Executive Council. A major focus of Dr. Farwell's service to the ATA has been in the area of education, initially chairing the Education Committee (1997–2000), serving as co-director of ATA/AACE workshops in San Francisco, Oakbrook Hills, and Atlanta, and chairing the Patient Education and Advocacy Committee from its inception in 2001 until last year. In the latter role, he served as editor of the web-based patient educational brochures on the ATA web site, which now average more than 3000 hits a day. As part of his commitment to that committee, Dr. Farwell has continued to serve as the chair of the ATA Alliance for Thyroid Patient Education. He also has served on the ATA's *ad hoc* Web Site Advisory Group, the Program Committee, and the Patient Education Task Force.

"Since the development of the Strategic Plan, the ATA has solidified its position as the leading voice in the study and management of thyroid disorders. This has been especially true in the patient education and advocacy arena. I believe that collaborative efforts with our sister endocrine societies and with thyroid patient advocacy groups allow the coordination of efforts that will maximize advances in knowledge, disease management, patient care, and patient education and minimize overlap, redundancy, and cost. Further, expansion of the ATA's fundraising efforts in this arena offers a potential means to fund ATA initiatives outside of member dues or pharmaceutical support."



Michael T. McDermott, MD

Candidate for Director

Michael T. McDermott, MD, is Director of the Endocrinology Practice at the University of Colorado Hospital in Aurora. Since joining the ATA in 1992, he has served on the Program

Committee (1997–2000) and the Publications Committee (2000 to the present). Dr. McDermott co-chaired the inaugural ATA Fellows Track at the Frontiers in Thyroid Cancer meeting in April 2005.

"I want to encourage the ATA to continue to expand its support of practicing clinicians by regularly updating and expanding published clinical practice guidelines and by increasing advocacy about current clinical coding and reimbursement issues. The ATA's public education efforts are outstanding and should continue with a concurrent focus on providing expert perspectives on the areas of misinformation that continually emerge in the print and Internet media. The ATA has been the leading organization to encourage basic, translational, and clinical research. I would continue to advocate for the advancement of this support through the ATA Endowment, partnerships with industry, and strong advocacy for increased NIH funding for thyroid research."



Matthew D. Ringel, MD

Candidate for Director

Matthew D. Ringel, MD, is Associate Professor of Medicine in the divisions of Endocrinology and Oncology at The Ohio State University. He is also the Director of The Ohio State Endocrinology

Fellowship Program and is the Co-director of The Ohio State Thyroid Cancer Unit.

Dr. Ringel is an active clinician, researcher, and educator. In addition to a clinical practice directed toward thyroid cancer, his research focus is on cell signaling and mechanisms of cancer progression, focusing on thyroid cancer.

A member of the ATA since 1995, he is a member of the Research Committee, has been the chair of the ATA *ad hoc* Web Site Advisory Group since 2003, and served on the Education Committee in 2001 and 2002. He currently serves on the Editorial Boards of *Thyroid* and the *Journal of Clinical Endocrinology and Metabolism*.

"My major goal for the ATA is to solidify its leadership roles in clinical thyroidology and in thyroid-oriented research to attract young endocrinologists and established researchers or clinicians not currently in the membership to be involved in the ATA, to enhance interactions with the lay public, and to be the leader in advocating for thyroid research. Advocacy efforts would include supporting and strengthening the ATA's growing commitment toward young endocrinology clinicians and researchers, expanding involvement with patient advocacy groups, and enhancing our presence on the Internet to ensure that the ATA functions as the primary resource for patients, clinicians, and researchers for thyroid-related information and support."



Mary H. Samuels, MD

Candidate for Director

Mary H. Samuels, MD, is Professor of Medicine at Oregon Health & Science University (OHSU) in Portland, Ore., in the Division of Endocrinology, Diabetes and Clinical Nutrition.

She also serves as the Associate Program Director of the OHSU General Clinical Research Center. Her interests and expertise are in the areas of dynamic TSH secretion, the effects of altered thyroid function on cognition, and thyroid cancer.

Dr. Samuels has been a member of the ATA since 1991, serving as the local arrangements committee chair for the 1998 Annual Meeting, and clinical co-chair of the 2004 Annual Meeting. She has also served on the ATA Program Committee as well as the editorial boards of *Thyroid*, the *Journal of Clinical Endocrinology and Metabolism*, and *Clinical Endocrinology*.

"The American Thyroid Association has been an integral part of my professional life since I attended my first ATA meeting as an endocrine fellow in 1987. It is a dynamic and close-knit organization that combines the best in rigorous science, the care of patients with thyroid disease, and a nurturing environment for young investigators. To continue this winning combination, I believe that the ATA should maintain and strengthen its commitment to translational research, training, and outreach to the broader community of physicians and the public."

Despite the data and other compelling information presented by the societies, industry, and patient advocates, the FDA said that it does not intend to alter its methods for approving generic levothyroxine products.

industry, and patient advocates, the FDA said that it does not intend to alter its methods for approving generic levothyroxine products. The agency did, however, voice its willingness to work with the societies to design and conduct a definitive clinical trial to compare the potency of different levothyroxine products. They also recognized the potential complexity for the pharmacist and patient of the current scheme of approved levothyroxine product interchangeability. They expressed interest in working with the societies to make this information clear and accessible.

In a follow-up letter to Steven Galson, MD, Director of the FDA's Center for Drug Evaluation and Research, the societies again laid out their concerns:

1. Current FDA bioequivalence standards are too lax and overlook modest, but clinically important, dosage differences in this narrow therapeutic index drug;
2. Current FDA standards for thyroxine therapeutic equivalence do not use the pharmacodynamic measure — TSH measurement — that is used by clinicians around the world every day to determine if patients are optimally treated;
3. Patients, pharmacists, and physicians are unaware and confused by the complex set of relationships among approved thyroxine products, which are frequently being substituted for one another with little regard for which formulations have, in fact, been defined as equivalent by even today's lax standard; and
4. A properly designed and executed clinical trial, including TSH measurement and appropriate control observations, needs to be performed to settle this issue.



Leonard Wartofsky offers his insight as part of the panel representing the ATA, The Endocrine Society, and AACE. Other panel members included Steve Sherman, Chester Ridgway, and James Hennessey.

As the societies considered the next steps to keep the dialog open with the FDA, the agency leveled another blow against the efforts to improve the safety and efficacy of levothyroxine products. In July, it came to the societies' attention that the FDA recently instructed some — and perhaps all — thyroxine manufacturers to delete the warning that patients have a retitration of their thyroxine dose when they are switched between brands.

The three groups yet again wrote to the FDA to express “deep concern and dismay” at this action. “At our recent joint workshop,” said the Aug. 3, 2005, letter co-signed by ATA President Paul Ladenson, The Endocrine Society President-elect Leonard Wartofsky, and AACE Immediate Past President Carlos Hamilton,

“the FDA itself acknowledged that not all thyroxine brands have been determined to be interchangeable. The FDA further pledged to cooperate in heightening public awareness of this fact.” The letter went on to describe the FDA's action as inconsistent and irresponsible. “It appears to neglect the welfare of the 13 million Americans who depend on precise dosing of their thyroxine, which is widely recognized to be a narrow therapeutic index drug. Consequently, we ask that you defer this action until there has been an opportunity to explain the agency's reasoning and consider our serious concerns.”

As the organizations wait for a response, the ATA will continue to monitor the situation and work with its sister societies to encourage the FDA to take a more careful and consultative approach to this issue. The recent letters — as would any updates — are posted on the ATA web site, www.thyroid.org.

As the organizations wait for a response, the ATA will continue to monitor the situation and work with its sister societies to encourage the FDA to take a more careful and consultative approach to this issue.

Thyroid Cancer Guidelines, *continued from front page*

S. Cooper, MD, Chair of the ATA's Guidelines Task Force. "For those who are very experienced thyroidologists, the guidelines should help them manage complex cases, as well as understand the controversies better and where further research needs to be done."

The ATA developed written guidelines for patients with thyroid nodules and cancer in 1996 (*Arch Intern Med.* 1996;156:2165-72.). However, there have been significant advances in the diagnosis and treatment of both thyroid nodules and differentiated thyroid cancer since then.

There are controversies in several areas of disease management, including the most cost-effective approach in the diagnostic evaluation of thyroid nodules, the extent of surgery for small thyroid cancers, the use of radioactive

iodine to ablate remnant tissue following thyroidectomy, the appropriate use of thyroxine suppression therapy, and the role of recombinant human thyrotropin.

To respond to the changes in the management of these issues, the ATA appointed a Guidelines Task Force to examine the current strategies used to diagnose and treat these diseases and to develop new clinical guidelines using principles of evidence-based medicine. This task force was composed of experts in thyroid nodule and thyroid cancer management, with specialties in endocrinology, surgery, and nuclear medicine.

The guidelines will be finalized in the next few weeks. Once they are published, they will be posted on the ATA web site (www.thyroid.org).

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Secretary's Report, *continued from front page 2*

important step. Manuscript submissions have increased significantly this year. As of June 25, the administrative support for *Thyroid* is located in the ATA administrative offices. Hard copy manuscripts are still being handled in New York, but all electronic submissions will be administered by the ATA.

The spring thyroid health and public policy meeting will be held in Washington, D.C., March 24, 2006, under the direction of Program Chairs Tom Zoeller and Lew Braverman. The focus of the meeting will be thyroid and the environment. The program committee is being formed and the preliminary response to the topic has been outstanding. We will once again present a one-day CME program designed to attract clinicians and scientists across a wide spectrum of disciplines in an area representing the interface of thyroid health and public policy.

The ATA has responded in a timely and accurate fashion to a number of public health issues. The Public Health Committee, chaired by Vic Bernet, responded to a draft statement on the use and distribution of potassium iodine for protection in the event of an incident that results in radiation exposure. The Lab Services Committee, chaired by Tom Bigos, developed a statement describing the withdrawal of the Advantage thyroglobulin assay. Alan Farwell, chair of the ATA Alliance for Thyroid Patient Education, developed a

lay version to distribute to the patient groups.

Diversifying our sources of revenue continues to be a goal of our organization. The Frontiers in Thyroid Cancer meeting, held in April, had several new exhibitors, who we hope will provide continued support. Our association and members have a large impact across clinical and academic endocrinology, and we need to communicate this to our sponsors.

Bobbi Smith and her staff expertly organized and managed the spring thyroid cancer meeting and completed an office move. Bobbi has transformed the administration of our organization and accomplishes an exceptional amount of work with our small but dedicated staff.

I look forward to joining many of you, along with our colleagues across the world, for the 13th International Thyroid Congress in Buenos Aires in November. Our program committee representatives, Marty Surks, Sheueyann Cheng, and Jorge Mestman, have done a wonderful job, and the program promises to be outstanding.

It is a privilege to serve as your Secretary.



Gregory A. Brent, MD
ATA Secretary

ATA 2005 Spring Meeting Explores Future of Thyroid Cancer

For the first time, the ATA brought together more than 500 experts and specialists — from the United States and around the world — to share the newest information in thyroid cancer clinical care and research findings.

“Frontiers in Thyroid Cancer 2005: Clinical Care and Research for the Future” took place April 14–17, 2005, in Baltimore. The meeting featured an international panel of speakers that provided in-depth coverage of clinical and experimental aspects of thyroid cancer.

“The organizing committee was delighted with the outcome of the meeting, which received uniformly strong evaluations from attendees,” said James A. Fagin, MD, Co-chair of the meeting. “It gave attendees a unique opportunity to update their knowledge on current disease management, which is now undergoing meaningful changes because of new approaches to diagnosis, surveillance, and therapy.”

The meeting also attracted media attention from several medical publications. *Internal Medicine World Report*, *Endocrine Today*, *Oncology Times*, and *Endocrine News* all covered the meeting.

Ultrasound Workshop

The ATA and the American Association of Clinical Endocrinologists co-sponsored a highly successful advanced ultrasound course at the meeting. More than 40 registered for this special hands-on workshop organized by Dan Duick and Jack Baskin. The focus was on the role of ultrasound and ultrasound-guided procedures in the diagnosis and surveillance of thyroid cancer patients. Speakers at this sold-out event were Susan Mandel, Dan Duick, Enrico Papini, and Jack Baskin.

Fellows Track

For the first time, the ATA offered a fellows track during an ATA scientific meeting. Chaired by Michael McDermott and Stephanie Fish, it provided fellows with special access to respected leaders in the field through panel discussions, lectures, and meet-the-professor sessions. This targeted track provided fellows with opportunities for skill enhancement and gave them insight into a broad range of thyroid care issues, as well as offering hands-on experience with ultrasound techniques, with special training by technicians.

“One important aspect of the meeting was the enthusiastic participation of so many endocrine fellows in training,” said Steven I. Sherman, MD, Co-chair of the meeting. “Their overwhelming response to the special Fellows Track is encouraging not only for their future patients but also for the ATA, which may have attracted a new generation of future members.”

Patient Education

The meeting also offered educational opportunities for thyroid patients and their families. In conjunction with the meeting, ThyCa held its 4th Annual Mid-Atlantic Thyroid Cancer Survivors’ Spring Workshop. ThyCa, in cooperation with the Light of Life Foundation, also sponsored a “Casino Night,” which raised funds for thyroid cancer research.

The public was invited to a free educational forum on April 13 about thyroid disorders and their treatment. The forum was presented by the ATA Alliance for Thyroid Patient Education, which includes the Thyroid

Foundation of America, ThyCa: Thyroid Cancer Survivors’ Association, National Graves’ Disease Foundation, and the Light of Life Foundation.

Awards

During the meeting, David Cooper, MD, received the ATA’s 2005 Distinguished Service Award in recognition of his important and continuing contributions to the organization. In addition, the ATA Thyroid Pathophysiology Medal was awarded to Samuel Refetoff, MD, recognizing his outstanding research contributions to the understanding of thyroid disease pathophysiology. The ATA 2005 Van Meter Award remains a secret until the award lecture is presented at the 13th International Thyroid Conference in Buenos Aires, Argentina, on Nov. 3, 2005.

Remote Access to Program

If you were not able to attend the meeting or a specific session or need to refer back to a presentation you heard, the content of the meeting is now available in streaming video on the ATA web site, www.thyroid.org.



President Paul Ladenson welcomed attendees and introduced Secretary Gregory Brent, Keynote Speaker Bert Vogelstein, and Program Chairs Steven Sherman and James Fagin.

Future of Thyroid Cancer Meeting Highlights



ATA colleagues Drs. Grace Chan, Susan Mandel, and Stephanie Fish gathered between sessions.

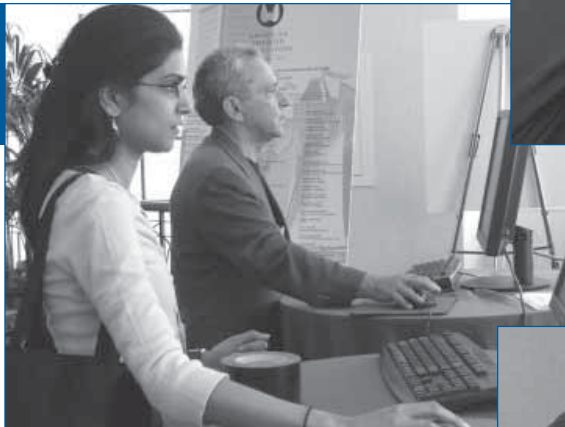


New ATA member Sethu Reddy discussed a poster with colleagues.



Matthew Ringel and colleagues discussed the latest research at the Poster Session.

ATA Past President Peter Singer and an ATA fellow took advantage of the ATA's e-mail service.



Clinical sessions attracted large crowds.



The 4th annual Women in Thyroidology meeting brought together women at all career stages.

Future of Thyroid Cancer Meeting Highlights (continued)

ATA Secretary Greg Brent introduced Samuel Refetoff, recipient of the 2005 Thyroid Pathophysiology Medal.



Gil Daniels and Richard Kloos welcomed fellows to the ATA.



ATA President Paul Ladenson and Awards Committee Chair Arthur Schneider awarded David Cooper with the 2005 Distinguished Service Award.



European Thyroid Association Reports on 30th Annual Meeting

The 30th Annual Meeting of the European Thyroid Association (ETA) was held in Istanbul, Turkey, Sept. 18–22, 2004. For the first time, the program was clearly delineated in a basic science track, a clinical science track, and an educational track. “The 30th Annual Meeting of the European Thyroid Association was a turning point in the history of the association,” reported Gerry Krassas, of Greece and a member of the ETA’s Executive Committee, “and all persons involved in the organization of this great meeting have to be congratulated.”

The scientific meeting also included a session devoted specifically to young investigators as well as awarding, for the first time, a young investigators prize. Approximately 320

abstracts were selected for presentation, which added to the program’s quality. The Istanbul meeting continued the ETA tradition of superb social programs with offerings of sailing on the Bosphorus Strait and remarkable outdoor dining in a dozen taverns.

ETA President Wilmar Wiersinga announced that the ETA celebrates its 40th anniversary this year and held a Jubilee Meeting in Athens on May 25, 2005. Past leaders gave research presentations in their areas of expertise, commenting also on the role of the ETA in their scientific careers. Young investigators also provided their perspectives.

For information about upcoming meetings, visit the ETA web site at www.eurothyroid.org.

13th International Thyroid Congress to Meet in Buenos Aires

The 13th International Thyroid Congress (ITC) will present the latest developments in thyroid disease at the Sheraton Buenos Aires Hotel and Convention Center in Buenos Aires, Argentina, Oct. 30 – Nov. 4, 2005. The ITC is held every five years and is a joint meeting of four sister associations: the ATA, European Thyroid Association (ETA), Latin American Thyroid Society (LATS), and Asia and Oceania Thyroid Association (AOTA).

“On behalf of the Local Organizing Committee of this 13th ITC, it is my great pleasure to invite you to this meeting, which will be memorable in terms of science, social activities, and personal friendships,” said Hugo Niepomniszcze, MD, PhD, Chair of the LATS Local Organizing Committee.

The ITC received 686 abstracts — a 10 percent increase from five years ago — from thyroid researchers representing 54 countries. The abstracts were peer-reviewed by members of the Program Organizing Committee and final selections were recently announced.

The Program Organizing Committee — composed of three members from each sister association, including Marty

Surks, Sheue-yann Cheng, and Jorge Mestman from the ATA — has developed an outstanding scientific program that covers the most up-to-date issues in thyroidology.

The ITC is also hosting several social activities for meeting attendees and their guests throughout the meeting. There will be a Welcome Reception at the Sheraton Buenos Aires Hotel and Convention Center from 7:00 p.m. to 10:00 p.m. on Oct. 30. This informal reception includes a light meal, drinks, and live music.

On Nov. 2, the ITC is hosting a free Dinner and Tango Show from 8:00 p.m. to midnight at the Rodizio Restaurants (Rodizio Puerto Madero, Rodizio Costanera, Rodizinho). The Congress Banquet will be at the Sheraton Buenos Aires Hotel from 8:00 p.m. to 11:00 p.m. on Nov. 4. The fee

is \$50 and includes dinner, drinks, and entertainment. Jacket and tie are required. Space is limited, and reservations must be made in advance.

To register for the ITC meeting or for more information, go to www.13itc.org. The ATA web site has a link to the ITC web site on its home page at www.thyroid.org.



President's Message, *continued from front page*

FDA practices and regulations related to thyroxine, one of the most widely prescribed drugs worldwide, similarly placed us in the front lines of public debate about this important clinical issue. Recent bulletins about issues as diverse as naturopathic medicines and thyroglobulin assays have confirmed our role as the “go to” source for thyroid information. Our first steps in establishing direct links with the lay public, as “Friends of the ATA,” have been taken and will accelerate in the year ahead.

With these growing opportunities come higher expectations for our society's leadership, members, and staff: additional dedicated time and effort, greater effectiveness, and more transparency. As President-elect Ernie Mazzaferri calls members to committee service this summer, think seriously about your willingness to make a real commitment of time and imagination.

Our Secretary Greg Brent and Executive Director Bobbi Smith are preparing to meet growing demands for staff support of our expanded portfolio of new programs. And our greater responsibilities demand that we not only “work hard,” but also “keep our noses clean.” Our sincerest efforts will be undermined without thoughtful consideration and appropriate disclosure of our societal and individual dualities of interest. The coming year will bring consideration of new policies related to this important issue.

I hope to see many of you in Buenos Aires this fall.

With best wishes,

Paul W. Ladenson, MD
ATA President

Recent bulletins about issues as diverse as naturopathic medicines and thyroglobulin assays have confirmed our role as the “go to” source for thyroid information.

ATA Signal



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ATA Spring Meeting to Examine the Thyroid and the Environment

Thyroid Health and the Environment

THREATS AND
EFFECTS

Friday, March 24, 2006

Washington, DC

Hamilton Crowne Plaza
at 14th and K Streets, NW

The ATA's spring thyroid health and public policy meeting will focus on the thyroid and the environment.

The meeting, titled *Thyroid Health and the Environment: Threats and Effects*, will take place on March 24, 2006, in Washington, D.C., at the Hamilton Crowne Plaza, located at 14th and K streets, and will be held under the direction of Program Chairs Thomas Zoeller, PhD, and Lewis Braverman, MD.

More information will follow in future issues of *Signal* and on the ATA web site, www.thyroid.org.