THE HIDDEN DANGERS OF PRIMARY ALDOSTERONISM

DECEMBER 2020 THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

Endocrine news

INTERNATIONAL

2020 VISIONARIES

Looking Back at an Unforgettable Year in Endocrinology

- **A YEAR OF GROUNDBREAKING SCIENCE:** Once again, Endocrine Society journal editors share their top picks for 2020's most significant advances in endocrine research.
- **A YEAR OF TREATMENT BREAKTHROUGHS:** As endocrine science advances, so too do cutting-edge treatment options, therapies, and technology that will improve the lives of patients living with various endocrine disorders.
- **A YEAR OF ENDOCRINE SOCIETY INNOVATIONS:** In a challenging year, the Endocrine Society initiated a variety of new offerings that enhanced the member experience and set a new standard for years to come.

ENDOCRINE SOCIETY
Hormone Science to Health

Endocrine news

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

IN THIS ISSUE

DECEMBER 2020

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www.endocrine.org

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ENDOCRINE SOCIETY
Hormone Science to Health

Harnessing Artificial Intelligence to Personalize Your Newsletter Experience

Artificial intelligence (AI) is on the verge of revolutionizing the way we use big data, diabetes technology, and numerous other aspects of endocrinology. We are excited to be deploying the same concepts to make it easier for you to keep pace with the field's latest news and developments.

We have launched an AI-driven e-newsletter to bring you the latest headlines from the world of endocrinology. Each of us is fascinated by different glands and hormones, drawn to different areas of research and clinical care. We are harnessing industry-leading technology to bring you a weekly e-newsletter personalized to you and your professional interests.

Our revamped *Endocrine Briefing* e-newsletter learns your preferences and selects stories specifically for you. As you click on the headlines and read more e-newsletter stories, the AI platform gains a better sense of your interests and tailors future issues to you.

More than 200 members of our community participated in a trial run of the technology this summer, and we appreciate all of the insightful feedback we received from those who took part. Watch your inbox each Monday for your customized e-newsletter experience.

> "Each of us is fascinated by different glands and hormones, drawn to different areas of research and clinical care. We are harnessing industry-leading technology to bring you a weekly e-newsletter personalized to you and your professional interests."

Raising Our Field's Profile

Journalists are relying on scientists and clinicians more than ever to accurately communicate our evolving understanding of COVID-19. Our members have stepped up, serving as trusted sources of information. *The Journal of Clinical Endocrinology & Metabolism* editor-in-chief Paul Stewart, MD, FRCP, and deputy editors Ursula Kaiser, MD, and Raghavendra Mirmira, MD, PhD, shared key points from their COVID-19 editorial with media outlets, including Chicago's WGN TV network and *HCPLive*. *PracticeUpdate* covered the paper *Endocrine Reviews* editor-in-chief Daniel Drucker, MD, authored on COVID-19 and diabetes.

Our press releases have highlighted more than 10 journal manuscripts exploring COVID-19 and its implications for endocrine patients. Our work has garnered significant attention for endocrinologists' role in understanding and combatting the pandemic. ABC's "Good Morning America" news program, Spanish national daily newspaper *ABC, Forbes* magazine, *The Atlanta Journal-Constitution*, consumer health news site *Healthline, Medscape*, and *NEJM Journal Watch* have covered COVID-19 research published in our journals. Our press release on a JCEM paper examining vitamin D deficiency in COVID-19 patients ranked among the top releases of the week of October

26 on the American Association for the Advancement of Science's newswire service, with more than 13,000 views from subscribing journalists.

Although we have pivoted to help journalists in their dogged pursuit of stories about the pandemic, we continue to ensure endocrinology remains prominent in the public consciousness. We transformed our planned **ENDO 2020** news conferences into six virtual events featuring speakers from five continents. We distributed more than 35 press releases on **ENDO 2020** abstracts published in the *Journal of the Endocrine Society* and the **ENDO Online 2020** program. Our outreach led to more than 600 mentions in outlets such as CNN.com, United Press International, *Newsweek, Everyday Health,* and *The San Francisco Chronicle*. The online media outlets that covered our meetings attracted 520 million unique monthly visitors.

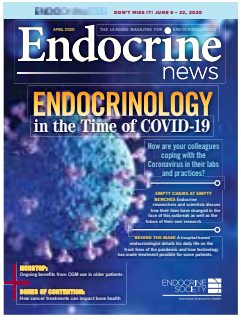
We also leveraged the media to elevate our journals. CNN.com — an outlet that reaches more than 200 million unique visitors worldwide each month — prominently featured a *Journal of the Endocrine Society* study on cinnamon and its role in managing blood glucose in individuals with prediabetes. Seventy-seven news outlets, including the *Daily Mail, Business Insider India,* and Fox News, linked to the research, and 131 Twitter accounts shared the paper, according to data science firm Altmetric. Widespread attention helped raise awareness of our three-year-old open access journal.

We are proud of the strategic relationships we have built with key medical and science journalists. By acting as trusted advisors to top-tier media outlets, we can help ensure the public and policy makers understand the importance of endocrine science and practice.

If you have any questions or comments, you can reach me at: ***president@endocrine.org*** EN

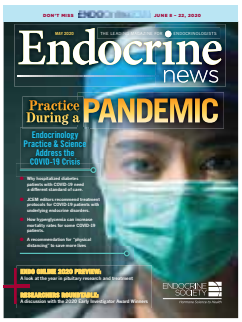
Gary D. Hammer, MD, PhD
President, Endocrine Society

Reflecting on a Monumental Year for *Endocrine News*

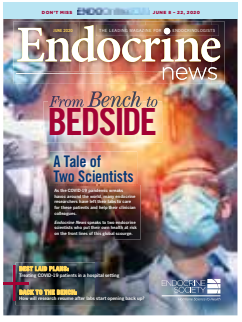


Canceled conferences. Remote meetings. Virtual gatherings. 2020 has been a year none of us will soon forget. However, it has taught many of us new ways to do our jobs. At *Endocrine News*, we discovered that as long as we all have a good wi-fi signal, anything is possible as we hunkered down to change the well-charted course we had set for ourselves almost a year ago.

For *Endocrine News*, the challenge in this new environment was immediate; we had to adapt our editorial planning to include stories on how COVID-19 was impacting patient treatment and research, but also how our members were adapting and how their lives were changing on a daily, sometimes hourly, basis. From research labs suddenly drained of personnel to clinicians thrown into unfamiliar and often dangerous situations, new stories had to be told that we had not planned on telling.



The first real sign that something was amiss came when we were told we'd be telecommuting full time in early March; Friday, March 13, was our last day in the Endocrine Society offices for most of us. Then came the cancellation of **ENDO 2020** in San Francisco later that month. While I was disappointed not being able to travel to one of my favorite cities to see so many of you in person, I was more concerned with the lack of content that we typically procure from **ENDO** every year.



I shouldn't have worried; the pandemic provided a plethora of story topics for *Endocrine News*. In fact, every cover story from April through July was somehow related to COVID-19, the impact it's had on our members, the research it's generated, as well as how it has forced so many in the world of endocrinology to rethink how they do their jobs. Aside from frontline tales of clinicians needing to wear unfamiliar layers of personal

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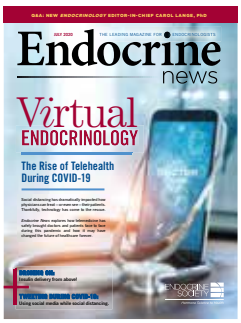

protective equipment, the rise of telemedicine was so swift that we devoted our July cover story to this phenomenon.

As a seasoned journalist with almost three decades under my belt in a variety of settings, the only thing that even comes close to the impact of COVID-19 are the 9/11 terrorist attacks. When that historic event took place, I had been the managing editor of a magazine about office buildings and commercial real estate for a mere two and a half months. Then the world changed. I had to hit the ground running to report on how this entire industry was suddenly upended by the events on the morning of that sunny September day.

The COVID-19 pandemic has the same feel. *Endocrine News* is not only occupied with bringing you the latest breakthroughs in the science and treatment of endocrine conditions, but as a magazine published by the Endocrine Society, we delve deeper to explore how our members have been affected on a personal as well as a professional level. The result has been a variety of stories that further emphasize the spirit of the endocrinologist. This dreaded pandemic has brought out the best in so many of you around the world throughout 2020, and *Endocrine News* has done its best to shine a light on the best and the brightest of endocrine science and practice.

We will continue to do so in 2021 and beyond. Luckily, thanks to all of you, finding unforgettable subjects in the world of endocrinology is the easiest part of my job.

As always, if you have any questions, comments, or even ideas for future articles, feel free to email me at: **mnewman@endocrine.org**.

— Mark A. Newman, Editor, *Endocrine News*

Endocrine Society Members Named 2020 Lasker Clinical Research Scholars

Endocrine Society members Alison Boyce, MD, and Stephanie Chung, MBBS, are among the five scientists that the National Institutes of Health (NIH) selected for the 2020 Lasker Clinical Research Scholars program, a partnership with the Lasker Foundation that supports the emergence of the next generation of clinician researchers.

Chief of the Metabolic Bone Disorders Unit, National Institute of Dental and Craniofacial Research at the NIH, Boyce is working toward a treatment for fibrous dysplasia/McCune-Albright syndrome (FD/MAS), a rare and debilitating skeletal disease that can cause bone fractures, deformity, pain, and loss of ambulation, vision, and hearing. Her research focuses on the role of the RANKL protein, which regulates bone resorption and plays a role in FD pathogenesis.

"I'm really honored and excited for this opportunity. Rare disease research has so much potential to advance health and well-being in this country, but there are a lot of challenges to overcome like small, complex patient populations and competing demands for clinical investigators," Boyce tells *Endocrine News*. "At the NIH, I have the support and resources to recruit and study patients at the NIH Clinical Center, which is one of the world's best and largest research hospitals. I also appreciate the wonderful, collaborative environment in the Intramural Research Program. Working in NIDCR with investigators who study complex mineralized tissues, like the teeth and skull, has given me a really valuable and nuanced perspective on bone metabolism. As endocrinologists, we're trained to think about how different systems interact; this makes it especially important for us to collaborate widely with investigators from many disciplines."

Alison Boyce, MD

Stephanie Chung, MBBS

Chung is with the National Institute of Diabetes and Digestive and Kidney Diseases and studies the complex association of biological, social, and environmental factors that contribute to the pathogenesis of type 2 diabetes and cardiometabolic disease. She focuses on diabetes health disparities in youth and young adults, with the goal to develop improved population-specific screening and therapeutic strategies.

> **The Lasker Foundation and the NIH have joined together in an innovative partnership to nurture the next generation of clinician researchers.**

"I am deeply honored and excited to receive the NIH Lasker Clinical Scholar Award. This award represents NIH's commitment to diversity and inclusion, and ongoing dedication to support diabetes and health disparities research," Chung tells *Endocrine News*. "This program will buttress my existing NIDDK/Children's National Hospital clinical metabolic research program, which examines reasons for high treatment failure rates in youth with type 2 diabetes while simultaneously evaluating innovative primary and secondary prevention therapies for cardiometabolic disease."

The Lasker Foundation and the NIH have joined together in an innovative partnership to nurture the next generation of clinician-researchers. This initiative supports early-career medical researchers and helps bridge the widening gap between cutting-edge research and improved patient care. This program provides scholars with five to seven years of support as independent investigators in the NIH Intramural Research Program, followed by the opportunity for additional years of financial support, either at the NIH or at an extramural research institution.

EndoBridge 2020 Was a Digital Success

The 8th Annual Meeting of EndoBridge® was held October 22–24, 2020, as a virtual event due to ongoing concerns regarding COVID-19 pandemic.

As usual, the three-day scientific program, accredited by the European Council, included state-of-the-art lectures and interactive expert discussion panels on challenging and interesting clinical cases. Simultaneous translation into Russian, Arabic, and Turkish was provided throughout the meeting.

"This year EndoBridge® took place as a fully digital, interactive meeting for the first time," says Bülent Yildiz, MD, a faculty member at Hacettepe University School of Medicine, Ankara, Turkey, and founder and president of EndoBridge®. "We had a record number of participants, with over 1,600 delegates from 92 countries. EndoBridge® Initiative continues enhancing crosscultural dialogue and collaboration beyond the borders in the world of hormones."

Next year's EndoBridge® Annual Meeting will take place in Antalya, Turkey, October 21 – 24, 2021. Further information can be found at: **www.endobridge.org**. EN

BY DEREK BAGLEY
Senior Editor

New Cardiovascular Drug Shows Promise in Patients with Hypertriglyceridemia, Type 2 Diabetes, and NAFLD

> **Results from the Phase 2 study bring essential insights about this investigational therapy that may help guide disease management strategies and clinical research moving forward.**

A late breaking clinical trial session at the ESC Congress 2020, the annual meeting of the European Society of Cardiology, showed positive data from Phase 2 of a clinical trial of the investigational antisense therapy vupanorsen in patients with hypertriglyceridemia, type 2 diabetes, and non-alcoholic fatty liver disease (NAFLD). Akcea Therapeutics presented the results.

Vupanorsen was developed to treat patients with cardiovascular diseases, and in this study, the drug met the primary endpoint of significant reductions in triglyceride (TG) levels and multiple secondary endpoints compared to placebo, with a favorable safety and tolerability profile.

The goal of the randomized, double-blind, placebo-controlled, dose-ranging Phase 2 study was to assess the safety and efficacy of vupanorsen. A total of 105 patients with hypertriglyceridemia (fasting plasma TG levels >150 mg/dL), type 2 diabetes, and NAFLD were randomized to three dosing cohorts in a 3:1 ratio (vupanorsen:placebo) within each cohort and treated for six months. The dosing cohorts explored different doses and dose regimens vs. placebo, with patients receiving either 40 mg or 80 mg every four weeks or 20 mg every week. Participants received either vupanorsen or placebo via subcutaneous injection.

Results from the Phase 2 study show:

- Statistically significant dose-dependent reductions in fasting TGs at all dose levels, with the highest mean reduction of 53% at the dose of 80 mg every four weeks (44% mean reduction compared to placebo, P<0.0001);
- Statistically significant dose-dependent reductions compared to placebo in ANGPTL3 (62%), very low-density lipoprotein (VLDL) cholesterol (38%), total cholesterol (19%), and non-high-density lipoprotein (non-HDL) cholesterol (18%) (numbers indicate mean reductions achieved with the 80 mg every four week dose);
- No effect on glycemic parameters and no decrease in hepatic steatosis;
- No significant reductions in low-density lipoprotein cholesterol (LDL-C) levels compared to placebo in this patient population, which did not have high baseline LDL-C levels; and
- A favorable tolerability and safety profile. The most common treatment-emergent adverse events were injection site reactions, which were mostly mild.

"Antisense-mediated reduction of ANGPTL3 has the potential to address significant unmet needs in patients with cardiovascular diseases," says Daniel Gaudet, MD, a professor of medicine in the Department of Medicine at the University of Montreal. "Results from the Phase 2 study bring essential insights about this investigational therapy that may help guide disease management strategies and clinical research moving forward."

COVID-19 Patients with Spinal Fractures Twice as Likely to Die

Patients with COVID-19 and vertebral fractures are twice as likely to die from the virus, according to a study recently published in *The Journal of Clinical Endocrinology & Metabolism*.

Researchers led by Andrea Giustina, MD, director of the Institute of Endocrine and Metabolic Sciences of the San Raffaele Vita-Salute University and IRCCS San Raffaele Hospital in Milano, Italy, point out that osteoporosis is one of the worldwide major health issues, and that vertebral fractures are associated with decreased survival and impaired quality of life. "[O]ther authors have hypothesized a possible increase in risk of fragility fractures and related mortality after the COVID-19 pandemic due to the strain on the health system during the emergency, with consequent interruption of adequate care for the patient with chronic diseases," the authors write. "However, beyond these expert opinions no real data are yet available on the hard clinical endpoint of bone fragility, i.e., fracture rates, in hospitalized COVID-19 patients."

In a retrospective cohort study performed at a tertiary care hospital in Italy, the researchers studied the x-rays of 114 COVID-19 patients and detected thoracic vertebral fractures in 35%. These patients were older and more affected by high blood pressure and heart disease. They were more likely to need ventilators and were twice as likely to die compared to those without fractures. The death rate was higher in patients with severe fractures.

Based on these findings, the authors conclude that "since thoracic VFs are easy to measure, associate with age, and integrate the cardiorespiratory risk of COVID-19 patients, they are a good marker of patient fragility and poor prognosis, and we suggest that morphometric vertebral x-rays evaluation should be performed in all patients with suspected COVID-19."

"Vertebral fractures are a marker of frailty, and for the first time we show that individuals who have such fractures appear to be at increased risk of severe COVID-19," Giustina says. "A simple thoracic x-ray can detect these fractures and morphometric evaluation should be performed in COVID-19 patients at hospital admission."

"Vertebral fractures are a marker of frailty, and for the first time we show that individuals who have such fractures appear to be at increased risk of severe COVID-19."

> These two classes work synergistically to help control a type 2 diabetes patient's glucose levels and other measures associated with diabetes. We can now feel more confident about prescribing these medications long term.

Combo-Drug Type 2 Diabetes Treatment Remains Effective After Two Years

A drug combo of dapagliflozin and exenatide continues to stay effective at controlling the progression of type 2 diabetes, without loss of effect, after two years of continual use, according to a study recently published in *Diabetes Care*.

In a multi-center double-blind, Phase 3, randomized controlled trial, a total of 695 adults whose type 2 diabetes was not controlled with metformin were randomly assigned to three study groups. One group received weekly exenatide injections in addition to metformin. Another group took daily dapagliflozin pills in addition to metformin, and a third group received both drugs together. The study was an extension study of the pivotal DURATION-8 trial, meaning that patients were given the option to continue in the trial longer.

"Many therapies in diabetes management are short-lived, which is why it's useful to test for long-term effect," says senior author Serge Jabbour, MD, director of the Division of Endocrinology and the Diabetes Center at Thomas Jefferson University, Philadelphia, Pa. "Our study showed that a combo regimen of dapagliflozin and exenatide continued to control patients' glucose for over two years. This is very encouraging."

The two classes of drugs act additively, improving the effects on a number of diabetes indicators. Dapagliflozin belongs to a class of drugs called sodium–glucose cotransporter-2 (SGLT2) inhibitors that cause excess glucose to be excreted in the urine. Exenatide belongs to a class of drugs called glucagon-like peptide-1 receptor agonists (GLP-1RAs), which enhance glucose-dependent insulin secretion, lower hepatic glucose output, slow gastric emptying, and increase satiety. Together, the two drugs promote and maintain better glucose control and produce additive weight loss and improve blood pressure.

The results confirmed that the group of patients receiving both drugs had better glycemic control than patients receiving just one of the drugs and demonstrated, for the first time, that the effect was stable for the duration of the extended two-year study period. The study also showed a clinically relevant reduction in weight and blood pressure, measures that can contribute to type 2 diabetes and overall health. The researchers saw no unexpected safety concerns related to the drug combination in the study participants.

Other studies with both drugs have also suggested that metabolic markers such as lipid profile also improved.

"These two classes work synergistically to help control a type 2 diabetes patient's glucose levels, and other measures associated with diabetes," Jabbour says. "We can now feel more confident about prescribing these medications long term." EN

Researchers Develop First-in-Class Humanized Antibody Targeting Bone and Fat

A treatment for obesity and osteoporosis could be on the horizon as Mount Sinai researchers have developed a first-in-class humanized antibody to the follicle-stimulating hormone (FSH) that will reduce body fat, increase bone mass, enhance metabolism, and lower cholesterol. The antibody has the potential to prevent and treat obesity, osteoporosis, and hypercholesterolemia — diseases that affect millions of people worldwide. The study provides a framework for clinical testing of the humanized antibody.

Researchers led by Mone Zaidi, MD, PhD, MACP, director of the Mount Sinai Bone Program and professor of medicine at the Icahn School of Medicine at Mount Sinai point out that while obesity and osteoporosis affect hundreds of millions of people worldwide, resources to prevent these diseases remain limited.

FSH was known for years to be an important part of the reproductive system. But research showed in a mouse model that FSH also plays a direct role in bone loss and belly-fat gain — and that blocking FSH would reverse those effects. In the most recent study, researchers explain the development of a "humanized" monoclonal antibody to block FSH signaling. Furthermore, new evidence was found that blocking FSH also lowers serum cholesterol.

The FSH research builds on a long-term collaboration spanning nearly two decades between Zaidi and Clifford Rosen, MD, a senior scientist at Maine Medical Center Research Institute. Mouse-based data that Zaidi and Rosen concurrently confirmed in each other's laboratories showed that blocking FSH reduces

obesity and increases energy expenditure in both male and female mice fed on a high-fat diet. The most recent study shows the humanization of this FSH-blocking antibody.

"This next stage brings us even closer to an effective therapy with an FSH-blocking antibody aimed at preventing and treating both obesity and osteoporosis," Zaidi says. "Targeting and blocking FSH was found in past studies to be effective in male as well as female mice, so its benefits could extend to both genders in people. What would be fascinating and incredibly rewarding is if we can actually show a significant increase in lifespan while regulating obesity and osteoporosis through a single, FSH-blocking agent."

"What would be fascinating and incredibly rewarding is if we can actually show a significant increase in lifespan while regulating obesity and osteoporosis through a single, FSH-blocking agent."

ENDO 2021

VIRTUAL EVENT
March 20 – 23, 2021

The all-virtual **ENDO 2021** will mirror the principal elements of **ENDO**, including top-flight educational programming, an interactive EXPO center, and networking opportunities. **ENDO 2021** is the leading global meeting for endocrinology research and clinical care.

Join us for the most well attended and valued translational endocrinology meeting in the world. Bringing together leading experts, researchers, and the most respected clinicians in the field, **ENDO 2021** represents a convergence of science and practice that highlights and facilitates breakthrough discoveries in the field of endocrinology. Spend time connecting with peers and colleagues, exchanging ideas and information, and getting out in front of the latest trends and advancements in hormone health.

ENDO 2021's comprehensive virtual program offers attendees the opportunity to learn about the latest developments in hormone science and medicine from renowned investigators, expert clinicians, and educators from all over the world. You will get inspired by experts and stay at the forefront of scientific discovery and high-quality patient care.

This year's program includes:

- More than 70 live sessions and another 70 sessions accessible on-demand;
- Six plenary sessions including two presidential plenaries on data in endocrine research and the impact of basic tissue engineering in emerging therapies;
- 24 live Meet the Professor sessions and another 20 available on-demand; and
- More than 20 oral sessions and a robust poster hall for accepted scientific abstracts.

www.endocrine.org/endo2021

IMPORTANT NOTE: To receive the member rate, your membership must be renewed for 2021 before registering for **ENDO 2021**.

Medical Management of the Metabolic-Bariatric Surgery Patient Webinar

February 3, 2021
10:00 a.m. – 5:45 p.m. (ET)

Severe obesity and its complications are best managed by an interdisciplinary team including both surgical and medical providers. This session will utilize presentations by leading experts, panel discussions, and dedicated time for interactive Q&A to cover best practice recommendations for the pre- and post-operative management of patients undergoing metabolic-bariatric surgery. Topics will include optimizing pre-operative care, as well as recognizing and developing approaches to the variability in post-operative weight loss and remission rates of obesity-related complications in both adult and pediatric patients.

www.obesity.org/meetings-education/webinars/

Clinical Endocrinology 2021

Live Streaming
March 9 – 13, 2021

For nearly 50 years, renowned experts in endocrinology at Harvard Medical School and Massachusetts General Hospital have delivered the CME course Clinical Endocrinology — the acclaimed annual update of current endocrine diagnostic and management strategies. If you provide care to patients with endocrine disorders, this course will be invaluable to your medical decision making and patient care.

https://endocrinology.hmscme.com/

Miami Thyroid Oncology Symposium

April 9 – 10, 2021
Miami, Florida

Organized by the Miami Cancer Research Center, this two-day program offers a course on Thyroid Nodules & Cancer: Cutting Edge Ultrasound and Molecular Diagnostics to provide a foundation for practicing physicians in understanding the evolving role of clinical molecular testing and its integration with the contemporary ultrasound imaging for diagnosis and management of thyroid nodules and cancer. The plenary session, Frontiers in Thyroid Oncology, will review the clinical guidelines, address the controversies, and bring new insight to the molecular and genomic theranostics in a didactic and interactive format. There will also be a Scientific Paper Presentations/Case Discussions session and a Multidisciplinary Tumor Board session led by experts in the field to offer a platform for physicians in training and all academic and practicing physicians to present and discuss their research work and clinical experience.

https://miamicancerresearch.org/events/symposium/

INTERNATIONAL **ITINERARY**

Virtual 16th International Thyroid Congress

December 16 — 20, 2020

Sessions will include: Recent Advances in Thyroidology, Plenary Lectures, Symposium Lectures, and Award Lectures. All sessions will be prerecorded. There will be no Meet the Professor/debate and discussion and oral sessions/poster sessions.

www.thyroid.org/16th-itc/

ICE 2021: 19th International Congress of Endocrinology

Virtual Meeting
February 24 – 28, 2021

19th International Congress of Endocrinology (ICE 2021), 4th Latin American Congress of Endocrinology (CONLAEN), and 13th Congress of the Argentine Federation of Endocrinology Societies (FASEN) is organized by MCI Group — Argentina. Topics to be discussed include: big data and its impact in health, human diseases, artificial intelligence, and big-data mining; thyroid cancer diagnosis and treatment; advances in pheochromocytomas and paragangliomas; the tsunami of diabetes in lower- and middle-income countries; preserving reproduction in cancer patients; and so much, much more.

https://icevirtualcongress.com

2nd BES Mayo Advanced Course in Endocrinology 2021

February 21 — 23, 2021
Dhaka, Bangladesh

The Advanced Course in Endocrinology is a collaboration between the Bangladesh Endocrine Society (BES) and the Mayo Clinic, Rochester, Minn. This intensive two-day, interactive course will cover all aspects of clinical endocrinology. Helmed by world-renowned faculty from the Mayo Clinic, this valuable course has garnered rave reviews from practicing endocrinologists throughout Southeast Asia.

https://besmayo.com/

> I see my role as a physician to include caring for the health of my community, of my country, and of my planet as all part of the same spectrum. I don't really differentiate between caring for patients and caring for the planet. **And when I look around and see one of the greatest existential threats to human survival, namely global climate change, it makes me want to do something about it."**

— Daniel Oppenheim, PhD, MD, clinical endocrinologist, Maine Medical Center, Scarborough, Maine, discussing the link between climate change and endocrine health in **"Third Rock from the Sun: Endocrinology and Climate Change"** on page 66.

MEMBER SPOTLIGHT

Naresh Hanchate, PhD

Naresh Hanchate's career goal is to understand the mechanisms through which the brain controls physiology and behavior. He completed his master's in biotechnology from the University of Hyderabad, India, and obtained two-year research training at the National Institute of Immunology, New Delhi. Hanchate received his PhD in neuroscience from the University of Lille, France, where his research uncovered novel hypothalamic pathways regulating mammalian reproduction, and identified genetic mutations in patients with Kallmann Syndrome, a neurodevelopmental disorder that leads to infertility and anosmia.

Hanchate then joined the laboratory of Linda Buck, PhD, at the Fred Hutchinson Cancer Research Center, Seattle, Wash., as a postdoc, to study the mammalian olfactory system and the neural circuits that mediate innate responses. Here, his pioneering studies using advanced, single-cell genomic methods provided novel insights into the developmental mechanisms that shape the sense of smell.

In more recent work, Hanchate developed a new method, termed "Connect-seq" by coupling single-cell transcriptomics and retrograde viral tracing to define the molecular compositions of individual neurons in specific neural circuits.

Hanchate envisions these innovations will help advance research in neuroscience and endocrinology to better understand how the brain controls behavior and physiology.

To learn more about some of the Endocrine Society's outstanding members, go to: ***www.endocrine.org/member-spotlight***.

The increase in U.S. medical school applications through August 2020, marking the sharpest rise in over a decade.

— **SOURCE:** ASSOCIATION OF AMERICAN MEDICAL COLLEGES

The amount of medical schools that have a women's health curricula.

— **SOURCE:** NIH.GOV

In June 2020, 18% of people with diabetes were unemployed compared to 12% of the general public. Many continue wrestling with tough choices on whether to pay for food, rent, utilities, or insulin.

— **SOURCE:** AIRA

86% – Since COVID-19, 86% of patients have reported doing at least one telemedicine visit.

#1 – Endocrinology tops the list as the No. 1 specialty adopting telemedicine.

$29 billion – Telemedicine will account for $29 billion in healthcare services in 2020.

20% – The portion of medical office visits that will be virtual in 2020.

— **SOURCE:** DOXIMITY'S 2020 STATE OF TELEMEDICINE REPORT

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2020 Eureka!

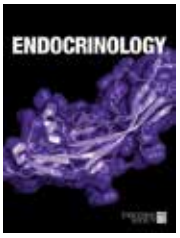
BY KELLY HORVATH

For the sixth year running, *Endocrine News* talks to editors from Endocrine Society publications to get the scoop on the top endocrine discoveries of 2020.

Despite the pandemic-related shutdown that reduced operations in most research laboratories around the world, endocrinologists unearthed plenty of science gold. This article compiles nuggets from what stood out to more than a dozen editors from *Endocrinology*, *Endocrine Reviews*, *Journal of the Endocrine Society*, and *The Journal of Clinical Endocrinology & Metabolism* (JCEM) as the most important endocrinology studies published in the past 12 (or so) months.

Despite the challenges posed by the shutdown, there's much to be excited about as this extensive list will show. Vital research ranges from studies about novel regulatory pathways to answering important questions about breast cancer to gaining a better understanding of how we age. Not surprisingly, a good number of these studies investigate the health threat that dominated 2020: COVID-19.

From the Editors of *Endocrinology*



Editor-in-chief **Carol A. Lange, PhD,** professor of medicine (Division of Hematology, Oncology, and Transplantation) and Pharmacology; Tickle Family Land Grant Endowed Chair of Breast Cancer Research; co-lead, Cellular Mechanisms of Cancer Program; and director, Molecular, Genetic, and Cellular Targets of Cancer Training Program at the University of Minnesota Masonic Cancer Center in Minneapolis, chose to highlight three focus areas that inspire her from studies published in *Endocrinology* as well as other journals.

Hormones and COVID-19. In short, vitamin D, melatonin, estrogen, and progesterone confer protection from infection by and severe symptoms of COVID-19, which in part explains some of the sex-related differences in COVID-19 mortality, says Lange.

These collective findings come from:

- Mauvais-Jarvis, F, et al., in "Estradiol, Progesterone, Immunomodulation, and COVID-19 Outcomes," published in September in *Endocrinology*
- Lazartiques, E, et al., in "Endocrine Significance of SARS-CoV-2's Reliance on ACE2," published in July in *Endocrinology*
- Singer, K, et al., in "The Collision of Meta-Inflammation and SARS-CoV-2 Pandemic Infection," published in September in *Endocrinology* (and featured in the October issue of *Endocrine News*)
- Bilezikian, JP, et al., in "Mechanisms in Endocrinology: Vitamin D and COVID-19," published in November in *European Journal of Endocrinology*
- Iddir, M, et al., in "Strengthening the Immune System and Reducing Inflammation and Oxidative Stress through Diet and Nutrition: Considerations during the COVID-19 Crisis," published in May in *Nutrients*

Hormonal/Signaling Regulation of Breast Cancer Stem Cells, Therapy Resistance, and Metastasis. This topic area is Lange's own research focus. In "Phosphorylated Progesterone Receptor Isoforms Mediate Opposing Stem Cell and Proliferative Breast Cancer Cell Fates," published in February 2019 in *Endocrinology*, Lange and her co-researchers investigated how two progesterone receptor isoforms are differentially linked to tumor behavior in the hope of developing pharmacologic therapies targeting cancer stem cells. Three months later, Sartorius, CA and Fettig, LM published "Phospho-PR Isoforms and Cancer Stem Cells: What Does the FOXO1 Say?" in *Endocrinology* as a positive commentary on the Lange study. Other related studies include:

- "Cytokeratin 5 Alters β-Catenin Dynamics in Breast Cancer Cells," by McGinn, O, et al., in *Oncogene* in March
- "Insulin Receptor Substrate-1 (IRS-1) Mediates Progesterone Receptor-Driven Stemness and Endocrine

Resistance in Oestrogen Receptor+ Breast Cancer," by Dwyer, AR, et al. (including Lange), published in the *British Journal of Cancer* in November

- "Glucocorticoid Receptors are Required Effectors of TGFβ1-Induced p38 MAPK Signaling to Advanced Cancer Phenotypes in Triple-Negative Breast Cancer," by Perez Kerkvliet C, et al. (including Lange), published in *Breast Cancer Research* in May

Lange also highlights "Differential Regulation and Targeting of Estrogen Receptor α Turnover in Invasive Lobular Breast Carcinoma," a study that provides new insights into this rare breast cancer subtype, by Sreekumar, S, et al., published in *Endocrinology* in September.

Targeting Cellular Senescence. Lange's third topic area is the role of cellular senescence and the signaling pathways that regulate senescence in health and disease. "Targeting senescent cells can be a valuable path to increased longevity, prevention, and treatment of debilitating diseases," she says. "The Role of Cellular Senescence in Ageing and Endocrine Disease," by Khoslo, S, et al., published in *Nature Reviews Endocrinology* in May and "ATM is a Key Driver of NF-κB-Dependent DNA-Damage-Induced Senescence, Stem Cell Dysfunction and Aging," by Zhao, J, et al., published in *Aging* in March tease out mechanisms underlying how and why the human body deteriorates over time.

"These three research topics are diverse on the surface," Lange explains in summary, "but they all touch on the role and regulation of multiple endocrine systems or signaling pathways in health and disease. I am really excited about the idea of leveraging what we learn and know about hormones, signaling pathways, and gene regulation to improve health and prevent or treat diseases, all the way from battling COVID-19 to treating metastatic breast cancer, to living a happy and healthy long and disease-free life in general."

More from *Endocrinology* Editors

Several associate editors of *Endocrinology* also contributed. **Patricia L. Brubaker, PhD, FRSC,** professor, Departments of Physiology and Medicine at the University of Toronto, in Ontario, credits "Dapagliflozin Does Not Directly Affect Human α or β Cells" by Dai, C, et al., from the August *Endocrinology* as worth highlighting, in which the authors clarified previous reports on the potential effects of dapagliflozin, an SGLT2 inhibitor, on islet function. "Using clinically relevant doses with human islets both in vitro and in an in vivo transplant model that mimics the clinical setting and drug exposure, they demonstrated that SGLT2 expression in human islets is extremely low and that this widely utilized agent for the treatment of hyperglycemia in patients with type 2 diabetes does not directly affect insulin or glucagon secretion from the human islet," Brubaker says.

Richard J. Auchus, MD, PhD, Division of Metabolism, Endocrinology, & Diabetes, Departments of Internal Medicine and Pharmacology at the University of Michigan, in Ann Arbor, chose "Pharmacodynamic Studies of Nasal Tetracosactide with Salivary Glucocorticoids for a Noninvasive Short Synacthen Test," by Elder, CJ, et al., published in August in JCEM. "The JCEM paper was very innovative," Auchus says, "using cosyntropin delivered intranasally with chitosan to improve exposure, and then saliva cortisol and cortisone to test adrenal function. It's totally non-invasive — no IV, no blood draws. In fact, you could do adrenal testing at home via telemedicine."

Auchus also highlights "Expression in *Escherichia Coli*, Purification, and Functional Reconstitution of Human Steroid 5α-Reductases" from his own lab published in August in *Endocrinology*. "The 5α reductases are critical for androgen physiology and prostate biology, as well as other steroid and drug metabolism," he explains. "They are extremely hydrophobic and have resisted biochemical characterization for that reason. The expression in *E. coli* and purification will allow more precise studies that have not been possible previously."

Hershel Raff, PhD, FAAAS, FAPS, professor of medicine, surgery, and physiology, and professor, Pharmacy School, at the Medical College of Wisconsin, and director of the Endocrine Research Laboratory at Aurora St. Luke's Medical Center, in Milwaukee, Wis., also selected two papers, both from *Endocrinology*.

"Targeted Disruption of *Lats1* and *Lats2* in Mice Impairs Adrenal Cortex Development and Alters Adrenocortical Cell Fate," by Boyer, A, et al., published in June caught his eye because the development of the fetal, neonatal, and adult adrenal gland has been of great interest for decades. "Understanding this phenomenon not only gives insight into cell signaling in general, but has potential clinical importance considering the critical role the fetal and neonatal adrenal plays in pathophysiology of endocrine disorders," he says. "With a series of elegant in vivo and histomorphometric and gene expression studies, this paper comprehensively demonstrated a previously unsuspected role of the Hippo pathway in the development of a normal adrenal gland using conditionally deleted kinase mice models."

From January, "Dysregulation of Hypothalamic Gene Expression and the Oxytocinergic System by Soybean Oil Diets in Male Mice," by Curras-Collazo, MC, et al., explores soybean oil, a basic component of the American diet, and may have public health ramifications, Raff says. "Although soybean oil's link to insulin

resistance and obesity is well known, this study in male mice demonstrated a heretofore unappreciated effect on the hypothalamic expression of the oxytocin gene, which correlated with insulin resistance. Also, coconut oil appeared to have no such major effect. This fascinating study suggests that soybean oil may affect behavior and neuropsychiatric diseases, in addition to its effects on insulin signaling."

David J. Handelsman, MB, BS, PhD, director, ANZAC Research Institute and Head of the Andrology Department, at Concord Hospital in Sydney, Australia, liked "Effects of Moderately Increased Testosterone Concentration on Physical Performance in Young Women: A Double-Blind, Randomised, Placebo-Controlled Study," by Hirschberg, AL, et al., published in the May issue of the *British Journal of Sports Medicine*.

"This is the first placebo-controlled randomized clinical trial to test whether a modest dose of testosterone (well below male replacement doses) improves athletic performance in healthy physically active young women," Handelsman says. "By showing unequivocally that testosterone does improve athletic performance, this study clearly supports the interpretation that the sex dichotomous circulating testosterone levels in healthy men (15 – 20 times greater than in women) are primarily responsible for the male sex advantage in athletic performance over females." Handelsman also touts Finkelstein, JS, et al., for "Dose-Response Relationships Between Gonadal Steroids and Bone, Body Composition, and Sexual Function in Aging Men," from the August JCEM. "This placebo-controlled randomized clinical trial unequivocally demonstrates the dose-dependent effects of testosterone on the principal androgen-sensitive endpoints in aging men confirming previous studies in healthy younger and older men," he says. "It also shows that different androgen-sensitive tissues display distinct thresholds for androgen action so that no criteria based on circulating testosterone levels alone are likely to represent sound decision limits for testosterone treatment."

Finally, from the June issue of JCEM, Handelsman gives us "Rate and Extent of Recovery from Reproductive and Cardiac Dysfunction Due to Androgen Abuse in Men," from his own lab: "This observational cohort study provides a comprehensive outline of the natural history of androgen abuse, notably the rate, extent, and determinants of recovery of male reproductive function. This study shows that, after cessation of androgen abuse, male

> **"Despite the unequivocal benefits of bisphosphonates, decline in their utilization and altered prescription patterns over the past several years have contributed to recent discouraging osteoporotic fracture trends.** One potentially promising approach to improve compliance, reduce patient burden, and close the treatment gap, at least in appropriately selected patients, could rely on very infrequent administration of zoledronic acid to prevent fractures, promote healthy aging, and reduce mortality."
>
> — JOSHUA NICHOLAS FARR, PHD, ASSISTANT PROFESSOR OF MEDICINE, DIVISION OF ENDOCRINOLOGY, KOGOD CENTER ON AGING, MAYO CLINIC COLLEGE OF MEDICINE, IN ROCHESTER, MINN.

“It would be hard this year not to focus on the COVID-19 pandemic and the key role that endocrinology has played in our mechanistic understanding of SARS-CoV-2 infection and its treatment. However, at the core of the pandemic has been its devastating impact on different communities where, again, metabolic comorbidities appear to play an important role.”

— PAUL M. STEWART, MD, FRCP, FMEDSCI, EXECUTIVE DEAN, PROFESSOR, UNIVERSITY OF LEEDS SCHOOL OF MEDICINE, LEEDS, UK; EDITOR-IN-CHIEF OF JCEM,

reproductive function recovers completely (apart from residual long-term reductions in testis volume and serum sex hormone–binding globulin) but slowly over 9 – 18 months.

Felix Beuschlein, MD, of the Medical Clinic and Polyclinic IV at the University Hospital of Munich in Germany, and the Clinic for Endocrinology, Diabetology, and Clinical Nutrition at the University Hospital Zurich in Switzerland, selected “Urine Steroid Metabolomics for the Differential Diagnosis of Adrenal Incidentalomas in the EURINE-ACT Study: A Prospective Test Validation Study,” by Bancos, I, et al., from the September issue of *Lancet Diabetes Endocrinology* as important. Its title tells much of the story, and this paper is indeed worth mentioning for helping clinicians more efficiently determine which tumors require surgery as well as helping patients avoid unnecessary treatments.

From the Editor of *Endocrine Reviews*

Endocrine Reviews editor-in-chief **Daniel J. Drucker, MD,** and senior scientist at the Lunenfeld Tanenbaum Research Institute of the Mt. Sinai Hospital in Toronto, Ontario, points to “Dexamethasone in Hospitalized Patients with COVID-19 — Preliminary Report,” by Horby, P, et al., about the RECOVERY trial from the July issue of *New England Journal of Medicine*. “This randomized clinical trial demonstrated that dexamethasone, 6 mg once daily for 10 days, reduced mortality in severely ill people with COVID-19,” Drucker explains. “Notably, about 25% of trial participants were people with diabetes, mostly type 2 diabetes. Dexamethasone a synthetic glucocorticoid hormone widely utilized experimentally and clinically by basic and clinical endocrine scientists, is known for its anti-inflammatory actions. This trial demonstrated that dexamethasone is the most effective therapy we have so far to treat acutely ill people with COVID-19 infection — it represents a great triumph for clinical investigation, it highlights the importance of endocrine science and glucocorticoid biology, and implementation of the trial results will save thousands of lives going forward.”

More from *Endocrine Reviews* Editors

Endocrine Reviews associate editor **Anna L. Gloyn, DPhil,** professor of pediatrics (and by courtesy) of genetics and associate chair for basic science research at the Stanford University School of Medicine, Stanford, Calif., finds "Exome Sequencing Identifies Genes and Gene Sets Contributing to Severe Childhood Obesity, Linking PHIP Variants to Repressed POMC Transcription," by Marenne, G, et al., published in the June issue of *Cell Metabolism* especially compelling. "This study used genetic discoveries across the allele frequency spectrum to identify causes of severe childhood obesity," Gloyn says. "They were able to show that one of their discoveries, *PHIP*, controls another gene involved in obesity (*POMC*), which regulates appetite, opening up the potential for treating these children with existing therapies."

Berenice B. Mendonça, MD, head professor of endocrinology at the Hospital das Clínicas, Instituto Central, in São Paulo, Brazil, offers five papers for consideration, the first two of which come from her group and were both published in JCEM. From April 2019, "Psychosexual Aspects, Effects of Prenatal Androgen Exposure, and Gender Change in 46,XY Disorders of Sex Development" is the largest cohort (144 individuals) with a clinical/molecular diagnosis of 46,XY disorder of sex development (DSD) in which psychosexual outcomes (gender role, gender identity, and sexual orientation) were assessed using questionnaires and a psychological test, explains Mendonça. "These data allowed the conclusions that prenatal androgen exposure influenced psychosexual development in 46,XY DSD favoring male psychosexuality in all psychosexual outcomes, helping in the management of DSD individuals." "DLK1 Is a Novel Link between Reproduction and Metabolism" from June 2019 "shows for the first time a strong link between reproduction and metabolic defects," Mendonça says.

From the May 2019 issue of the *Journal of Nuclear Medicine*, "Efficacy and Safety of High-Specific-Activity ^{131}I-MIBG Therapy in Patients with Advanced Pheochromocytoma or Paraganglioma," by Pryma, DA, et al., describes therapeutic advances in a devastating disorder. In "Hypothalamic miR-30 Regulates Puberty Onset via Repression of the Puberty-Suppressing Factor, Mkrn3" from the November 2019 issue of *PLOS Biology*, Tena-Sempere, JN, et al. demonstrate a new regulatory factor in puberty. Finally, Matsumoto, R, et al create a model of congenital pituitary disease and show how OTX2 regulates pituitary development in "Congenital Pituitary Hypoplasia Model Demonstrates Hypothalamic OTX2 Regulation of Pituitary Progenitor Cells," published in February in the *Journal of Clinical Investigation*.

Sally A. Camper, PhD, Margery Shaw Distinguished University Professor of Human Genetics and professor of internal medicine, University of Michigan Medical School in Ann Arbor, Mich., nominated "Proinsulin Misfolding Is an Early Event in the Progression to Type 2 Diabetes," from the June 2019 issue of *eLife* by Kaufman, RJ and Arvan P, et al. "This common theme really resonated with me," Camper says, "because it is becoming increasingly clear how much protein misfolding contributes to many types of diseases — from neurologic disease to diabetes."

From Editors of the Journal of the Endocrine Society

JES editor-in-chief **J. Larry Jameson, MD, PhD,** professor of medicine, dean of the Perelman School of Medicine, and executive vice president for the Health System at the University of Pennsylvania in Philadelphia, highlights "Influence of Cinnamon on Glycemic Control in Individuals With Prediabetes: A Randomized Controlled Trial," from the November issue of JES. "Given the prevalence and impact of type 2 diabetes," Jameson says, "I recommend that our members read the paper by Romeo, GR, et al., using a randomized trial to examine the effect of cinnamon on blood glucose in individuals with prediabetes. This provocative finding merits further study including potential mechanisms of action."

More from Journal of the Endocrine Society Editors

Ana Claudia Latronico, MD, PhD, head professor of the Endocrinology and Metabolism Division of São Paulo University in Brazil, nominates a JES paper from December 2019, in the reproductive biology and sex-based medicine topic area. "Next-Generation Sequencing Reveals Novel Genetic Variants (SRY, DMRT1, NR5A1, DHH, DHX37) in Adults With 46,XY DSD," by Achermann, JC, et al., analyzed known and candidate genes for disorders of sex development (DSD). "In this study, a likely genetic cause was found in 30.8% individuals," Latronico says. "Pathogenic variants were found in different genes, reaching a specific diagnosis, providing new insights into the role of these proteins in sex development."

"My pick for the basic science nuclear receptor area is 'Structural Insights of Transcriptionally Active, Full Length Androgen Receptor Coactivator Complexes,' by O'Malley, BW, et al., published in July in *Molecular Cell*," says associate editor **Nancy L. Weigel, PhD,** professor of molecular and cellular biology at Baylor College of Medicine in Houston, Texas. "Determining structures of nuclear receptors and their interactions with coactivators has been challenging. Although crystal structures of isolated DNA or

hormone-binding domains have been available for some time, the apparently unstructured or flexible amino terminus has not been analyzed by x-ray crystallography," she explains. "Using cryo-EM, the O'Malley lab has determined the DNA-bound structure of full-length androgen receptor (AR) dimer as well as its structure in the presence of SRC-3 and p300. The structure reveals novel intramolecular and intermolecular interactions that had been hypothesized by others from molecular biology studies and shows that, unlike estrogen receptor, AR recruits the SRC-3 coactivator through its N terminal domain (NTD). Moreover, the dimer recruits only one molecule of SRC-3 rather than one molecular per monomer."

John L. Leahy, MD, an endocrinologist at the University of Vermont Medical Center and a professor at the Larner College of Medicine at UVM in Burlington, picked a number of diabetes-themed papers:

- "Coronavirus Infections and Type 2 Diabetes — Shared Pathways with Therapeutic Implications" is an "interesting paper that reviews biological and signaling overlaps between coronavirus infections and multiorgan pathophysiology," Leahy says, "as well as a potential role of DPP-4 and GLP-1 therapeutics." From the June 2020 issue of *Endocrine Reviews,* this selection is from that journal's editor-in-chief Daniel J. Drucker.
- "GLP-1 Receptor Agonists in the Treatment of Type 2 Diabetes—State-of-the-Art," by Nauck, MA, et al., and published in the November issue of *Molecular Metabolism,* provides an "up-to-date comprehensive review on GLP-1 receptor agonist agents."
- By Battelino, T, et al., "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations from the International Consensus on Time in Range" from the August 2019 issue of *Diabetes Care* provides a very timely review of the recommendations from an expert international panel on the analysis of CGM data using time in range parameters.
- Also timely, "Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline" was published in the November issue of the *Journal of Diabetes Science Technology* by Galindo, RJ, et al.

From The Journal of Clinical Endocrinology & Metabolism

Editor-in-chief of JCEM, **Paul M. Stewart, MD, FRCP, FMedSci,** executive dean and professor at the University of Leeds School of Medicine in the United Kingdom, says, "It would be hard this year not to focus on the COVID-19 pandemic and the key role that endocrinology has played in our mechanistic understanding of SARS-CoV-2 infection and its treatment." Accordingly, he chose "Predicting Mortality Due to SARS-CoV-2: A Mechanistic Score Relating Obesity and Diabetes to COVID-19 Outcomes in Mexico," by Bello-Chavolla, OY, et al. "However, at the core of the pandemic has been its devastating impact on different communities where, again, metabolic comorbidities appear to play an important role. In this already highly cited paper published in JCEM in August 2020, researchers from Mexico evaluating over 170,000 patients infected with COVID-19 defined the crucial importance of obesity and diabetes mellitus in predicting mortality," Stewart says.

More from JCEM Editors

Joshua Nicholas Farr, PhD, assistant professor of medicine, Division of Endocrinology at the Kogod Center on Aging, Mayo Clinic College of Medicine, in Rochester, Minn., cites "Ten Years of Very Infrequent Zoledronate Therapy in Older Women: An Open-Label Extension of a Randomized Trial," by Grey, A, et al., published in the April issue of JCEM as important for several reasons. "Indeed, nitrogen-containing bisphosphonates are the most commonly prescribed drugs for the management of osteoporosis. However, concerns about long-term use and their well-publicized associated risk of extremely rare, yet serious, side effects has led to fear among many patients to adhere to therapy and hesitance on the part of some clinicians to prescribe these drugs, even to those who clearly need therapy. Sadly, despite the unequivocal benefits of bisphosphonates, decline in their utilization and altered prescription patterns over the past several years has contributed to recent discouraging osteoporotic fracture trends. One potentially promising approach to improve compliance, reduce patient burden, and close the treatment gap, at least in appropriately selected patients, could rely on very infrequent administration of zoledronic acid to prevent fractures, promote healthy aging, and reduce mortality," he says.

Sangeeta R. Kashyap, MD, professor of medicine, Cleveland Clinic Lerner College of Medicine and associate program director of the Endocrinology Fellowship Program in Ohio, chose four JCEM studies to highlight as noteworthy:

- "Effects of Intermittent Fasting or Calorie Restriction on Markers of Lipid Metabolism in Human Skeletal Muscle," by Heilbronn, LK, et al., from October
- "Metabolite Signature of Albuminuria Involves Amino Acid Pathways in 8661 Finnish Men Without Diabetes," by Laakso, M, et al., from September, in which "we learned that albuminuria is a vascular and metabolic predictor of disease"
- "Identification and metabolic profiling of a novel human gut-derived LEAP2 fragment," by Knop, FK, et al., from November, that highlights the role of gut in remission of diabetes following gastric bypass surgery in diabetes

- "Predicting Mortality Due to SARS-CoV-2: A Mechanistic Score Relating Obesity and Diabetes to COVID-19 Outcomes in Mexico," by Bello-Chavolla, OY, et al., from August, that increases our understanding of risk factors in patients with obesity and type 2 diabetes that leads to worse COVID outcomes (this article was also favored by JCEM editor-in-chief, Paul M. Stewart, above)

Elizabeth N. Pearce, MD, MSc, Boston University School of Medicine, Section of Endocrinology, Diabetes, and Nutrition, Boston, Mass., had three top picks:

- "Teprotumumab for the Treatment of Active Thyroid Eye Disease," by Douglas, RA, et al., from the January issue of NEJM. "This phase 3 clinical trial of teprotumumab therapy showed significant benefits for patients with moderate to severe Graves eye disease," she says. "This is a novel therapy that appears to provide greater benefits than any other nonsurgical approach to date."
- From the March issue of JCEM, "Controlled Antenatal Thyroid Screening II: Effect of Treating Maternal Suboptimal Thyroid Function on Child Behavior," Hales, C, et al., "suggests an adverse effect of overtreatment of hypothyroid pregnant women on child neurobehavioral outcomes. I think these results will require confirmation in future studies, but this is a provocative paper. It has been thought that mild overtreatment of hypothyroid women with levothyroxine in pregnancy was harmless (since there are no adverse obstetric consequences), but if this is correct, the optimal therapeutic range is narrow and very careful dose titration is likely required," Pearce says.
- Finally, she explains, "It's hard to avoid picking a COVID-19 paper in light of the events of the past year" and cited "Subacute Thyroiditis After SarsCOV-2 Infection," by Latrofa, F, et al., and published in July in JCEM (and written about in the September issue of *Endocrine News*) as the first to document an association between COVID -19 and subacute thyroiditis.

And so, conditions from disorders of sex development to diabetes — and even COVID-19 as well as just about everything in between — are now better elucidated thanks to the work of these endocrinologists. They are surely worth their weight in gold. EN

– HORVATH IS A FREELANCE WRITER BASED IN BALTIMORE, MD. SHE WROTE ABOUT THE EVOLUTION OF INSULIN IN THE NOVEMBER ISSUE.

"…dexamethasone is the most effective therapy we have so far to treat acutely ill people with COVID-19 infection — it represents a great triumph for clinical investigation, it highlights the importance of endocrine science and glucocorticoid biology, and implementation of the trial results will save thousands of lives going forward."

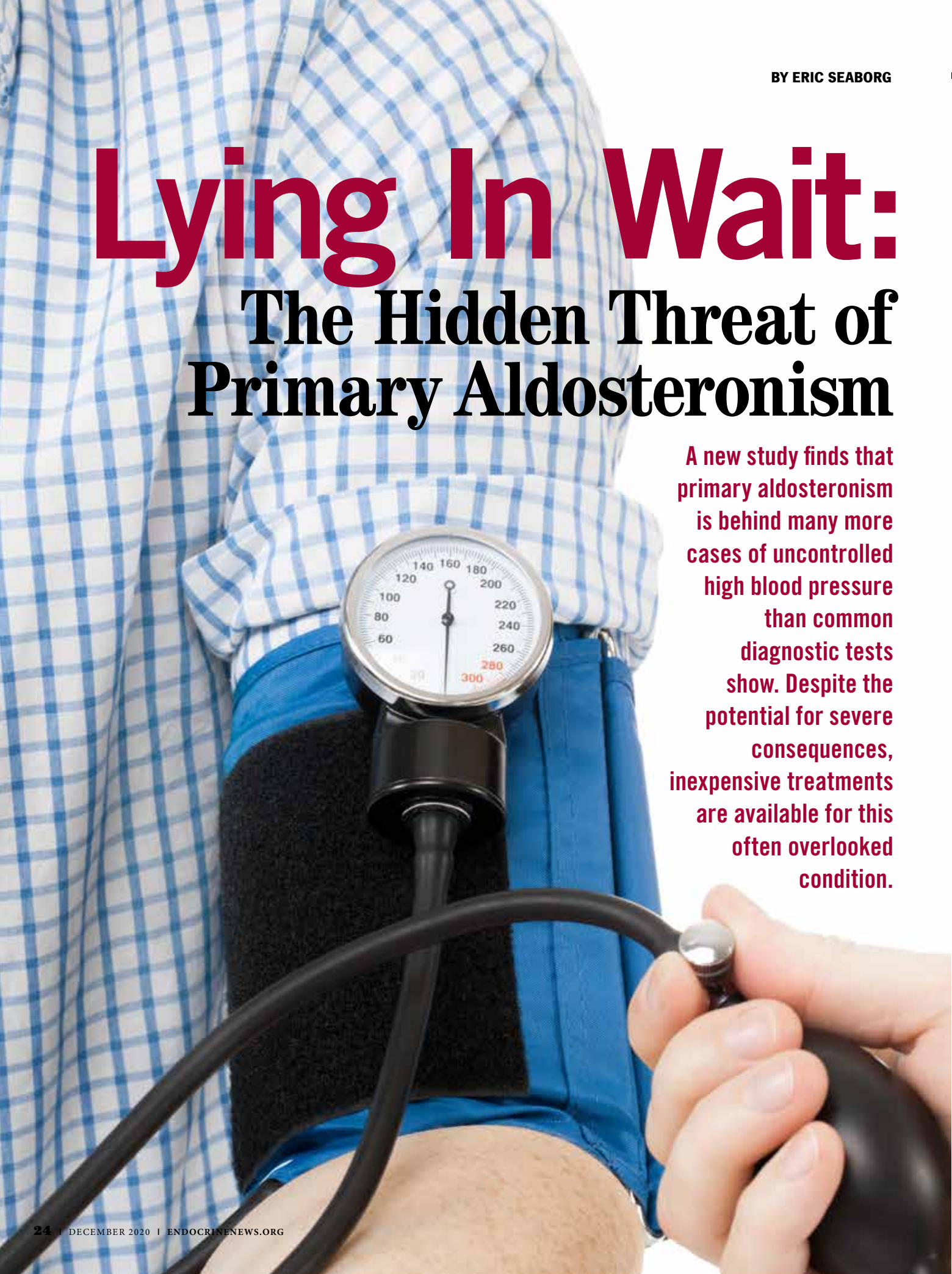
— DANIEL J. DRUCKER, MD, SENIOR SCIENTIST, LUNENFELD TANENBAUM RESEARCH INSTITUTE, MT. SINAI HOSPITAL, TORONTO, ONTARIO; EDITOR-IN-CHIEF, *ENDOCRINE REVIEWS*

BY ERIC SEABORG

Lying In Wait:

The Hidden Threat of Primary Aldosteronism

A new study finds that primary aldosteronism is behind many more cases of uncontrolled high blood pressure than common diagnostic tests show. Despite the potential for severe consequences, inexpensive treatments are available for this often overlooked condition.



Some endocrinologists have long argued that primary aldosteronism is not the rare disease that it is commonly considered. That argument got a big boost with a recent study in the *Annals of Internal Medicine* that found that the "prevalence of primary aldosteronism is high and largely unrecognized" — some three to five times higher than previous tests have indicated.

The new study is a "game-changer," says John Funder, MD, PhD, of the Hudson Institute of Medical Research in Victoria, Australia. Funder chaired the panel that wrote the 2016 Endocrine Society guideline on primary aldosteronism, an update of which is currently under consideration by the Clinical Guidelines Committee.

"The central problem is that plasma aldosterone concentration is a very poor index of total daily aldosterone secretion," Funder writes in an editorial that accompanied the *Annals* article. "The study shows that the single-spot measurement of plasma aldosterone concentration, which clinicians have used for decades to screen for primary aldosteronism, is not merely useless but actually misleading."

24-Hour Test

The study involved more than 1,800 participants at four U.S. academic centers, classified in four groups: normal blood pressure, stage 1 hypertension, stage 2 hypertension, and resistant hypertension. The participants were prescribed a high-sodium diet and standardized potassium intake before completing a 24-hour urine collection. The researchers diagnosed primary aldosteronism when urinary aldosterone levels exceeded 12 micrograms over 24 hours.

This cut-off led to the conclusion that "the prevalence of primary aldosteronism is high and largely unrecognized. The aldosterone-renin ratio (ARR) had poor sensitivity and negative predictive value for detecting biochemically overt primary aldosteronism."

But in addition to identifying a high number of patients over the cut-off, the study found that every blood pressure category had a continuum of renin-independent aldosterone production, with higher aldosterone production associated with higher blood pressure and lower serum potassium levels.

A Continuum

"For decades, primary aldosteronism has been considered a binary or categorical disease," says Anand Vaidya, MD, director of the Center for Adrenal Disorders at Brigham & Women's Hospital in Boston, Mass., and lead author of the study. "People have used arbitrary thresholds of what a high aldosterone was. What we showed is that excess aldosterone exists across a broad continuum. It is not a binary diagnosis. It exists across a severity spectrum from mild to severe and is very common. You can find it very frequently in patients with hypertension."

This finding is significant given that almost half the American population has high blood pressure, which is "the world's leading risk factor for death," according to Robert M. Carey, MD, professor of medicine at the University of Virginia, in Charlottesville, Va. Carey was a member of the team that wrote the 2016 Endocrine Society guideline and is also a co-author of the *Annals* article.

> "Primary aldosteronism represents an independent cardiovascular risk, just like we view diabetes as an independent cardiovascular risk. For patients with primary aldosteronism, the goals of treatment go beyond blood pressure control **and must include strategies to buffer the cardiovascular and renal morbidity."**
>
> — ADINA TURCU, MD, MS, ASSISTANT PROFESSOR, DIVISION OF METABOLISM, ENDOCRINOLOGY, AND DIABETES, UNIVERSITY OF MICHIGAN, ANN ARBOR, MICH.

Beyond Blood Pressure

But the dangers go well beyond simply blood pressure. "Primary aldosteronism is a deadly disease from the standpoint of cardiovascular target-organ damage," Carey says.

Adina Turcu, MD, MS, assistant professor in the Division of Metabolism, Endocrinology, and Diabetes at the University of Michigan, in Ann Arbor, Mich., agrees that the study's findings are important when "at the most, only about 50% of patients with hypertension are effectively treated. The proportion of patients who have their hypertension under control hasn't really increased over the past 20 years. This reflects the 'one-size-fits-all' approach to hypertension treatment and is a missed opportunity to identify and customize care patients with specific types of hypertension."

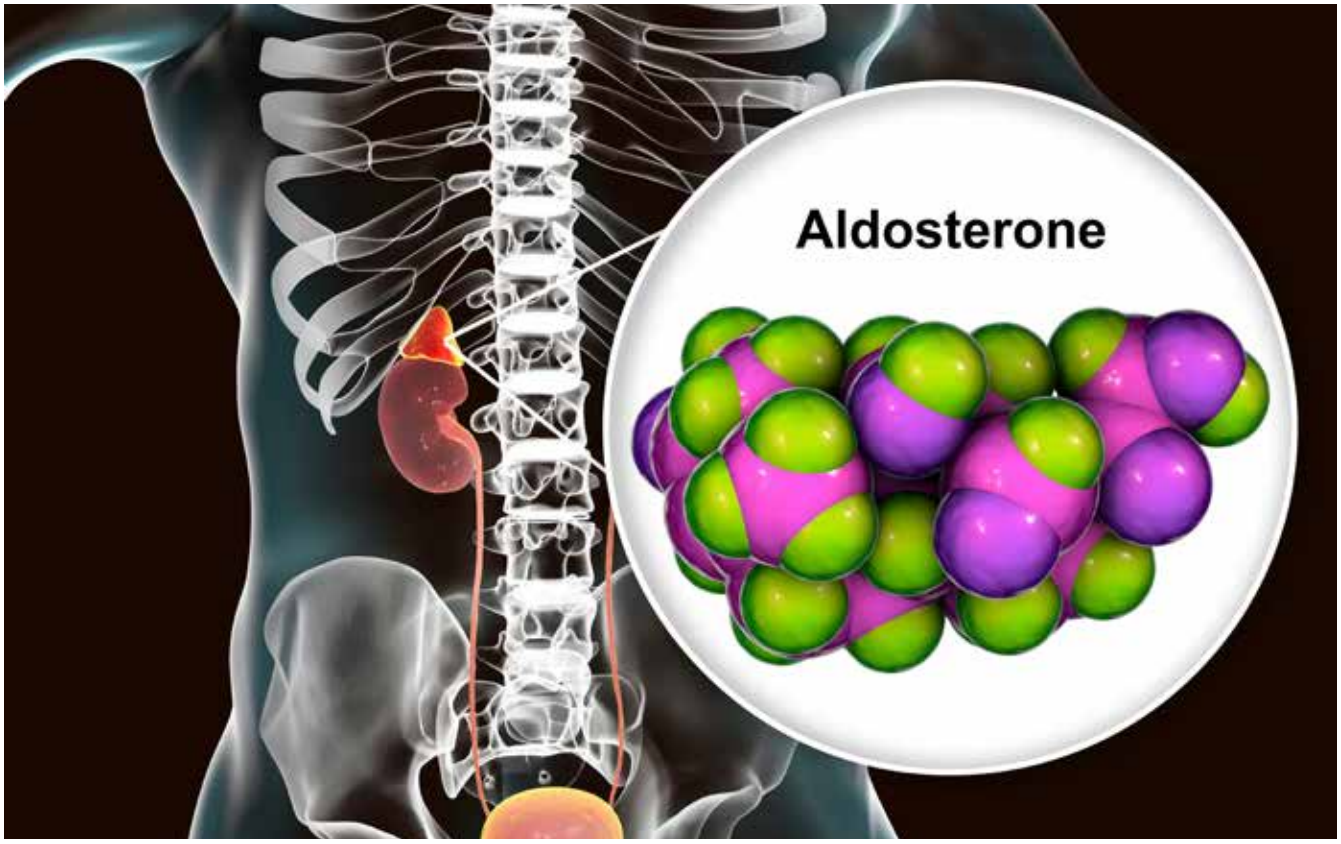
"Primary aldosteronism represents an independent cardiovascular risk, just like we view diabetes as an independent cardiovascular risk," Turcu says. "For patients with primary aldosteronism, the goals of treatment go beyond blood pressure control and must include strategies to buffer the cardiovascular and renal morbidity."

From his study of the literature, Funder estimates that "the prevalence of primary aldosteronism in hypertensive patients may be on the order of 45% to 50%. There is very good evidence that for the same blood pressure, patients with primary aldosteronism have at least three times higher morbidity and mortality."

The failure to find and treat patients with primary aldosteronism is doubly troubling considering that its effects can be easily counteracted with mineralocorticoid receptor blockers, which are safe and inexpensive. "If we are missing a substantial number of people that could receive a mineralocorticoid blocker and be improved or cured, this is a great opportunity for us that we are missing," Carey says.

Screening Schemes

And that point raises the fundamental question of when and how to screen hypertensive patients for primary aldosteronism. Funder believes every patient newly diagnosed with hypertension



Aldosterone, a steroid hormone produced by the adrenal cortex in the adrenal gland, is essential for sodium conservation throughout the body. Primary aldosteronism occurs when too much aldosterone is produced, thus raising sodium levels.

> The prevalence of primary aldosteronism in hypertensive patients may be on the order of 45% to 50%. **There is very good evidence that for the same blood pressure, patients with primary aldosteronism have at least three times higher morbidity and mortality."**
>
> — JOHN FUNDER, MD, PHD, HUDSON INSTITUTE OF MEDICAL RESEARCH, VICTORIA, AUSTRALIA; CHAIR, 2016 GUIDELINE WRITING COMMITTEE OF "THE MANAGEMENT OF PRIMARY ALDOSTERONISM: CASE DETECTION, DIAGNOSIS, AND TREATMENT"

could be screened by determining the amount of aldosterone in a 24-hour urine collection. He believes that would be a practical means of overcoming the pulsatile nature of hormone secretion. He notes that endocrinologists are not likely to see these patients until their disease is progressing, so he hopes to raise awareness of the need for screening among primary care physicians.

The *Annals* article says that "clinicians should consider screening for primary aldosteronism much more frequently, especially in the general hypertensive population" without specifying a particular test. The authors note that "the ARR can be a simple and useful screening method" but that levels can vary and "a single ARR is insensitive, even among patients with resistant hypertension."

Carey notes: "Although we are not to the point of being able to recommend specific testing for clinical medicine at large," the ARR is a simple test, and "if the renin is suppressed, then the likelihood goes way up that the patient has autonomous aldosterone production."

Turcu notes that the ARR can be repeated, and if the patient's hypertension is uncontrolled and continues to progress, physicians may catch primary aldosteronism if they are more aware that they should be looking for it.

A recommended testing regimen is the sort of question that a guideline-writing process could help elucidate, but all these experts agreed that the study had proven its point that "primary aldosteronism is grossly underdiagnosed, even among high-risk patients with hypertension who clearly meet indications for diagnostic testing."

"We have had cheap generic medications available for decades that are relatively safe to block aldosterone. So, the impetus to diagnose or consider this diagnosis needs to be underscored," lead author Vaidya concludes. EN

— SEABORG IS A FREELANCE WRITER BASED IN CHARLOTTESVILLE, VA. IN THE NOVEMBER ISSUE, HE WROTE ABOUT THE POTENTIAL LINKS BETWEEN AIR POLLUTION AND DIABETES.

AT A GLANCE

- **A definitive new study finds that primary aldosteronism occurs much more frequently than is generally recognized. It has been considered rare because the commonly used diagnostic tests fail to detect it.**
- **Among the many patients unable to control their blood pressure — and especially in cases of resistant hypertension — a primary aldosteronism diagnosis should be considered.**
- **Primary aldosteronism has severe consequences but can be treated with inexpensive generic mineralocorticoids.**

2020: A Year of challenges and progress

Endocrine research remains at the forefront of medical breakthroughs, which has led to cutting-edge treatment options, therapies, and products. *Endocrine News* reviews some of these new methods to treat a variety of endocrine complications as we come to the end of a year that saw far more than its share of challenges and, in turn, opportunities.

BY DEREK BAGLEY

What a year. The previous progress report for this publication concluded with the line: "Wonder what's in store for 2020." As it turns out, a lot more than most of us could have imagined. But in a year that will be remembered for a lot of turmoil and uncertainty, the healthcare system was able to pivot to new technologies and methods of care, and endocrinologists seemed to lead that charge.

A Doximity study published in August found that telemedicine will account for $29 billion in healthcare services and that since the start of the COVID-19 pandemic, 86% of patients had reported at least one telemedicine visit. And of all the specialties adopting telemedicine, endocrinology tops the list at No. 1.

So, endocrinologists know plenty about telemedicine by now, and it's a method of care that won't disappear in a post-COVID-19 world — that's a genie that will not go back in the bottle. And while the pandemic showed how endocrine science remains at the crossroads of so many other specialties, endocrinologists continued to make advancements both within and beyond the scope of COVID-19.

First FDA-Approved Oral Treatment for Testosterone Deficiency

In February, a new treatment for hypogonadism was launched in the form of testosterone undecanoate capsules, the first Food and Drug Adminstration (FDA)-approved oral treatment for testosterone deficiency. Clarus Therapeutics markets the drug as JATENZO.

In a clinical trial, 87% of hypogonadal men (145 of 166) treated with JATENZO achieved a mean total testosterone concentration in the eugonadal range at the end of treatment. The efficacy and safety of JATENZO was evaluated in 166 adult, hypogonadal males in a

> "Children with [central precocious puberty] require treatment for several years and missing treatment or stopping treatment too soon may lead to significant short stature and **misalignment between chronological age and physical and emotional development.**"
>
> — KAREN KLEIN, MD, ASSOCIATE CLINICAL PROFESSOR, UNIVERSITY OF CALIFORNIA SAN DIEGO, SAN DIEGO, CALIF.

four-month, open-label study. The primary endpoint was the percentage of patients with mean plasma total testosterone concentration (Cavg) over 24 hours within the normal eugonadal range on the final pharmacokinetic (PK) visit of the study. JATENZO can cause blood pressure increases that can increase the risk of major adverse cardiovascular events, including non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death.

"The launch of JATENZO means that healthcare providers, and their patients with indicated forms of hypogonadism, finally have an oral option, where liver toxicity was not observed in trials," says Endocrine Society member Ronald S. Swerdloff, MD, who was the lead investigator in the inTUne (investigational testosterone undecanoate) clinical trial, a distinguished professor of medicine at the David Geffen School of Medicine at UCLA, and chief of the Division of Endocrinology at Harbor-UCLA Medical Center. "JATENZO offers patients a convenient softgel formulation and eliminates the worry of gel transference, skin irritation from patches, or pain from injections that other testosterone treatments carry."

New Injectable Suspension for Pediatric Patients with Central Precocious Puberty

In May, the U.S. Food and Drug Administration (FDA) approved leuprolide acetate for injectable suspension for the treatment of pediatric patients two years of age and older with central precocious puberty (CPP). Tolmar Pharmaceuticals is marketing the drug as Fensolvi.

Leuprolide acetate is the most widely used treatment for CPP. Fensolvi utilizes a proprietary polymeric gel technology that forms an in-situ solid after injection and releases leuprolide acetate in a sustained and controlled manner over time. This technology enables a small volume of injection of only 0.375mL, subcutaneous administration, and a six-month dosing cycle.

FDA approval was based on results from a multicenter, open-label, single arm Phase 3 study evaluating the efficacy, safety, and pharmacokinetics of leuprolide acetate (LA) 45 mg for injectable suspension in 64 children with central (gonadotropin-dependent) precocious puberty. The study achieved its primary endpoint, with 87% of children achieving a serum-luteinizing hormone concentration of <4 IU/L at six months post-injection. The study also demonstrated that Fensolvi suppressed sex hormones to pre-pubertal levels and stopped or reversed the progression of clinical signs of puberty.

"Children with CPP require treatment for several years and missing treatment or stopping treatment too soon may lead to significant short stature and misalignment between chronological age and physical and emotional development," says Society member Karen Klein, MD, associate clinical professor at the University of California San Diego. "Fensolvi offers treating physicians and their patients with CPP a safe and effective treatment option that is administered twice a year with a small injection volume that has the potential to improve compliance."

Treatment emergent adverse events (TEAEs) were mostly mild or moderate, with none leading to withdrawal from the study. The most common TEAEs were injection site pain (31%), nasopharyngitis (22%), and fever (17%).

New App Helps Improve Diabetes Care in Patients with COVID-19

That same month, an international group of healthcare experts developed an app to help the providers on the front lines of

caring for patients with diabetes who have been hospitalized with the novel coronavirus.

The app, called COVID-IN-DIABETES (**C**ollaborative **O**pen-Access **V**irtually **I**ndividualized **D**ecision-**A**lgorithms for **I**npatient **D**iabetes — **covidindiabetes.org**) was developed with the goal of achieving glycemic control with a community-centered perspective, which means caring for patients while preserving personal protection equipment (PPE) and decreasing the spread of COVID-19. (The project is partially supported by the National Institute of Diabetes and Digestive and Kidney Diseases.)

Francisco J. Pasquel, MD, MPH, assistant professor of medicine in the Division of Endocrinology at Emory University in Atlanta, Ga., who developed the app and serves as its content editor, says that he and his colleagues had actually already been working on a project with the goal of individualizing therapy in the hospital, with recent experience they have gained in the inpatient setting and through knowledge gained through observational studies and clinical trials. "With COVID-19 there was actually an immediate need to learn how people were transforming care in the inpatient setting," Pasquel says. "We observed changes in protocols, ways people are trying to be creative to care for patients, and to protect our nurses and the community. So, we decided to target this as our first effort and see where it would take us."

Each section of the site will have relevant literature, a repository to share protocols along with other experiences and knowledge, and a "news section." "This initiative also represents our 'response and mitigation' efforts in a broader concept we are working on which consists of adapting the Preparedness Cycle framework to understand transformations in diabetes care during the COVID-19 pandemic," Pasquel says.

Since releasing the app, Pasquel tells *Endocrine News* that they have received lots of feedback and interest from many investigators and physicians caring for patients with diabetes and COVID-19 in the U.S. and around the world. David Klonoff, MD, medical director of the Diabetes Research Institute at Mills-Peninsula Medical Center in San Mateo, Calif., signed on as the project's co-editor to help with the content. "[We've received] recommendations about including sections that may be of interest, suggestions on the most relevant topics, and opportunities/ideas for collaborations," Pasquel says. "We are very excited about other colleagues joining so we can hopefully have a place where it will be easy to access relevant information related to the transformations in care related to the interaction of diabetes, COVID-19, and advances in technology."

Advancing Acromegaly Treatment

In late June, the FDA approved octreotide capsules for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. Chiasma, Inc., is marketing this formulation as MYCAPSSA.

MYCAPSSA is the first and only oral somatostatin analog (SSA) approved by the FDA. Acromegaly is a rare chronic disease often caused by a benign pituitary tumor and characterized by

excess production of growth hormone and insulin-like growth factor-1 hormone that is frequently treated with chronic burdensome injections. If left untreated, acromegaly can lead to serious and sometimes life-threatening medical conditions. The company estimates that approximately 8,000 patients are on injectable SSAs in the U.S.

"For patients living with acromegaly and for their physicians and nurses, the FDA approval of oral octreotide capsules ushers in a new era of treatment," says Society member Shlomo Melmed, MB, ChB, MACP, executive vice president of Academic Affairs and dean of the Medical Faculty at Cedars-Sinai, Los Angeles, Calif. "Over the last 30 years treating physicians have come to trust octreotide in the treatment of acromegaly, and an oral alternative allows patients to avoid many of the documented treatment burdens associated with injections."

Melmed goes on to explain that the capsules contain the same octereotide molecule, so the side-effect profile should be similar since the drug has not been changed, just the delivery method. "This will be of advantage to patients for several reasons," he says. "Firstly, it's an oral capsule administered twice a day, and many patients may prefer a pill to an injection. Secondly, injections are quite painful, inconvenient, and time-consuming. The patient has to come to the clinic or to the hospital for their monthly injection. They may have to miss work, have to find parking, and register. Therefore, receiving the injection is not a trivial undertaking, and some patients experience bruising, pain, and local site inflammation. For patients who suffer from injection phobia, availability of a safe oral alternative is an advantage."

A New Hope for Early-Onset Type 1 Diabetes?

A clinical trial investigating a possible novel treatment of early-onset type 1 diabetes in September met the primary endpoint assessing the safety and tolerability of a new class of microbe-based therapeutic agents. Precigen ActoBio is evaluating this therapy — AG019 ActoBiotics — as a monotherapy and in combination with teplizumab.

AG019 is formulated as an oral capsule consisting of engineered Lactococcus lactis specifically modified to deliver autoantigen human proinsulin (hPINS) and the tolerance-enhancing cytokine human interleukin-10 (hIL-10) to the mucosal lining of the gastrointestinal tissues. Administration of AG019 is designed to induce specific regulatory T cells (Tregs) that could reduce or eliminate the destruction of insulin-producing cells, potentially stabilizing or improving insulin production.

The Phase 1b open-label portion of the study evaluates the safety and tolerability of AG019 administered as a single dose and repeated daily doses as a monotherapy in adult and adolescent patients. The primary endpoint for assessing safety and tolerability is treatment-emerging adverse events (TEAEs) reported up to six months after treatment initiation. Nineteen patients were treated in the Phase 1b monotherapy portion of the study, and 17 patients were evaluated at six months. The Phase 2a portion of the study is currently ongoing and investigates the safety and tolerability of AG019 in combination with teplizumab (PRV-031), which is currently under

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>
> — SHLOMO MELMED, MB, CHB, MACP, EXECUTIVE VICE PRESIDENT, ACADEMIC AFFAIRS; DEAN, MEDICAL FACULTY, CEDARS-SINAI, LOS ANGELES, CALIF.

investigation in the PROTECT Phase 3 study for the treatment of newly diagnosed type 1 diabetes.

Key findings from the Phase 1b AG019 monotherapy portion study for patients six months after treatment initiation include:

- The study met its primary endpoint demonstrating safety and tolerability. No serious or severe TEAEs were reported in any of the patients treated with AG019 monotherapy, and no patient discontinued treatment.
- Eight-week treatment with AG019 monotherapy was safe and well-tolerated in daily dosages up to 6 x 1011 CFU (colony-forming units) in adult and adolescent patients with type 1 diabetes.
- There was no evidence for systemic exposure of bacteria and proteins (hPINS/hIL-10) in the circulation, confirming the safety profile of AG019. The analysis of fecal samples confirmed gastrointestinal exposure of AG019 in most treated patients.
- C-peptide levels, a common biomarker used to measure pancreatic beta cell function, demonstrate slower decline in C-peptide levels in 67% of adult patients (six out of nine) receiving AG019 monotherapy with 44% of these adult patients (four out of nine) showing stabilization of mean four hours C-peptide area under the curve (AUC) levels at six months (within 9.7% of the baseline level). This was based on the comparison of the median percent decline in mean four hours C-peptide AUC from baseline between patients receiving AG019 monotherapy and patients who received placebo from previous studies.

Furthermore, in a preliminary analysis performed by the Immune Tolerance Network, a leading independent research group, AG019 monotherapy shows an increase in the frequency of islet-specific Tregs expressing inhibitory receptors, a potential mechanistic indicator of therapeutic activity, for patients three months after treatment initiation.

The Next-Generation of Integrated CGMs

An integrated continuous glucose monitor (iCGM) is now available for adults and children (4 years of age and older) living with diabetes, following its clearance in June from the FDA. Abbot is marketing this new technology as the FreeStyle® Libre 2.

The FreeStyle Libre 2 system uses Bluetooth to automatically alert users when their glucose is high or low without needing to scan the sensor. Users also have the option of turning off the customizable, real-time alarms. The system has a combined mean absolute relative difference (MARD), a measurement of performance for CGMs, of 9.3% (9.2% for adults and 9.7% for pediatrics).

This new CGM system met or exceeded the FDA's rigorous iCGM special control standards and is designed to digitally connect and communicate with other devices. This can allow people to tailor and potentially simplify how they manage their diabetes.

The sensor is worn on the back of the upper arm for up to 14 days and measures glucose every minute to help users and their healthcare providers make informed treatment decisions. With a one-second scan using a handheld reader, users can see their glucose reading, trend arrow, and eight-hour history.

"Innovations like FreeStyle Libre 2 will change the way people manage their diabetes, especially among children,"

says Endocrine Society member Larry Kurt Midyett, MD, a pediatric endocrinologist at Midwest Women's and Children's Specialty Group, Overland Park, Kan. "Using this technology can improve time in optimal glucose range and lower HbA1c because we can get a full picture of what a child's glucose levels are doing without having to disrupt their play or sleep with painful finger sticks. The alarms are a bonus because they provide parents a level of reassurance."

Insulin Titration Software, CGM Improve Time in Range

This past summer, Glytec published the first proof-of-concept study that combines FDA-cleared remote insulin titration software and data from continuous glucose monitoring systems. Results of the study showed a 26% increase in time in range for participants living with diabetes — an improvement from 48% at baseline to 74% after only four weeks of care.

The study evaluated 25 adults who used the Abbott Freestyle Libre CGM system and Abbott LibreLink app on their mobile phone. Patient data was provided to Glytec's Glucommander software — a cloud-based, FDA-cleared solution for outpatient basal-bolus insulin titration. All participants met the criteria of living with type 2 diabetes, reporting A1C levels > 8.0%, and owning a smartphone capable of running the LibreLink app.

The four-week study began with a nurse educator helping participants set up the Abbott Freestyle Libre 14-day CGM system while collecting baseline data. Participants went to the Atlanta Diabetes Associates office every two weeks for CGM sensor changes, and insulin titration was done during these visits or by phone on the weeks not requiring visits. To obtain updated doses, nurse educators reviewed participant CGM data, remotely generated dose updates from Glucommander, examined the recommendation and passed it on to the patient. No intervention by the licensed provider was necessary.

Without this combined CGM and Glucommander approach, individuals living with diabetes in the outpatient setting rely on finger pricks and meters to measure blood glucose levels. Patients using these methods traditionally visit their provider every few months to adjust insulin dosing based on historical data and can go years without achieving their optimal dosing regimen.

"This approach delivers significantly improved outcomes for patients on basal bolus insulin with multiple daily injections, while optimizing the use of clinical resources," the authors conclude. "The combination of Glucommander software and CGM data can continually optimize insulin doses and improve outcomes while relieving the burden on patients and providers."

New Registry Tracks Hospital CGM Use During COVID-19 Pandemic

Dexcom recently announced the first ever registry dedicated to tracking the outcomes of patients and healthcare professionals using continuous glucose monitoring in hospitals in response to the COVID-19 pandemic.

The current standard of care for glucose monitoring in the hospital is a fingerstick blood glucose test, which requires healthcare providers to draw blood from a patient to obtain a glucose reading. Due to the need to preserve personal protective equipment, reduce potential hospital staff exposure to COVID-19, and lessen the overall burden on nursing care, Dexcom made their G6 CGM system available to remotely monitor the glucose levels of all hospitalized patients during the COVID-19 pandemic. The decision was made in April based on feedback received from the FDA.

> Using this technology can improve time in optimal glucose range and lower HbA1c because we can get a full picture of what a child's glucose levels are doing without having to disrupt their play or sleep with painful finger sticks. **The alarms are a bonus because they provide parents a level of reassurance."**
>
> — LARRY KURT MIDYETT, MD, PEDIATRIC ENDOCRINOLOGIST, MIDWEST WOMEN'S AND CHILDREN'S SPECIALTY GROUP, OVERLAND PARK, KAN.

"In our previous use of the Dexcom G6 system in our hospitals as part of exploratory studies over the last three years, we have found that the device improves glucose control without any increased risk in hypoglycemia," says Endocrine Society member Athena Philis-Tsimikas, MD, an endocrinologist and corporate vice president for the Scripps Whittier Diabetes Institute in San Diego, Calif. "More recently, we have begun using the system on some ICU and COVID-19 hospital floors where minimizing contact is important for both our patients and staff members. A registry to examine experiences across many hospitals would be hugely beneficial."

The registry will be accessible to healthcare providers using real-time continuous glucose monitoring (rtCGM) in an inpatient or critical care setting. Providers will be able to upload information regarding the in-hospital care of each CGM patient, such as admissions, discharges, medications, status changes, diabetes history, comorbidities, and more. The data collected will be deidentified and will not include any protected health information.

The data collected through the registry will eventually be cross-referenced with patient CGM data and evaluated by Dexcom for future product innovation or to be included in future regulatory submissions to make rtCGM the ongoing standard of care in hospitals.

Clinical Drug Candidate Offsets Hyperglycemia Caused by Cancer Therapies

In late October, the clinical-stage oncology company SynDevRx, Inc., announced the completion of a series of preclinical studies demonstrating that its anti-cancer drug candidate, SDX-7320, inhibits PI3K/Akt inhibitor-induced hyperglycemia and subsequent hyperinsulinemia in normal mice and inhibits tumor growth in multiple models of HR+ breast cancer.

SDX-7320 inhibits MetAP2, a clinically validated target that plays a key role in tumor growth, metastasis, angiogenesis, and metabolic dysfunction. In a series of efficacy and safety studies in a variety of syngeneic cancer models (breast, melanoma), SDX-7320 displayed single agent anti-tumor activity while improving metabolic dysfunction (in particular, hyperglycemia, insulin resistance, and leptin resistance). SDX-7320 prevented the hyperglycemia and hyperinsulinemia associated with Piqray® (Novartis' PI3Kα inhibitor) administration in normal mice — serious side effects of drugs from these classes that have been reported to lead to treatment resistance. Furthermore, in a xenograft model of ER+/Her2- breast cancer, SDX-7320 and Piqray® (alpelisib), administered together at low doses, showed synergy at inhibiting tumor growth.

In addition to preclinical studies, SynDevRx has data from mono-therapy clinical studies in late-stage cancer patients that further support the hypothesis that drugs targeting the PI3K/Akt pathway should see better safety and anti-tumor activity by administering SDX-7320 in combination with those agents. They will soon be starting Phase 2 studies in patients with late-stage breast cancer.

This piece could go on and on and fill not just the pages of this issue, but probably several more. Advancements in endocrinology continue to be made, and you'll get to see even more during the all-virtual **ENDO 2021** — another step forward for the endocrinology community. Here's to a new year. EN

– BAGLEY IS THE SENIOR EDITOR OF *ENDOCRINE NEWS*. IN THE NOVEMBER ISSUE, HE WROTE ABOUT HOW INNOVATIONS IN DIABETES CARE WERE BEING SPURRED ON BY THE COVID-19 PANDEMIC.

ENDOCRINE SOCIETY

2020 Hindsight

The Endocrine Society's *Unforgettable* Year

We were somewhere on the edge of finalizing plans for **ENDO 2020** in San Francisco, Calif., when the world pivoted to what many have referred to as the "new normal." Suddenly there were masks and lockdown orders everywhere — along with a frantic rush of activity to change or cancel plans, to set up home offices, and download various telework and virtual classroom apps, to try for some sense of old normalcy.

And when it was quiet again, when the crushing reality of the COVID-19 pandemic set in, the Endocrine Society staff found that they were able to adapt to this new normal, to adopt new ways of working, and continue to make incredible strides supporting the Endocrine Society's mission of promoting the practice and science of endocrinology and advancing healthcare overall around the world.

"Back in March, we made a commitment to our global community of endocrinologists and basic scientists that COVID would not keep us from

BY DEREK BAGELY

As 2020 winds down, *Endocrine News* is taking a quick jaunt down memory lane to focus on the many accomplishments the Endocrine Society had over the course of the last 12 months. Despite various obstacles and upended plans, 2020 turned out to be a remarkable year for progress and successful new endeavors.

providing them with the best of meetings, education, and community," says Society interim chief executive officer Robert Lash, MD. "With **ENDO Online**, CEU/EBR, our COVID resources, and our virtual communities, our staff has gone above and beyond to meet that commitment. I'm so proud of the work they've done and the commitment they've demonstrated during a difficult time for everyone."

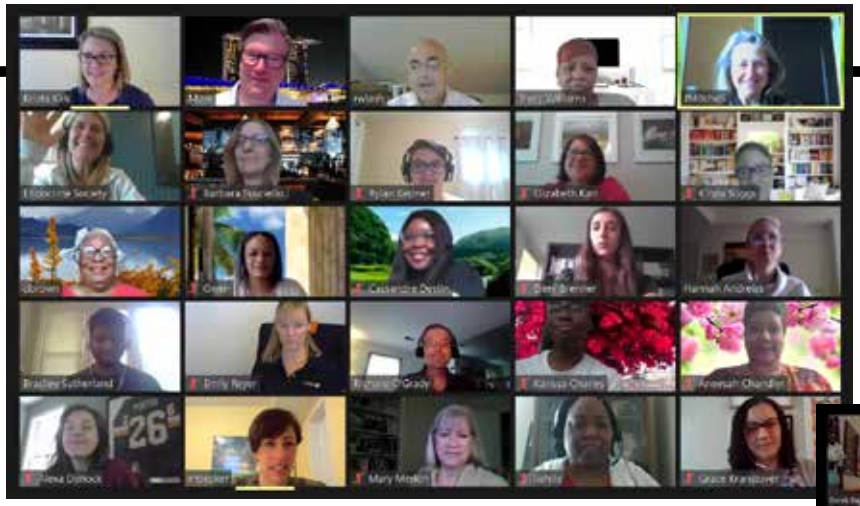
If anything, this hectic past year proved that the Society staff comprises storytellers, innovators, dealmakers, and savvy policy experts. Endocrine Society staff are often rightly referred to as "unsung heroes." Let's sing their praises for a bit.

Breaking Meeting Attendance Records

This past year saw the rise of many technological innovations that allow many to continue to work and live in a kind of virtual reality. These pages have touched on many of those throughout 2020 — including the smash hit that **ENDO Online 2020** turned out to be. More than 27,000 registrants and 17,000 attendees. More than 2,300 abstracts. Hard to beat those kinds of numbers, especially given the circumstances.

Here are some more numbers: The Endocrine Society's first virtual Clinical Endocrinology Update (CEU) and Endocrine Board Review (EBR) meetings

Although the lobby of the Endocrine Society's headquarters has sat largely empty for most of 2020, that belies the amount of work being done by the staff at dozens of remote locations throughout the Washington D.C. area.



Zooming in for meetings has definitely become the new normal for the Endocrine Society staff. Whether it's the entire staff convening for the monthly all staff meetings (above), or the thrice-weekly departmental meetings of the Marketing and Communications team (right), face-to-face contact is easier — and safer — than ever.

collectively attracted more than 1,700 global participants. CEU 2020 had more than 1,100 participants, and EBR 2020 had over 600, setting records for both meetings as the largest to date in the Society's history.

But as Society chief learning officer Christopher Urena, MBA, CAE, says, "It's not just about the number of attendees who participate at these meetings, it's about ensuring we maintained the caliber of content our attendees expect and experience at our signature, in-person meetings." CEU and EBR are renowned for high-quality content, as well as the forum in which participants can engage directly with experts during live Q&A.

"We led with the flexibility that comes with online learning, blending synchronous and asynchronous programming, and creating meaningful connectivity between participants and presenters," Urena continues. "The pandemic forced us to experiment with alternative learning modalities and formats, and we're discovering new and highly effective models. The most impactful learning experiences are those that impart lasting knowledge, skills, and connections. Despite format changes, our 2020 programs have proudly delivered on those tenets."

It's December, and the pandemic is entering its tenth month. The Endocrine Society has already announced an all-virtual **ENDO 2021**, and even in a post-COVID-19 world, virtual meetings won't suddenly vanish. But neither will in-person meetings. "That's one of the things I think we've learned from this, is when we get to the other side of COVID, yes many of us will meet back in person, but it's going to look different," Urena says. "What that exactly means is still to be determined; however, it's fair to expect that hybrid formats will take a more dominant position and become commonplace."

> "Amidst the uncertainty this year, our staff has demonstrated innovation, creativity, and unwavering commitment to keep this organization running smoothly. Our ability to refocus our efforts in this virtual environment has enabled us to effectively operate and provide unique value to our members. **The way we work has changed dramatically and will continue to be a challenge."**
>
> — KRISTA KIRK, CHIEF OF STAFF, ENDOCRINE SOCIETY

> We found out that people on the Hill were actually more interested to talk to us because they were also stuck in their apartments, and hearing from constituents who were back at home, **who had eyes and ears on the ground and can say what was happening at the university or what was happening at this major health center, was very helpful to them."**
>
> — MILA BECKER, CHIEF POLICY OFFICER, ENDOCRINE SOCIETY

Indeed, it remains a time of uncertainty, but in the meantime, the Endocrine Society's meetings department continues to look to new methods of digital learning, from monthly webinars to certificate programs. Plenty to look forward to in 2021.

Virtual Advocacy

Just because people are meeting over webcams now doesn't mean the Society's work stopped or even slowed down — even on Capitol Hill. The Endocrine Society's Government and Public Affairs team had to pivot to virtual advocacy, as they were informed on March 13 that the Capitol complex was closed by order of the Capitol physician. They were one of the last groups to go to the Hill for Researcher Hill Day before lockdown orders were in place. But on April 14, just a month after the closing announcement, the GPA team held a virtual Hill Day, which was able to attract more members to attend because they didn't have to travel to Washington, D.C.

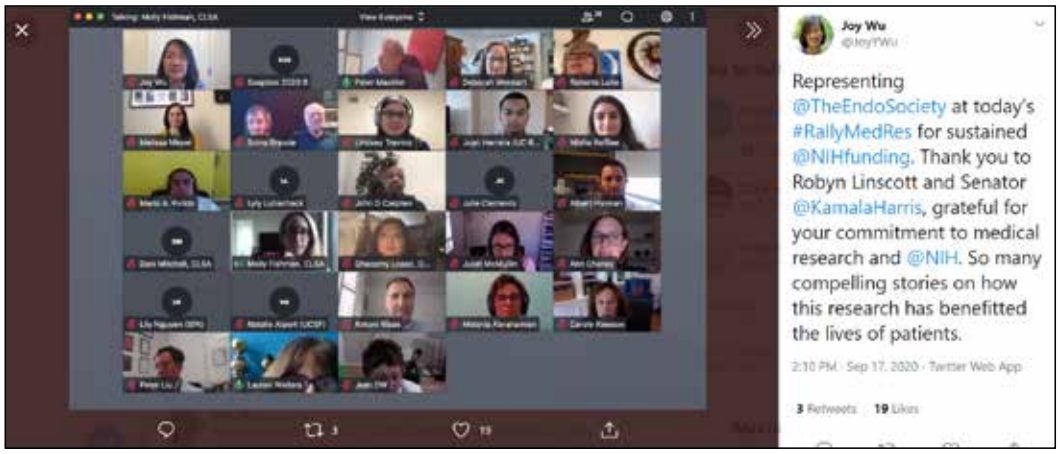
"We found out that people on the Hill were actually more interested to talk to us because they were also stuck in their apartments, and hearing from constituents who were back at home, who had eyes and ears on the ground and can say what was happening at the university or what was happening at this major health center, was very helpful to them," says Society chief policy officer Mila Becker. "And we figured out how to train our members virtually by having Zoom prep calls."

Becker continues by saying through these virtual meetings they were able to not only hear from clinician members about being reimbursed for telemedicine visits, they were also able to talk to a number of House and Senate members to and help them see that they should write the Centers for Medicare and Medicaid Services to loosen restrictions for telemedicine reimbursements. "That was a direct result of us being there," she says.

The GPA team influenced the Trump administration to extend the public health emergency so that many of these Medicare waivers could continue, and they continue to work with Congress on COVID-19 relief packages that would benefit physicians and researchers.

The GPA team continues to advocate for improved physician reimbursement and telehealth flexibilities during the pandemic. Society director of advocacy and policy Rob Goldsmith explains that the COVID-19 pandemic has transformed the way physicians provide care to patients. The Society has urged the Center for Medicare and Medicaid Services (CMS) to adopt payment policies that address the longstanding challenges that endocrinologists have faced during this crisis. The Society also supports making many of the CMS telehealth flexibilities permanent. "Our members treat patients who are vulnerable to COVID-19 infection and these flexibilities allow patients to continue to receive necessary care without unnecessary exposure

(pictured l to r): Heather Patisaul, PhD; Rebecca Riggins, PhD; Cyrus Desouza, MD; and FLARE Fellows Kayla Titialii-Torres and Rashaun Williams with type 1 diabetes patient Abigail Pepper outside Senate majority leader Mitch McConnell's office were one of the last groups allowed into the U.S Capitol complex prior to lockdown.



The Endocrine Society's Government and Public Affairs Department has demonstrated great agility in corralling members for virtual rallies to support endocrinology. Pictured is a screenshot of the Rally for Medical Research that Joy Wu, MD, PhD, tweeted out of other Society members and staffers from the office of Sen. Kamala Harris (D-CA).

to the virus," Goldsmith says. "The Society submitted comments on a proposed rule issued by CMS that would address some of these concerns. We support the adoption of this rule which is expected to be finalized in December." However, given the uncertainty of the pandemic this will continue to be a rapidly changing situation in the months ahead.

And while the GPA team keeps their eye on Congress, they've made sure not to take their focus off of the European Union as well, securing a win for the Society, as it has advocated for prioritization of endocrine-disrupting chemicals (EDCs) in the European Union's "Chemicals Strategy for Sustainability Towards a Toxic-Free Environment," as part of the EU Green Deal. The strategy includes many key measures advocated by the Endocrine Society to protect the public and the environment from EDCs.

And again, this all played out in a virtual environment. "We were able to still set up meetings and conversations with EU policy makers, and in particular European Commission staff from several offices, as well as with the new Commissioner for Health and Food Safety, to talk about our priorities related to EDCs and how they should be incorporated into the new chemical strategy," says Society director of science policy Joseph Laakso, PhD. "And that was largely a success."

The GPA team look forward to using advancing the Society's policy priorities in 2021. "We hope our members realize that advocacy is part of what they need to do, and we love working with them and we encourage them to reach out to us and join us," Becker says.

Getting the Message Out

This past year certainly brought a lot of static with it, so it's important for the Society to try to cut through the noise as best it can and share not just the stories of the important work the members do, but what the staff is up to as well. After all, what good really is a medical breakthrough or policy win if no one is aware of it.

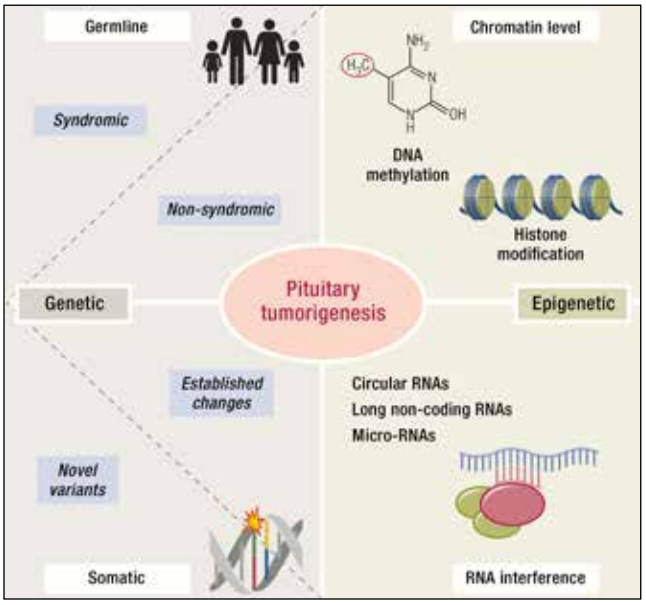
One new way the Society's communications department began disseminating these stories this past year is through its new artificial intelligence (AI)-driven newsletter, which launched in

> "The resilience, dedication, and creativity of our staff, in collaboration with member leaders, have been exemplary in 2020 and the results have been outstanding. We have been and will continue to be nimble and adapt to the needs of our members, our patients, and the world as we move forward. **Our continued courage and resilience will get us through this difficult time, and we will come out stronger as the new year dawns. Onward and upward."**
>
> — GARY D. HAMMER, MD, PHD, PRESIDENT, ENDOCRINE SOCIETY

November. This newsletter seems to be a hit with members so far — the membership had to field calls asking where it was when the newsletter was delayed by a technical glitch one day.

This AI-driven newsletter, when done well, is the simplest and most effective curator for delivering relevant content, according to the Society's chief communications officer Aaron Lohr. "The end user doesn't need to do anything other than read the articles that interest them," he says. "The AI then evaluates a series of tags that accompany each article and curates future content delivery to include more articles that feature similar tags. Whether a reader is interested in advocacy, advances in science, clinical practice guidelines, or all of the above, their weekly newsletter will deliver more of that kind of content."

And while the Society felt it was important to continue to share the most relevant stories, it felt it was also crucial to provide a virtual environment where members could share their own stories with each other — a kind of symposium where members can swap ideas, show off breakthroughs, or ask for help. The Endocrine Society's new Community Connect platform has been used to facilitate ongoing engagement with members and provide a foundational platform to share webinars, says Rodneikka Scott, the Society's director of membership. "This platform has allowed us to maintain connections with members around the globe," she says. "The platform has also allowed for a virtual space where members could share resources like articles, science, and more."



Endocrine Society Journals By the Numbers

Submissions of manuscripts to our journals are strong to growing:

- JCEM in 2019: 2,577; in 2020 (projected as of 11/16/2020): 3,319
- *Endocrinology* in 2019: 779; in 2020 (projected as of 11/16/2020): 870
- *Endocrine Reviews* in 2019: 40; in 2020 (projected as of 11/16/2020): 40
- JES in 2019: 422; in 2020 (projected as of 11/16/2020): 434

And world-wide online usage and readership of all our journals is increasing, especially JES, whose usage in 2020 is five times that of 2019.

Sharing Endocrine Science

And speaking of sharing science, perhaps no vehicle is as important and necessary to the world of endocrinology than the Society's publications department, which continued its long streak of innovation for journal authors and readers throughout 2020. At the beginning of the year, *Endocrine Reviews* introduced color graphical abstracts — redrawn by professional illustrators, these are a sure-fire way of promoting articles via social media and downloading for use in presentations.

The publications team also launched two new article types: Approach to the Patient in *The Journal of Clinical Endocrinology & Metabolism* (*JCEM*) and Expert Endocrine Consult in *Journal*

***Endocrine Reviews*' new graphical abstracts not only illustrates the science, but it also gives the authors an easy way to share their research on social media.**

of the Endocrine Society (*JES*), with both offering in-depth discussion of the treatment of prismatic cases. And to ease the burden on authors, the team made manuscript submission to Society journals format-neutral, so authors can submit new manuscripts as a single Word, RTF, or PDF file; formatting is not required until after peer-review acceptance.

This past year, Carol A Lange, PhD, of the University of Minnesota, took the helm as editor-in-chief at *Endocrinology* mid-year, and named as her deputy, Zane B. Andrews, PhD, of Monash University, who continues work to boost invited content. According to the publications team, Lange expanded the journal's Early Career Reviewer mentorship program and re-worked the Aims and Scope of *Endocrinology* to re-emphasize its focus on basic science, including molecular studies, stem cells, and tissue regeneration. *Endocrinology* authors who are Society members continue to receive the benefit of no page charges on the first eight pages of their articles; and color in *Endocrinology* is always free.

As pandemic shutdowns curtailed lab work, JES and *Endocrinology* promoted Brief Reports (up to 2,400 words) as a vehicle for quickly getting important research findings into the scientific literature. And JCEM editors re-worked the journal's Aims and Scope to stress its expanded interest in conditions including cardiovascular disease, cancer, and aging.

The Society's journals serve a wide, diverse market. Institutional subscription sales remain steady, with over 7,750 paid subscriptions in 72 countries. That's in addition to the approximately 8,000 non-profit research institutions in over 100 developing countries eligible for access to JCEM, *Endocrinology*, and *Endocrine Reviews* through these programs. Approximately 70% of eligible institutions are in Africa, 9% are in Europe, and the remaining 21% are distributed throughout South East Asia and Oceania, Asia, and South America. And JES, being open access, is free to view everywhere.

"Publications staff have worked closely with our editors, authors, and reviewers to accommodate those situations in which COVID-19 has had an impact on their duties and responsibilities," the team writes. "With this feedback we have been able to continue with the same level of excellent peer review while providing needed support. In addition, we have asked for and received critical information from the members of the Publications Core Committee about their institutional experiences with COVID-19 across the globe, allowing us to anticipate additional shifts and provide extra support where needed."

Prioritizing Strategic Partnerships

But all these wins and innovations might not be possible without some outside help, and thanks to the Society's development and strategic partnerships team, in 2020, the Society added eight new industry partners — expanding membership in the Corporate Liaison Board to 30 — by implementing a proactive outreach strategy and enhancing the benefits of partnership.

Michel Farhat, PhD, the Society's chief strategic partnerships officer tells *Endocrine News* that his team also adapted to the changing industry landscape by providing a yearlong, more diversified portfolio of programs (beyond the traditional focus on **ENDO** and CEU) to appeal to smaller companies with limited budgets. "This has helped enrich our library of content, especially in the rare endocrine disease area which traditionally

> "The pandemic forced us to experiment with alternative learning modalities and formats, and we're discovering new and highly effective models. The most impactful learning experiences are those that impart lasting knowledge, skills, and connections. **Despite format changes, our 2020 programs have proudly delivered on those tenets."**
>
> — CHRISTOPHER URENA, MBA, CAE, CHIEF LEARNING OFFICER, ENDOCRINE SOCIETY

> With **ENDO Online**, CEU/EBR, our COVID resources, and our virtual communities, our staff has gone above and beyond to meet that commitment. **I'm so proud of the work they've done and the commitment they've demonstrated during a difficult time for everyone."**
>
> — ROBERT LASH, MD, INTERIM CHIEF EXECUTIVE OFFICER, ENDOCRINE SOCIETY

has suffered from limited industry support," he says. "Programs like ECHOs, webinars, podcasts, and patient educational tools have generated a heightened interest from many of our corporate sponsors operating in the rare disease space."

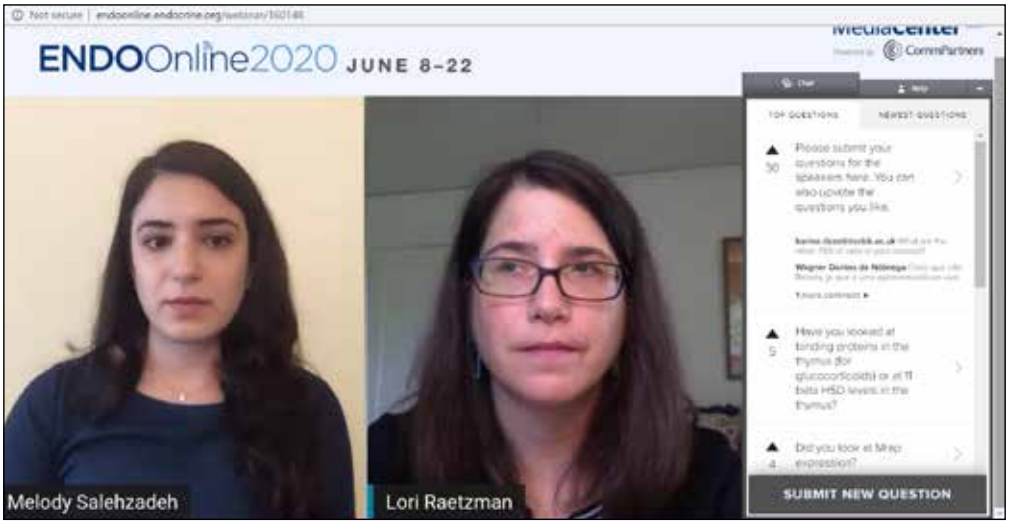
Farhat goes on to say that collaboration with different stakeholders is a key priority for the Endocrine Society and a desired outcome for industry sponsors. This past year his team led a collaborative effort with key primary care associations, which helped deliver two key projects: a CGM patient pocket guide and a diabetes and cardiovascular disease curriculum. "Both deliverables were co-developed, endorsed, and disseminated by all participating organizations resulting in a more efficient, streamlined scientific content with a broader reach," Farhat says.

Onward and Upward

This strange year may be coming to a close, but again, it showed just how resilient a group of people can be when committed to these noble goals.

"Amidst the uncertainty this year, our staff has demonstrated innovation, creativity, and unwavering commitment to keep this organization running smoothly," says Society chief of staff Krista Kirk. "Our ability to refocus our efforts in this virtual environment has enabled us to effectively operate and provide unique value to our members. The way we work has changed dramatically and will continue to be a challenge."

Endocrine Society president Gary D. Hammer, MD, PhD, agrees. "While nothing has been close to business 'as usual', with challenges come opportunities, and we have certainly made the best of these times," he says. "The resilience, dedication, and creativity of our staff, in collaboration with member leaders, have been exemplary in 2020, and the results have been outstanding. We have been and will continue to be nimble and adapt to the needs of our members, our patients, and the world as we move forward. Our continued courage and resilience will get us through this difficult time, and we will come out stronger as the new year dawns. Onward and upward." EN



The new virtual format for Endocrine Society meetings turned out to be surprisingly effective for all involved. During this talk at the all new ENDO Online 2020, the virtual platform not only allowed for an "up close and personal" session with the speakers, but there were no lines at microphones in the aisles to ask questions; attendees could just send questions via the messaging component and the moderator could query the speakers.

— BAGLEY IS THE SENIOR EDITOR OF *ENDOCRINE NEWS*. IN THE NOVEMBER ISSUE, HE WROTE ABOUT HOW INNOVATIONS IN DIABETES CARE WERE BEING SPURRED ON BY THE COVID-19 PANDEMIC.

Third Rock from the Sun: Endocrinology and Climate Change

Endocrine News speaks with Daniel Oppenheim, MD, PhD, who represents the Endocrine Society on the Medical Society Consortium on Climate & Health, which consists of dozens of medical associations that have joined together to heal the planet as well as their patients.

BY GLENDA FAUNTLEROY SHAW

The Endocrine Society recently joined nearly 30 medical associations that make up the Medical Society Consortium on Climate & Health — an organization focusing on the science behind climate change and public health. Whether it is extreme weather events and temperatures, wildfires, food-related or insect-born infection, or air and water quality, human-caused climate change has already harmed millions and threatens the health of everyone.

Daniel Oppenheim, PhD, MD, a clinical endocrinologist at Maine Medical Center, Scarborough, Maine, represents the Endocrine Society on the Consortium's Steering and Policy Committees and spoke with *Endocrine News* about its efforts to lead clinicians in the fight against this great challenge to public health.

***Endocrine News*: How did you come to represent the Society on the Consortium?**

Daniel Oppenheim: I've been involved with the Endocrine Society for almost 35 years. I first joined when I was a fellow in 1986, and I've had various roles at the Society ever since.

I have also been involved with work around climate change with a number of organizations for many years. My personal view of being a doctor is that it involves much more than taking care of patients one on one. I see my role as a physician to include caring for the health of my community, of my country, and of my planet as all part of the same spectrum. I don't really differentiate between caring for patients and caring for the planet. And when I look around and see one of the greatest existential threats to human survival, namely global climate change, it makes me want to do something about it.

I learned about the Medical Society Consortium on Climate & Health fairly recently. We hear a lot of talk about the effects of climate change on infrastructure and the economy, but not so much about the effects of climate change on human health, and that's really one of the greatest threats there is.

So, when the Endocrine Society was invited to join the Consortium, and I was asked to be their representative, I readily accepted.

> "I see my role as a physician to include caring for the health of my community, of my country, and of my planet as all part of the same spectrum. **I don't really differentiate between caring for patients and caring for the planet. And when I look around and see one of the greatest existential threats to human survival, namely global climate change, it makes me want to do something about it."**
>
> — DANIEL OPPENHEIM, PHD, MD, CLINICAL ENDOCRINOLOGIST, MAINE MEDICAL CENTER, SCARBOROUGH, MAINE

***EN*: How can individual endocrinologists play a role as advocates to our elected officials?**

DO: The first step is to recognize that global climate change is a terribly important issue, and that human health is being impacted by global climate change. So, education, getting the word out that this is a crisis that's relevant to human health, and we as physicians, scientists, and people who care about human health, is key.

Once we understand that's the case then we have to think about what to do about it. And there's a whole host of ways people can get involved in advocating for policy changes that will hopefully mitigate the progression of global warming, of global climate change. Some people will feel comfortable educating others, just getting the word out. Some people will feel comfortable writing letters to the editor or op-ed pieces in their local papers, as issues arise or contacting their legislative representatives, either at the state or federal level.

Our hope is that as specific pieces of legislation or regulatory policy come up for public comment, we will be able to mobilize our membership to get the word to policy makers and legislators that we care about this as physicians, as scientists, as endocrinologists. So, the more people know, and the more people feel motivated to do something, the more we can involve our membership when specific issues arise.

***EN*: The Consortium's website has fact sheets about how climate change impacts health. One way to impact change is to reduce carbon emissions from transportation because**

traffic-related air pollutants increase the risk of conditions such as heart disease, asthma, and diabetes. What other climate issues are important for endocrinology?

DO: There are many. For example, extreme weather events such as floods, hurricanes, wildfires, and their impacts on the energy infrastructure. We saw this when Hurricane Katrina produced widespread power outages and large numbers of people were displaced. People with diabetes who required insulin and either couldn't get it or couldn't refrigerate it because there was no power, really suffered badly. So, when the supply chain for critical medications goes down, when power goes down to prevent refrigeration of medicines, particularly insulin, then people with diabetes suffer. And this is certainly going to happen more and more.

Another important area that endocrinologists care about involves endocrine-disrupting chemicals. For example, in these huge California fires, it's not just wood that burns. It's plastic that burns. When houses go up in flames, plastic siding goes up in flames and all kinds of other plastics ignite as well, releasing a host of toxins, many of which are endocrine-disrupting chemicals. They eventually fall as ash entering the water supply, polluting the air and soil, and eventually we breathe, drink, and eat them. The massive fires and the associated winds, both in part the result of global climate change, have the potential to spread endocrine-disrupting chemicals throughout the globe.

In addition, it is clear that the effects of global climate change are not equally distributed. Communities of color, poor, marginalized, and disadvantaged communities suffer disproportionately. The Endocrine Society cares deeply about equality of health and health care, so this issue matters to us for this reason as well.

Photo credit: Nicole Glass Photography / Shutterstock.com

"Decision makers at all levels really do listen to doctors and scientists, and we have a degree of credibility that's unique. **It's important for us to leverage this unique position, as a voice for health, for science-based and data-based policy, and to use our voice to effect positive change in the world."**

— DANIEL OPPENHEIM, PHD, MD, CLINICAL ENDOCRINOLOGIST, MAINE MEDICAL CENTER, SCARBOROUGH, MAINE

***EN*: What else does the Society hope for with its new partnership with the Medical Consortium?**

DO: Decision makers at all levels really do listen to doctors and scientists, and we have a degree of credibility that's unique. It's important for us to leverage this unique position, as a voice for health, for science-based and data-based policy, and to use our voice to effect positive change in the world.

The Endocrine Society, under the direction of Mila Becker, has a very strong advocacy program, and they are extremely active in all sorts of advocacy issues. The role of the Consortium is to work in the areas of education and advocacy around climate change on behalf of its member medical societies that themselves have more specific areas of focus.

So, the Consortium can do that work on behalf of the Endocrine Society. It's a two-way street. The Consortium can help do the work and provide the educational materials and action alerts, and the Endocrine Society, both itself and through its members, can serve to raise the issue to a higher level.

Learn more about the work of the Medical Society Consortium on Climate & Health at: medsocietiesforclimatehealth.org. EN

– FAUNTLEROY SHAW IS A FREELANCE WRITER BASED IN CARMEL, IND. SHE IS A REGULAR CONTRIBUTOR TO *ENDOCRINE NEWS*.

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ENDOCRINE SOCIETY
Hormone Science to Health

Endocrine Society and Pediatric Endocrine Society Partner on Transgender Advocacy

The Endocrine Society is an advocate for transgender patients and ensuring their access to gender-affirming, evidence-based healthcare. During the fall, the Society's Transgender Special Interest Group and members of the Pediatric Endocrine Society formed a working group to update Society documents and develop new material on care for transgender individuals to be used in advocacy activities. The group updated the Society's Transgender Health Position Statement to provide further background and support on the treatment of transgender minors and developed a new fact sheet focused on ways to improve pediatric care for transgender minors.

In addition, the Endocrine Society's Special Interest Group also published a policy perspective in *The Journal of Clinical Endocrinology & Metabolism* in December, which reaffirms the Society's support for its members that provide gender-affirming care to transgender patients and the Society's overall positions that:

1. There is a durable biological underpinning to gender identity that should be considered in policy determinations;
2. Medical intervention for transgender individuals (including both hormone therapy and medically indicated surgery) is effective, relatively safe (when appropriately monitored), and has been established as the standard of care;
3. Federal and private insurers should cover such interventions as prescribed by a physician as well as the appropriate medical screenings that are recommended for all body tissues that a person may have; and
4. Increased funding for national research programs is needed to close the gaps in knowledge regarding transgender medical care and should be made a priority.

We would like to extend a special thanks to Caroline Davidge-Pitts, MBBCH, and Sean Iwamoto, MD, co-chairs of the Endocrine Society Transgender Special Interest Group, as well as Kara Connelly, MD, Ximena Lopez, MD, Stephanie Roberts, MD, Stephen Rosenthal, MD, Joshua Safer, MD, Vin Tangpricha, MD, PhD, and Abby Walch, MD, all of whom participated in the development of these documents.

The Endocrine Society's advocacy team will use these new and updated documents to educate lawmakers on the importance of evidence-based policies for transgender patients, protecting their access to care, and providing better funding and research to address transgender health gaps.

More information on our work, including the amended Transgender Health Position Statement, fact sheet, and link to the Transgender Special Interest Group's published policy perspective can be found at: **endocrine.org/transgenderadvocacy.**

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- Outstanding Public Service Award
- Outstanding Scholarly Physician Award
- Richard E. Weitzman Outstanding Early Career Investigator Award
- Roy O. Greep Award for Outstanding Research
- Sidney H. Ingbar Award for Distinguished Service
- Vigersky Outstanding Clinical Practitioner Award

ENDOCRINE SOCIETY

Hormone Science to Health

Endocrine Society Advocates During Lame Duck Congressional Session for NIH Funding and Extension of Special Diabetes Program

Following the November elections, Congress returned to Washington, D.C., for a "lame duck" congressional session to complete legislation for the year, and the Endocrine Society ramped up its advocacy on two issues that will greatly impact endocrine researchers, clinicians, and patients — funding for the National Institutes of Health (NIH) and renewing the Special Diabetes Program (SDP).

We are urging Congress to extend the SDP for five years and to support biomedical research by passing a final appropriations bill with a $2 billion increase for the NIH and providing $15.5 billion in emergency supplemental funding to the NIH before December 11 when funding expires.

Take Action

We need all U.S. researchers and clinicians to join our online campaign to help us advocate. Please visit **www.endocrine.org/takeaction** to contact your representative and senators. Our Contact Congress site will provide you with a sample email and direct it to the appropriate congressional offices once you provide your ZIP code. Taking action will not take much time, but it will have significant impact.

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