

2025-2026

President

M. Regina Castro, MD Rochester, MN

Secretary

Christopher McCabe, PhD Birmingham, UK

Treasurer

Mark E. Zafereo, Jr., MD Houston, TX

Past-President

Jacqueline Jonklaas, MD, PhD

President-Elect

Anthony N. Hollenberg, MD Boston, MA

Directors

Zubair W. Baloch, MD, PhD (2023-2026) Philadelphia, PA

Kristien Boelaert, MD, PhD (2025-2028) Birmingham, UK

Maria Cabanillas, MD (2023-2026) Houston, TX

Elizabeth G. Grubbs, MD (2024-2027) Houston, TX

Cari Kitahara, PhD (2024-2027) Bethesda, MD

Maya Lodish, MD (2024-2027) San Francisco, CA

Maria Papaleontiou, MD (2025-2028) Ann Arbor, MI

Kepal Patel, MD (2025-2028) New York, NY

David Steward, MD (2023-2026) Cincinnati, OH

Executive Director

Pamela Mechler, CAE

Headquarters' Office

American Thyroid Association 2000 Duke Street, Suite 300 Alexandria, VA 22314

Phone: 703.998.8890 Fax: 703.998.8893 Web: www.thyroid.org October 8, 2026

Commissioner Martin Makary, MD, MPH Commissioner's Office Food and Drug Administration 10903 New Hampshire Ave Silver Spring, MD 20993-0002

VIA EMAIL: commissionersoffice@fda.hhs.gov

Dear Commissioner Makary,

The American Thyroid Association is a professional medical society with the vision of "Optimal Thyroid Health for All". Our members include physician endocrinologists, surgeons, radiologists, and others who provide care for patients with thyroid disorders. The recent position taken by the Food and Drug Administration, beginning with the August 6th notification to companies manufacturing and distributing desiccated thyroid extract, has been of great concern to our members, the patients we serve, and patient advocate groups.

While we fully recognize the shortcomings of the current system, whereby desiccated thyroid extract is not regulated for its bioavailability, potency, and purity in the same way that synthetic thyroid hormones are, we also recognize that over a million patients are currently using desiccated thyroid extract and consider this to be the only thyroid hormone replacement that adequately treats their condition. We also share the Food and Drug Administration's concern about adverse events stemming from use of desiccated thyroid extract.

We urge the Food and Drug Administration to expeditiously develop a quality control system for desiccated thyroid extract to apply the same safety standards that are applied to synthetic thyroid hormones. American Thyroid Association members have clinical and research expertise in hypothyroidism treatment and could potentially, if desired, assist the Food and Drug Administration in the development of mechanisms for safe regulation of desiccated thyroid extract from a scientific and medical standpoint. However, in the interim, we advocate to allow continued access to desiccated thyroid extract for patients.

We appreciate the opportunity to provide input to the Food and Drug Administration and to advocate for the best possible care for our patients with thyroid diseases.

Sincerely,

M. Regina Castro, MD ATA President

Jacqueline Jonklaas, MD, PhD

Jacque Jonklass

ATA Past-president