

JUNE 2019

THE LEADING MAGAZINE FOR • ENDOCRINOLOGISTS

Endocrine news

INTERNATIONAL

One Step **CLOSER:**

Is Male Hormonal Contraception
Finally Within Reach?

New research presented at **ENDO 2019** in New Orleans has reignited anticipation of a potential novel male hormonal contraceptive. After recent scientific breakthroughs, how long before men are “on the pill” or another means of hormonal contraceptive?

THE LONG HAUL:

Testosterone treatment & men with obesity.

TAKING LEAVE:

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FEATURE

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Every **ENDO** is packed with exciting, groundbreaking science, and of course, one of the highlights each year is the presidential plenary. To officially open the proceedings of **ENDO 2019** in New Orleans, attendees were fortunate to have Francis S. Collins, MD, PhD, the director of the National Institutes of Health, deliver the Presidential Plenary speech, "Translating Whole Genome Data to Disease."

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Strategically Advancing the Global Influence of Endocrinology

Spring was a little late to start in Iowa, but summer is around the corner! It has been two months since I began serving as our Society's president. Since then, we have continued our focus on implementing priorities in our strategic plan, and I am pleased to share the following updates with you:

- We continue our advocacy on Capitol Hill for our members and patients. The Society called attention to rising insulin costs in the U.S. Alvin C. Powers, MD, Vanderbilt University, presented our testimony for the House Energy and Commerce Oversight and Investigations Subcommittee. Since the hearing, we have continued to work with members of Congress to inform discussions on draft legislation and future hearings.
- We launched a Basic Science Advisory Committee to develop a strategy plan to support our basic science members, identify leaders, and evaluate areas of emerging science for our Society to champion. Lee Kraus, PhD, UT Southwestern, will serve as chair, and we expect an interim report and recommendations from the group later this year.

“

Together, with novel and innovative session delivery, I expect that ENDO 2020 will be a superlative event that celebrates the best of endocrinology!

”

- We continued our global outreach activities with representatives attending endocrine conferences in India, Japan, Korea, and Europe. I had the great honor to participate in the Korean Endocrine Society Congress and am working with the leadership to explore an expanded partnership between our organizations. I write this letter from the European Society of Endocrinology meeting in Lyon, France, where we had strong representation from members of the Endocrine Society and continued productive collaborations with the

European Society of Endocrinology. In late June, I will travel to Brazil to represent the Society and deliver a lecture at ENDO Recife.

- We had great interest as we piloted Special Interest Groups (SIGs) at ENDO. There is initial energy and enthusiasm around new groups on Pituitary and Adrenal, Transgender Medicine & Research, and an Early Career group. A workgroup constituted by the Council continues to model this out, and I will be working to identify SIG leaders to formally launch these groups later this year. If you are interested in learning more, please email info@endocrine.org for more information.
- We began our planning for **ENDO 2020** during the Annual Meeting Steering Committee (AMSC) meeting in early May. Many thanks to the AMSC chairs Carolyn Smith, PhD, (overall chair), David D'Alessio, MD, (clinical science chair), Maralyn Druce, PhD, (clinical chair), and Stephen Hammes, PhD, MD, (basic science chair) for their leadership and dedication. We have already confirmed some speakers for our plenaries and symposium as I write this message, and I am energized by ideas and contributions of all our AMSC members. We will share more over the coming months, but I am excited that we will expand our Science Pathway sessions adding a fourth pathway (Diabetes and Metabolism). Our plenaries will feature Nobel Laureates, leaders in big data science and population health among other compelling experts that span the interests of our field. We will also leverage our meeting's location in the Bay Area by incorporating sessions focused on innovation, biotech, and venture. Together, with novel and innovative session delivery, I expect that **ENDO 2020** will be a superlative event that celebrates the best of endocrinology!

In addition to these activities, as you know, Council (Board of Directors) approved the Governance Task Force (GTF) recommendations in March. I am pleased to report that you, our members, voted by a large margin to ratify the bylaws changes that will codify these recommendations. We have already made progress on implementation:

- We are working on the initial expansion of our member profiles so that we may better understand and categorize our diverse membership.

- Enhancing our "Call for Nominations" for the Nominating Committee, which resulted in 71 nominees from our membership and enabled collection of personal and professional characteristics and leadership attributes that would make these members strong candidates for Nominating Committee membership. We will review this information to help us implement the recommendation to expand the Nominating Committee to 15 members. The Board of Directors will make these appointments this month, and the new members will participate in the Nominating Committee calls and meetings immediately after appointment.
- Launching an expanded "Call for Nominations" for the Board of Directors. We have created a more robust nomination form to help us select the right leaders at the right time with the right skills. We are now asking each nominee to provide a brief explanation of what leadership roles they've held including leadership and professional development they have completed outside of the Society that they could bring to our leadership team. This, along with the enhanced member profile, will allow the Nominating Committee to develop a balanced slate for the Board of Directors and identify two candidates for the president-elect positions. Nominations are due in late June, and I encourage you to submit a nomination on endocrine.org. Please consider nominating someone for the new "Early Career" ex-officio position on the Board. The Nominating Committee will submit its slate to members in late September.
- Established a Leadership Development Working Group that is charged with developing programs and strategies to identify, support, and advance the professional development of our members across the career spectrum, with the goal of developing a robust leadership pipeline for our Society that will serve us for decades to come.

We look forward to continuing to implement the GTF's recommendations over the coming year. These new directions guided by the GTF recommendations and passed bylaws changes will allow the Society to support SP4 with a strategic and goal-oriented Board that will help us accelerate scientific breakthroughs, improve health worldwide, and advance the influence and reach of endocrinology.

Feel free to contact me at president@endocrine.org. 



FROM THE **EDITOR**

Groundbreaking Science & Special Guests: The Lingering Impact of ENDO 2019

ENDO 2019 was a treat for so many reasons — as you saw in last month's record-breaking, 22-page wrap up — but there are still more stories from New Orleans to tell. From the breaking research that was presented to appearances by very special guests, we are telling even more ENDO stories in this issue as well.

In that latter category, on page 24 we are featuring the presidential plenary talk by Francis S. Collins, PhD, director, National Institutes of Health (NIH), who spoke to a packed house on "Translating Whole Genome Data to Disease." In his speech, Collins covered everything from the prevalence of big data in medical research to the NIH's far-reaching *All of Us* program, which aims to become the world's largest resource for biomedical data. According to Collins, the new program will answer many questions. "A lot of the future is still unclear," he says in his talk. "We're trying to enable it." He added that a group like those assembled at ENDO 2019 could facilitate a future "that gives us more and more of an opportunity for people to enjoy full and healthy lives."

This month's cover story lands squarely in the former category mentioned above as we take a deep dive into one of the most talked-about studies presented in New Orleans, which centered around the ever-elusive male hormonal contraception. In "One Step Closer" (page 34), contributor Kelly Horvath writes about the concentrated efforts by teams of researchers from the Los Angeles Biomedical Research Institute (LABiomed) in Torrance, Calif., and the University of Washington (UW) School of Medicine, in Seattle, Wash., in association with and sponsored by The Eunice Kennedy Shriver National Institute of Child Health and Human Development, that have all been working together in pursuit of male contraception. "Our lab, and all the people in this field I think I can safely say, feel that developing a male contraceptive is important

Answers to the Advocacy Puzzle on page 43

1. SpecialDiabetes, 2. PartD, 3. QP, 4. NIDDK, 5. Appropriations, 6. Evaluation, 7. TitleX, 8. DeGette, 9. NancyPelosi, 10. EuropeanParliament, 11. Obamacare, 12. CMS, 13. EDCs, 14. NIH, 15. Walmart

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because of the global problem of unplanned pregnancy, despite the fact that there are many contraceptive choices for women,” says Stephanie Page, MD, PhD, University of Washington and a co-senior investigator. “While contraceptive access remains an issue here and across the globe and needs to be addressed, we feel that providing more options for men, who currently have very limited options in terms of contraceptives, could help to make a dent in the problem of unplanned pregnancy.”

Senior editor Derek Bagley shares the findings of another study presented at **ENDO 2019** that demonstrates how long-term testosterone therapy in men with both hypogonadism and obesity can actually help these patients lose weight in the long run without any added risks for major cardiovascular events or mortality. In “The Long Haul” (p. 30), lead study author Karim Haider, MD, says that men with hypogonadism and obesity receiving long-term testosterone therapy achieved progressive and sustained weight loss, while untreated controls gained weight over the course of the 10-year study. “The favorable decreases in weight and waist circumference may have contributed to the observed reductions in mortality and



Eli Tulchinsky, a VERY early-career member, seeing what he missed at **ENDO 2019** in New Orleans! PHOTO: David Tulchinsky

major cardiovascular events,” Haider says.

Each year **ENDO** has proven to impact the world of endocrinology for months and even years. Rest assured, *Endocrine News* will continue to report on these groundbreaking studies all year long! **EN**

**CLINICAL
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GUIDELINES**
FROM THE ENDOCRINE SOCIETY

Pharmacological Management of Osteoporosis in Postmenopausal Women

A NEW STANDARD FOR CARE

Get the latest recommendations on how to promptly diagnose, treat, and provide ongoing care for postmenopausal women to help prevent osteoporosis and reduce the likelihood of fractures.

Recommendation Highlights:

- ▶ Treat postmenopausal women at high risk of fractures with pharmacological therapies, as the benefits outweigh the risks.
- ▶ Prescribe initial treatment with bisphosphonates to reduce fracture risk.
- ▶ Reexamine fracture risk after three to five years in women taking bisphosphonates. Women who remain at high risk of fractures should continue therapy, while those who are at low-to-moderate risk should be considered for a “bisphosphonate holiday.”

**READ THE GUIDELINE AT
[ENDOCRINE.ORG/2019OSTEOPOROSIS](https://www.endocrine.org/2019osteoporosis)**

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Christopher Urena Named Endocrine Society's Chief Learning Officer

The Endocrine Society has hired Christopher Urena, MBA, CAE — a seasoned association executive with more than a decade of leadership experience — as chief learning officer where he will oversee the Society's education and meeting activities.



As chief learning officer, Urena will bring innovative leadership for the identification, development, and evaluation of learning-based education and products by using instructional design techniques and leveraging technologies for e-learning. He will also oversee and manage the diverse activities of the Education, Programs, and Meetings Department to include: the annual meeting (ENDO),

Clinical Endocrinology Update (CEU), Continuing Medical Education Symposia (CMES), and patient resources through the Hormone Health Network (HHN).

Urena has a unique combination of nonprofit and for-profit adult education development for large medical associations. Most recently, he was the director of professional development for the American Speech-Language-Hearing Association (ASHA) where he oversaw the operations for the strategic planning, production, marketing, and success measurement for ASHA's continuing education portfolio. Prior to ASHA, Urena was the vice president, business development for CommPartners consulting firm, which offered synchronous/asynchronous e-learning and content management to associations.

"Chris brings expertise, passion, and a wealth of experience to the Endocrine Society," says Society CEO Barbara Byrd

Keenan, FASAE, CAE. "We are thrilled to have such a respected association professional of his caliber to provide guidance and leadership to develop the Society's educational resources and to expand our educational programs as well as our impact around the world."

For more than 10 years, Urena has assisted numerous associations advance their continuing education programs with an unwavering commitment to delivering exceptional learning experiences, in-person and online. At CommPartners, he helped associations create ambitious learning strategies, backed with achievable blueprints that yielded positive, desired results. While at ASHA, he grew the association's education department by \$1 million (annually) in just two years by leveraging new instructional design frameworks, future-focused business models, and evidence-based intelligence, setting ASHA up to experience another \$1 million annual leap in 2020.

"I recognize and take very seriously my responsibility to advance and strengthen the Society's learning portfolio — that's critically important and am confident we, as a team, will accomplish fantastic results," Urena says. "That said, my passion and drive is rooted in something deeper than just increasing the number of learners/attendees and non-dues revenue. I never lose sight that our continuing education programs are ultimately designed to enhance the clinical and functional outcomes of the patients our learners serve."

Urena received his BA in social sciences from Towson University and his MBA from University of Maryland University College. He is the recipient of a 2017 Forty Under 40, Association Forum of Chicagoland award as well as a Power of A (Silver Award) from the American Society of Association Executives for the "Case Studies by ASHA Professional Development" (a series of high-impact, 30-minute courses available to ASHA members for free — one of ASHA's most successful goodwill, member engagement offerings in its history).

Endocrine Society Congratulates 2019 Early Investigators Award Winners

The Endocrine Society has selected five recipients for its Early Investigators Awards.

The Early Investigators Awards were established to assist in the development of early-career investigators and to provide greater recognition of their accomplishments in endocrine-related research.

“One of the biggest challenges endocrine fellows and junior faculty face is gaining recognition and obtaining access to the resources they need for professional development,” says Society President E. Dale Abel, MD, PhD. “The Early Investigator Awards are just one of the many ways the Society values and supports our early-career professionals and their research to prepare them to lead in their institutions and the field at large.”

The Endocrine Society’s 2019 Early Investigators Award winners are:

- ▶ Caroline Gorvin, of the University of Birmingham in the United Kingdom. Her research investigates signaling (non-steroid hormone signaling), neuroendocrinology, and bone health.
- ▶ Joanna Spencer-Segal, MD, PhD, of the University of Michigan in Ann Arbor. Her work focuses on adrenal health, neuroendocrinology, steroid hormone and receptors, and diabetes.
- ▶ Mary Ellen Vajravelu, MD, of Children’s Hospital of Philadelphia in Pennsylvania. Her research focuses on diabetes and pediatric endocrinology.
- ▶ Monica Laronda, PhD, of the Ann & Robert H. Lurie Children’s Hospital of Chicago in Illinois. Her research area is reproductive health and genetics.



- ▶ Subhamoy Dasgupta, PhD, of Roswell Park Cancer Institute in Buffalo, N.Y. His research focuses on endocrine cancer and neoplasia, diabetes, lipids, steroid hormones and receptors, and signaling.

Recipients received a monetary award, one-year complimentary membership to the Society, one-year complimentary access to the Society’s online journals, public recognition of research accomplishments in various Society platforms, and an invitation to attend the Excellence in Endocrinology event at **ENDO 2019** in New Orleans, Louisiana.

Additional information on this award and the recipients is located on the Society’s website at www.endocrine.org/awards/student-and-early-career-awards/early-investigators-awards.

The new application cycle opens in September 2019.

Editor’s Note: A roundtable with the award winners will appear in an upcoming issue of *Endocrine News*.

Endocrine Society Condemns Administration Rule that Would Weaken Healthcare Protections for Transgender People

Last month, the Endocrine Society expressed major opposition to a rule proposed by the Department of Health and Human Services (HHS) that would jeopardize transgender individuals' access to healthcare.

The proposed regulation would weaken the previous administration's definition of "sex discrimination" to remove protections for gender identity. Patients could be turned away or denied medical care because they are transgender.

The Society worked with 30 other healthcare organizations on a letter to HHS expressing deep concerns with the rule and reiterating its firm stance supporting transgender individuals' access to care. The Society urges HHS to withdraw the proposal and adopt strategies to focus on better access to health services and improved health outcomes for the millions of LGBTQ people in the U.S.

The Endocrine Society calls on policy makers to remember that gender identity has a biological underpinning when making healthcare policy decisions. While there continue to

be gaps in knowledge about the optimal care for transgender individuals, the framework for providing care is increasingly well-established as is the recognition of needed policy changes. Medical intervention for transgender individuals is effective and relatively safe, and any interventions prescribed by a physician should be covered by insurance.

The Society developed a position statement to further advocate for this issue that can be found at: <https://www.endocrine.org/advocacy/priorities-and-positions/transgender-health>.

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BY DEREK BAGLEY
Senior Editor

Vascular Endothelial Growth Factor May Prevent Defective Uterine Artery Remodeling

Vascular endothelial growth factor (VEGF) delivery selectively to the placental basal plate (PBM) may prevent maternal and neonatal impairments caused by defective uterine artery remodeling (UAR), according to a primate study recently accepted for publication in *Endocrinology*.

Researchers led by Eugene Albrecht, PhD, a professor of medicine in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of Maryland School of Medicine in Baltimore, point out that a defect in remodeling of the uterine spiral arteries early in pregnancy impairs uteroplacental blood flow and fetal development and underpins the etiology of preeclampsia, preterm birth, and fetal growth restriction. These adverse conditions of human pregnancy occur in more than 10% of all pregnancies and result in maternal and neonatal morbidity and mortality. “However, despite the absolute importance of UAR to successful pregnancy, the regulation of UAR has not been clearly established,” the authors write.

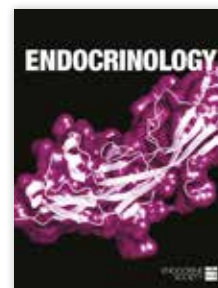
Albrecht and his team developed a primate model of adverse pregnancy by prematurely elevating estrogen in early baboon pregnancy, which causes a defect in uterine spiral artery remodeling and consequently a reduction in uteroplacental blood flow and fetal development. “Using the baboon as a translational model, we have shown that the low level of ovarian estradiol (E2) during the first trimester of normal pregnancy is essential for promoting UAR,” the authors write. “Thus, simply shifting the normal rise in E2 from the second- to the first-third of pregnancy suppressed UAR and this was associated with a decrease in [extravillous trophoblast] VEGF expression, although this did not prove that VEGF mediated this process.”

For this current study, the researchers noninvasively delivered the VEGF gene specifically to the PBM by contrast-enhanced ultrasonography/microbubble

(CEU/MB) technology early in pregnancy in estrogen-treated baboons. “Baboons treated on days 25-59 of gestation (term = 184 days) with E2 alone or with E2 plus VEGF DNA conjugated MB briefly infused via a maternal peripheral vein on days 25, 35, 45, and 55,” the authors write. “At each of these times, an ultrasound beam was directed to the PBP to collapse the MB and release VEGF DNA. VEGF DNA labeled MB/contrast agent was localized in the PBP but not the fetus.”

VEGF gene delivery prevented the defect in spiral artery remodeling, showing for the first time that VEGF has a pivotal role in regulating remodeling of these vessels. “Remodeling of uterine arteries >25 μ m in diameter on day 60 was 75% lower ($P < 0.001$) in E2-treated ($7 \pm 2\%$) than in untreated baboons ($30 \pm 4\%$) and restored to normal by E2/VEGF,” the authors write. “VEGF protein levels (signals/nuclear area) within the PBP were 2-fold lower ($P < 0.01$) in E2-treated (4.2 ± 0.9) than in untreated (9.8 ± 2.8) baboons and restored to normal by E2/VEGF (11.9 ± 1.6), substantiating VEGF transfection.”

Findings: The authors go on to write that this study is highly significant from a clinical perspective considering the impact that defective spiral artery transformation has in underpinning the devastating consequences of abnormal human pregnancy and that this study is foundational for future investigation of therapeutic VEGF delivery to prevent the maternal and neonatal impairments caused by defective uterine artery remodeling. “We propose that the low level of ovarian E2 in the first trimester of pregnancy promotes placental EVT VEGF expression and consequently a rapid rate of UAR and the progressive rise in placental E2 levels during the second and third trimesters, as experimentally induced by prematurely elevating E2 in the first trimester, has an important role in repressing EVT VEGF formation and thus the extent of UAR to promote a physiologically normal level of uteroplacental perfusion,” they conclude.



“

Using the baboon as a translational model, we have shown that the low level of ovarian estradiol (E2) during the first trimester of normal pregnancy is essential for promoting UAR.

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We found that patients with diabetes who are discharged with low or even near normal glucose values during the last day of the hospital stay are at a higher risk of dying or being readmitted to the hospital.
”

Patients with Diabetes Are 40% More Likely to Be Readmitted to the Hospital

Patients with diabetes and low blood glucose have higher rates of death following hospital discharge, according to a study published in *The Journal of Clinical Endocrinology & Metabolism*.

Researchers led by Elias Spanakis, MD, of the Baltimore VA Medical Center and the University of Maryland School of Medicine in Baltimore, point out that patients with diabetes have 40% higher re-hospitalization rates than patients without diabetes, and that 30% of patients with diabetes experience two or more readmissions per year. “In 2012 and also in 2017, the cost of hospitalizations for [diabetes] patients in the U.S. was close to \$123 billion,” the authors write. “Assuming a 20% readmission rate, the cost of 30-day readmissions is estimated to be close to \$25 billion.”

The authors go on to write that while studies have identified risk factors for readmissions among patients with diabetes, little is known about the effect of glycemic control and the readmission risk. So the researchers set out to examine the association of minimum glucose values in diabetes patients during the last 24 hours of hospital stay and the risk of 30-day readmission and post-discharge mortality. “More importantly, the main aim of this work was to investigate whether there is a specific lower glucose value threshold above which [diabetes] patients can be safely discharged from the hospital without experiencing increased risk for either readmission or death,” the authors write.

“In our novel nationwide study, we examined data of almost 1 million hospitalizations at the VA health care system,” Spanakis says. “We found that



patients with diabetes who are discharged with low or even near normal glucose values during the last day of the hospital stay are at a higher risk of dying or being readmitted to the hospital.”

In the nationwide cohort study, researchers examined 843,978 admissions of patients with diabetes at the Veteran Affairs hospitals over a 14-year period to determine the readmission and mortality rates. They found patients with diabetes experienced greater 30-day readmission rates; 30-, 90-, and 180-day post-discharge mortality; and higher combined 30-day readmission/mortality when they had blood sugar levels below 100 mg/dl.

And while this study has several strengths, such as its large cohort and its analysis of national data to examine readmission rates in an integrated health system, the authors note that there are some limitations to consider when considering the results. Their analysis was restricted to a single healthcare system, and the veteran cohort may be different from the overall U.S. population as the veterans were more likely to be male, elderly, and suffer from chronic illnesses. “Despite these differences, our ability to adjust for demographic data and an extensive list of comorbid conditions leads us to believe that our findings are applicable to the general population,” the authors write.

Findings: Based on their findings, the authors conclude that patients with diabetes who had hypoglycemia or near normal glucose values at the last day of the inpatient stay were at a higher risk for a 30-day readmission and post-discharge mortality. “Although future studies are needed, physicians should avoid discharging patients with diabetes from the hospital until glucose values above 100 mg/dl are achieved during the last day of the hospitalization,” Spanakis says. ^{EN}

Fournier Gangrene Rare Side Effect of SGLT2 Inhibitors, Study Finds

Physicians prescribing a sodium-glucose cotransporter-2 (SGLT2) inhibitor for type 2 diabetes should be on alert for symptoms of Fournier gangrene (FG), a rare form of the necrotizing bacterial infection that affects soft tissue in the genitals, according to a review of spontaneous post-marketing cases recently published in *Annals of Internal Medicine*.

FG is a rare urologic emergency characterized by a rapidly progressive necrotizing infection of the external genitalia, perineum, and perianal region requiring broad-spectrum antibiotics and immediate surgical intervention. Diabetes is a comorbid condition in 32% to 66% of cases. The most common adverse reactions identified with SGLT2 inhibitors in clinical trials were genital mycotic and urinary tract infections, but the SGLT2 inhibitor class can also be associated with FG.

Researchers from the Food and Drug Administration led by Susan J. Bersoff-Matcha, MD, reviewed adverse event reports to describe and compare reported cases of FG in patients receiving SGLT2 inhibitors versus other antidiabetic agents.

The researchers identified 55 cases among patients receiving SGLT2 inhibitors during the six years since canagliflozin received U.S. marketing approval in March 2013. Serious complications and death are likely if FG is not recognized immediately and surgical intervention is not carried out within the first few hours of diagnosis. All patients in the case series were hospitalized, some required several surgeries, some had complications, and three died as a result of FG.

The researchers found only 19 FG cases in 35 years among patients receiving other classes of antidiabetic agents. According to the researchers, awareness of the association between FG and SGLT2 inhibitor use may be an important factor in an informed prescriber-patient discussion regarding appropriate diabetes therapy.

Findings: FG is a newly identified safety concern in patients receiving SGLT2 inhibitors that should receive immediate attention, if suspected. “Awareness of the association between FG and SGLT2 inhibitor use may be an important factor



in an informed prescriber-patient discussion regarding appropriate diabetes therapy. Although the risk for FG is low, serious infection should be considered and weighed against the benefits of SGLT2-inhibitor therapy,” the authors conclude.

“

Awareness of the association between FG and SGLT2 inhibitor use may be an important factor in an informed prescriber-patient discussion regarding appropriate diabetes therapy.

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2019 Clinical Endocrinology Update/Endocrine Board Review

**CEU East:
Miami, Florida,
Sept. 5 – 7, 2019**

**CEU West/
EBR: Seattle,
Washington, Sept.
17 – 21, 2019**

Once again this year, endocrine clinicians from around the world will have a choice about which Clinical Endocrinology Update (CEU) they choose. CEU East will take place in Miami while CEU West/Endocrine Board Review (EBR) will land on the West Coast in Seattle.

Miami's Intercontinental Hotel will be the location of the 2019 CEU East on September 5 – 7, and the Hyatt Regency Seattle will be where the joint meeting of the EBR and CEU West take place on September 17 – 21. Each year CEU brings together hundreds of endocrine clinicians for a unique learning experience and opportunities to network with expert faculty and colleagues. Attend the 71st CEU to receive the most trusted and clinically relevant information about recent advances in the field of endocrinology. The educational programming at CEU appeals to clinicians at all levels of practice, as well as fellows and other members of the clinical practice team.

Unlike other board preparation meetings, the Endocrine Society's EBR offers a comprehensive mock-exam format with case-based American Board of Internal Medicine–style (ABIM) questions forming the bulk of the presentations. Each section follows the ABIM blueprint for the board exam, covering the breadth and depth of the certification/recertification examination. Each case will be discussed in detail, with the correct and incorrect answer options reviewed. The mock exam appeals to endocrine fellows who have completed or are nearing completion of their fellowship and are preparing to take the board certification exam. Practicing endocrinologists may appreciate the EBR's comprehensive self-assessment of endocrinology either to prepare for recertification or to update their practice.

www.endocrine.org/ceu
www.endocrine.org/eb/2019

**EARLY REGISTRATION:
NOW – AUGUST 1, 2019**

Growth Hormone and Prolactin Family in Biology and Disease West Palm Beach, Florida, July 7 – 12, 2019

This FASEB Science Research Conference is the only meeting of its kind related to the study of the regulation and actions of GH/PRL and their associated hormones, which include IGF1, placental lactogens, and vasoinhibins. This conference brings together senior clinicians and basic scientists, industry representatives, early-career investigators, and trainees interested in multiple aspect of GH/PRL regulation and function in health and disease. Participants will be able to engage in meaningful, in-depth discussion on the

integrative (patho)physiology of these hormones, and cross-foster national and international collaborations. Additionally, trainees and young investigators will be encouraged to continue to pursue a career path in biomedical research.

<http://src.faseb.org/ghprl>

Cardiometabolic Health Congress

**Chicago, Illinois,
October 11 – 13, 2019**

CMHC is the largest, U.S.-based, multidisciplinary conference that is solely focused on the management of cardiometabolic risk and the prevention of cardiovascular and metabolic disease.

This event allows today's busy healthcare professionals a uniquely exclusive opportunity to learn, internalize, and integrate real-world solutions into their toolboxes, and ultimately, their clinical practices and patient care.

www.cardiometabolichealth.org/2019/chicago-14th-annual-cmhc.html

89th Annual Meeting of the American Thyroid Association Chicago, Illinois, October 30 – November 3, 2019

The ATA Annual meeting is open to the community of endocrinologists, internists, surgeons, basic scientists, nurse

practitioners, and other healthcare professionals who wish to broaden and update their knowledge of the thyroid and thyroid cancer.

www.thyroid.org/89th-annual-meeting-ata/

ObesityWeek

Las Vegas, Nevada, November 3 – 7, 2019

ObesityWeek is a unique, international event focused on the basic science, clinical application, surgical intervention, and prevention of obesity. By combining both American Society for Metabolic & Bariatric Surgery (ASMBS) and The Obesity Society (TOS) annual meetings, ObesityWeek brings together world-renowned experts in obesity to share innovation and breakthroughs in science unmatched around the globe. This year, the international conference will focus on the heart, the cardiac component of obesity. Attendees will enjoy the diverse educational opportunities, networking events, and scientific synergies created through the collaboration of these leading obesity organizations.

www.obesityweek.com



American Diabetes Association 79th Scientific Sessions

**San Francisco, California,
June 7 – 11, 2019**

The Scientific Sessions offers researchers and healthcare professionals an opportunity to share ideas and learn about the significant advances in diabetes research, treatment, and care. Over the course of five days, attendees will receive access to more than 2,800 original research presentations, take part in in-depth conversations with leading diabetes experts, and expand professional networks with colleagues from around the world.

www.professional.diabetes.org

INTERNATIONAL ITINERARY

International Conference on Clinical Diabetes, Diabetic Medication, and Treatment

Osaka, Japan, June 17 – 18, 2019

Clinical Diabetes 2019 is a congress designed to provide an exclusive forum for doctors, dieticians, researchers, scholars, students, and scientists to discuss the latest advances, challenges, trends, concerns, applications, and solutions in mitigating diabetes. Some of the topics for this year's sessions include cellulite and endocrinology, cell therapy for diabetes, and diabetes medications and pharmacotherapy.

www.meetingsint.com/conferences/clinicaldiabetes

4th International Conference and Exhibition on Metabolic Syndrome

Paris, France, June 20 – 21, 2019

The theme of Metabolic Syndrome 2019 is "Promoting Care, Prevention, and Cure Worldwide" and will highlight recent research and findings in endocrinology and metabolic syndromes. The two-day conference includes workshops, symposiums, and special keynote sessions that focus on topics including male and female reproductive health, PCOS and metabolic syndrome, energy metabolism and stress management, and tissue engineering and stem cell transplantation.

www.metabolicsyndromes.conferenceseries.com

World Congress on Thyroid Cancer

Rome, Italy, June 20 – 22, 2019

This scientific meeting is organized for experts in the fields of endocrinology and oncology from around the world to share research and ideas to further the understanding of the management of thyroid cancer. The delegates attending this congress lay the groundwork for collaborations and the direction of future thyroid cancer research.

www.thyroidworldcongress.com

9th International Conference on Children's Bone Health

Salzburg, Austria, June 22 – 25, 2019

ICCBH meetings provide an international forum for the presentation and discussion of current basic and clinical science in the field of bone metabolism and bone mass in children, adolescents, and young adults. The conference topics will include bone and mineral metabolism, development, pediatric endocrine practice, among others. (20 CME credits offered.)

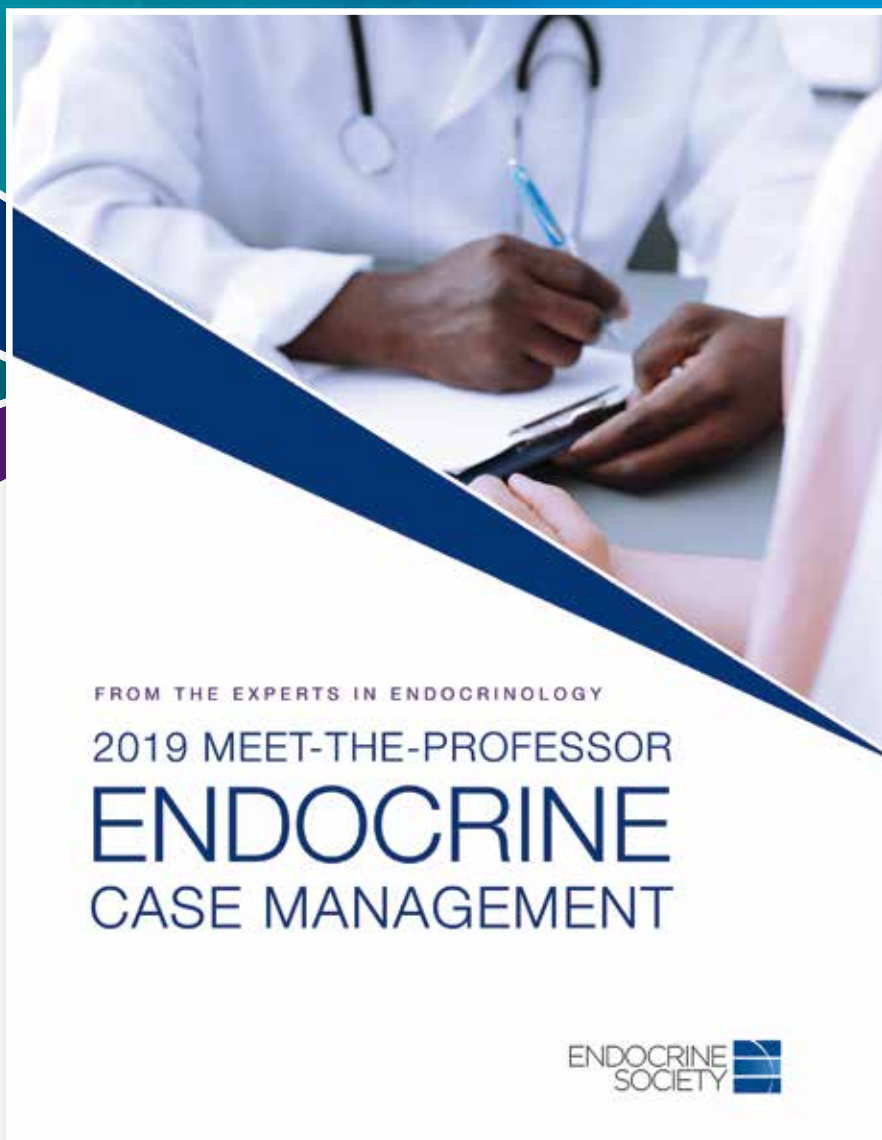
www.iccbh.org

28th European Diabetes Congress

Edinburgh, Scotland, July 17 – 18, 2019

The Euro Diabetes 2019 Conference invites academic scientists, endocrinologists, surgeons, primary care physicians, pharmaceutical industrial delegates, and students from across the globe to network and learn about the latest advancements, growth, and research in diabetes and endocrinology. The theme of the conference is "Recent Advancements and Developments for Changing Life of Diabetes World."

www.diabetesexpo.com



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We all work as a team toward developing effective male contraceptives — team science is so important in accelerating development of novel solutions to health problems. Dr. [Christina] Wang and I work very closely together, and we were honored that our DMAU paper (‘Effects of 28 Days of Oral Dimethandrolone Undecanoate in Healthy Men: A Prototype Male Pill,’ published in JCEM in February) was recognized by the Endocrine Society’s ‘Women in Endocrinology’ organization. It’s always great to highlight how collaborative science can move things forward.”

— STEPHANIE PAGE, MD, PHD, commenting on the important role team science played when her lab at the University of Washington in Seattle collaborated with the lab of Christina Wang, MD, LABiomed, Los Angeles, Calif., to further the progress of male hormonal contraception in “One Step Closer” on page 34.

HALL OF PRESIDENTS

Maria I. New

Endocrine Society President
(1991–1992)

Maria I. New, MD, is a professor of pediatrics, genomics, and genetics, at Icahn School of Medicine at Mount Sinai and is one of the nation’s leading pediatric endocrinologists. Her studies of congenital adrenal hyperplasia (CAH) has led to treatments to correct the disorder before the baby is born. Her groundbreaking identification of apparent mineralocorticoid excess has resulted in a new area of receptor biology. She is also the first to describe dexamethasone suppressible hyperaldosteronism, another form of low resin hypertension. New’s seminal research on the mechanism and genetics of steroid disorders has established standards for prenatal and postnatal care for patients with CAH and apparent mineralocorticoid excess.



300,000 Americans break a hip every year as a result of osteoporosis

Men age **50+** are more likely to have an osteoporosis-related bone break than prostate cancer

Drugs can reduce fractures by **40%** in women and up to **67%** in men

— SOURCE: READER'S DIGEST



28%

the increase in diabetes risk among women reporting four or more pregnancies compared to those who became pregnant two or three times

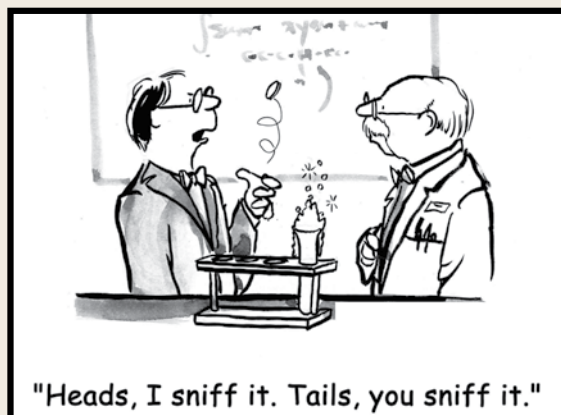
—SOURCE: NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY



73%

the percentage of childhood cancer survivors likely to develop endocrine disorders

—SOURCE: THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION





Every **ENDO** is packed with exciting, groundbreaking science, and of course, one of the highlights each year is the presidential plenary. To officially open the proceedings of **ENDO 2019** in New Orleans, attendees were fortunate to have Francis S. Collins, MD, PhD, the director of the National Institutes of Health, deliver the presidential plenary speech, “Translating Whole Genome Data to Disease.”



STANDING ROOM ONLY

NIH's Francis S. Collins, MD, PhD, Opens ENDO 2019

O

n Saturday March 23, there was only one place to be as **ENDO 2019** got under way in New Orleans and that was in the New Orleans Theater at the Ernest N. Morial Conference Center. Crowds of eager attendees poured in from every direction to listen to the presidential plenary speech by one of the most renowned and high-ranking scientists in the U.S., Francis S. Collins, MD, PhD, director of the National Institutes of Health (NIH), the largest supporter of biomedical research in the world.

BY DEREK BAGLEY



A FIRESIDE CHAT

Toward the end of the plenary, Collins shared the stage with the Endocrine Society's immediate past-president, Susan J. Mandel, MD, for a brief discussion. Here are some highlights.

MANDEL: "As a practicing physician, as someone who uses [electronic health records], if I have a patient who's enrolled in *All of Us*, and especially since we find so many things that as of yet we're not quite sure what that means, what is the type of conversation that the investigators have with the patient, that I have with the patient? How is that going to work?"

COLLINS: "It's an opportunity to empower patients to be more engaged in their care, and people who are signing up seem pretty interested in that and glad they're going to be told the results of the lab studies that are done. They're going to get results back in terms of biochemistry. They will get back results about genetics. We're actually piloting that with genetic counselors available to try to help people think it through. It will be our goal to give information to people in a fashion that is interpretable, that they can share with their physician.

"This is going to be an interesting experiment. I think one of the reasons to come and speak to a group like this is to be sure that we're connecting with practicing physicians about how this could be a real opportunity."

Mandel then asked about inheritable and environmentally determined epigenetic factors.

COLLINS: "Clearly epigenetics is where the action is in terms of gene-environment interactions. If something's happening in your body because of an environmental exposure, it's happening perhaps because of a DNA mutation that's been created if it's a carcinogen. But if it's just modifying gene expression, that's going to work through this whole epigenomic pathway. The more we can learn about how that mechanism works and then study it in people who have had specific environmental interactions, the better."

Collins is a world-renowned physician and geneticist who has made landmark discoveries of disease genes. He's perhaps most well-known for his leadership of the Human Genome Project, a 13-year project that set out to map all the genes in the human genome.

For his presidential plenary talk, Collins touched on three areas that he and his colleagues have been working on, starting with the Human Genome Project and then leading into practical applications for this map of the human genome and what this all means in the modern world of big data. One of Collins' slides showed the cover of an issue of *Nature* magazine; the coverline read, "Science in the Petabyte Era."

Big Data Problems

"We hear, 'Well, you don't really have big data problems like the cosmologists,'" Collins says. "We do have big data problems. The amount of information generated by NIH-funded research every day is absolutely breathtaking, and we need to have a way to store it and make it accessible." He goes on to say that it might be a good time for endocrinologists to familiarize themselves with large data sets and maybe even learn some coding, since we're in the dawn of the time of artificial intelligence and machine learning, tools that physicians will increasingly need to use.

Collins then narrowed his talk down to one practical application — especially interesting to an audience of endocrinologists — type 2 diabetes, a disease dubbed "the geneticist's nightmare." "I think we're beginning to wake up from the nightmare," Collins says.

Collins and his team at the NIH, along with worldwide collaborators, have now identified more than 100 highly statistically significant variants in the genome that are associated with an elevated risk of type 2 diabetes. According to Collins, what they've found is that many non-coding genome-wide association study risk variants lie in long stretches called "stretch enhancers," and that these enhancers are typically tissue-specific and influence the level of expression in nearby genes, but not the nearest ones. "Their effect appears to be mediated by reduction or enhancement of the binding of specific transcription factors," he says. "These epigenomic findings open up a whole new world of potential therapeutic targets."

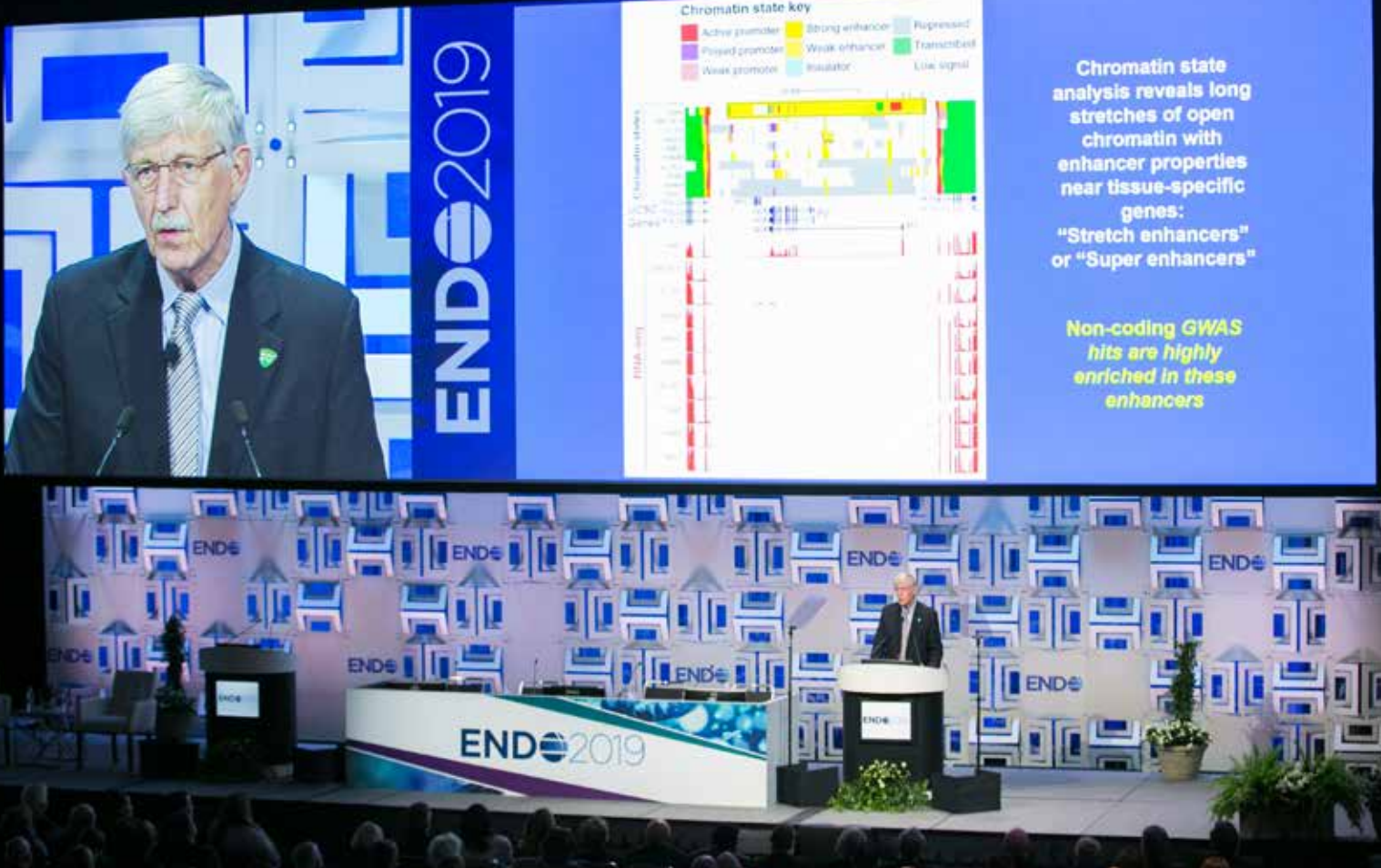
From there, Collins detailed the NIH's *All of Us* Research Program, which aims to prevent and treat all common illnesses, not just diabetes, and to bring more precision to medicine. "We already do precision medicine," he says. "Think about the glasses you're wearing or blood transfusions. But in many instances, we are still a one-size-fits-all world. We'd like to change that but to do that you need a lot of data."



“Clearly epigenetics is where the action is in terms of gene-environment interactions. **If something's happening in your body because of an environmental exposure, it's happening perhaps because of a DNA mutation that's been created if it's a carcinogen.**”

— FRANCIS S. COLLINS, MD, PHD, DIRECTOR, THE NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD.





“ We already do precision medicine. Think about the glasses you’re wearing or blood transfusions. But in many instances, we are still a one-size-fits-all world. We’d like to change that but to do that you need a lot of data.”

— FRANCIS S. COLLINS, MD, PHD, DIRECTOR, THE NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD.

All About *All of Us*

The *All of Us* Research Program launched in May 2018. It’s a historic, longitudinal effort to gather data from one million or more people living in the U.S. that takes into account individual differences in lifestyle, socioeconomics, environment, and biology. So far, the program has enrolled 200,000 participants. The participants are partners, meaning they can receive every piece of information the program collects on them. The program also sought to enroll at least 50% of participants from groups typically underserved in research, and they have already hit that target.

The goal of the *All of Us* Research Program, Collins says, is to become the largest-ever biomedical resource, which will be able to answer questions like: Are there distinct subtypes of type 2 diabetes? Do polygenic risk scores alter health behavior? What genetic and environmental risk factors contribute to racial or ethnic disparities in risk for type 2 diabetes? What controls progression or lack thereof in individuals with risk of diabetes? What genetic or environmental factors determine risk of developing diabetic nephropathy? What combination of care providers leads to the best outcomes for persons with diabetes?

“A lot of the future is still unclear,” Collins says. “We’re trying to enable it. I hope a group like this will make that dream come true, of enabling a future that gives more and more of an opportunity to people to enjoy full and healthy lives.” **EN**

— BAGLEY IS THE SENIOR EDITOR OF *ENDOCRINE NEWS*. HE WROTE THE EXTENSIVE **ENDO 2019** WRAP UP IN THE MAY ISSUE.

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THE LONG HAUL:



BY DEREK BAGLEY

Treating Men with Obesity with Testosterone

A study presented at **ENDO 2019** shows that long-term testosterone therapy in men with hypogonadism and obesity can actually contribute to prolonged weight loss without an added risk for mortality or major cardiovascular incidents.

As obesity rates around the world continue to climb — the number of people with obesity has tripled since 1975 — physicians and health organizations continue to look at how to treat this disease. And it's widely agreed upon that obesity is a disease, since it's no longer solely a matter of “eat fewer calories,” but a complex physiological disorder with various underlying causes as well as myriad comorbidities, both tangible and not. It's well documented that for people with obesity, lifestyle intervention alone can be ineffective, especially in the long term, and for many patients, obesity can set off a vicious cycle from which it's difficult to escape.



But recent studies are producing glimmers of hope, and many of these studies were presented this past March at **ENDO 2019** in New Orleans. One such study showed that long-term testosterone therapy can help men with hypogonadism lose weight and maintain their weight loss. Obesity is common in men with hypogonadism, and the authors write in their **ENDO** presentation abstract that testosterone therapy has previously shown promising results in the long term but not the short term.

“Men with hypogonadism and obesity receiving long-term testosterone therapy achieved progressive and sustained weight loss, while untreated controls gained,” says lead study author Karim Haider, MD, a urologist and andrologist in private practice in Bremerhaven, Germany, who presented the 10-year results of the ongoing study at **ENDO 2019**. “The favorable decreases in weight and waist circumference may have contributed to the observed reductions in mortality and major cardiovascular events.”

“ Men with hypogonadism and obesity receiving long-term testosterone therapy achieved progressive and sustained weight loss, while untreated controls gained. **The favorable decreases in weight and waist circumference may have contributed to the observed reductions in mortality and major cardiovascular events.”** — KARIM HAIDER, MD, UROLOGIST AND ANDROLOGIST, BREMERHAVEN, GERMANY

“

Up to now we have not seen an increase in the risk of cardiovascular events during therapy although it was added by the FDA as a warning. On the contrary, we saw a much higher mortality and incidence of major adverse cardiovascular events in the untreated control group.”

— KARIM HAIDER, MD, UROLOGIST AND ANDROLOGIST, BREMERHAVEN, GERMANY

Like Father, Like Son

In the early 1990s, Haider’s father Ahmad, also a urologist and andrologist in private practice in Bremerhaven, Germany, started treating patients diagnosed with primary hypogonadism with testosterone therapy, and within months these patients showed improvements in their motivation and energy levels, sexual function, compliance, and back pain. A few years later, Ahmad also began treating patients with hypogonadal symptoms but without a diagnosis of primary hypogonadism with testosterone and saw similar results.

In 2004, with the approval of testosterone undecanoate (TU) three-month injections, Ahmad recruited his son into the practice, and the two, along with their colleagues, recorded urological parameters, blood parameters, and questionnaires in patients treated with injectable TU. They also collaborated with other specialists like orthopedists, gastroenterologists, and the local diabetes center in order to include as many parameters as possible.

Their patients were older men with overweight and obesity and no intention of changing anything in their lifestyles. “At every one of their visits in our office we encourage all of our overweight and obese patients to start exercising and to eat healthier,” Haider says. “When being treated with testosterone, these patients suddenly start to listen to our recommendations and come back asking for more than just the usual template of exercises and food-tips we hand out. Hence, we do observe an increase in motivation and physical activity.”

For this current study, Haider and his colleagues followed 805 patients with hypogonadism who were, on average, in their late fifties to mid-sixties. The 462 (57.4%) patients with obesity were given the choice whether to be treated with long-term testosterone therapy with TU 1,000 mg every 12 weeks. Of these, 273 opted to receive testosterone, and the 189 who declined treatment served as controls. “We had many reactions, and most were positive,” Haider says. “[Seventeen] patients who at first refused treatment changed their mind



AT A GLANCE

- ▶ Obesity — a complex physiological disorder — is more common in men with hypogonadism.
- ▶ A study presented at **ENDO 2019** showed that men with hypogonadism and obesity lost weight and were able to keep the weight off long term.
- ▶ Testosterone treatment not only reduced weight but also the risk for mortality and major adverse cardiovascular events.

after several years during which they encountered major adverse cardiovascular events and were strongly advised by their cardiologist to start the treatment.”

Over 10 years, the testosterone-treated men lost 20.3% of their baseline weight (50.5 lb; 22.9 kg); their waist circumference dropped by 12.5 cm (4.9 in). BMI decreased by 7.3 kg/m², and the waist-to-height ratio decreased by 0.07. By contrast, the untreated men gained 3.9% of their baseline weight (3.2 kg; 7.1 lb), and their waist size increased by 4.6 cm (1.8 in). In this group, BMI increased by 0.9 kg/m², and waist-to-height ratio increased by 0.03. During this time, 12 (4.4%) men in the testosterone group died, while in the untreated control group, 57 deaths (30.2%), 47 myocardial infarctions (24.9%), and 44 strokes (23.3%) occurred.

“The first big moment was when the reason for initiating this study was confirmed with significant changes in weight and waist circumference compared to the baseline,” Haider says. “This is something we realized the first time when the study was running for four years and four-year data were analyzed. We were then the first to publish weight loss as a result of testosterone therapy.”

Unexpected Benefits

It’s well known that testosterone therapy changes body composition, during which patients lose fat mass and increase muscle mass. Testosterone therapy improves the structure and function of mitochondria, resulting in more energy expenditure. The authors write in their conclusion to the **ENDO** presentation abstract that long-term testosterone therapy in men with hypogonadism resulted in profound and sustained improvements in anthropometric parameters.

But it’s not just decreases in BMI and waist circumference Haider and his team have observed in patients treated with testosterone therapy. Haider says they saw gastroenterological patients who reported remissions in their Crohn’s disease once starting on testosterone therapy. Some of their patients with hypogonadism and type 2 diabetes receiving standard diabetes treatment went into remission and did not need their diabetes medication anymore.

“The fact that this study was the first to show that testosterone therapy does not increase the risk for prostate cancer was awarded with a presentation in the main plenary during the most important minutes of the 2014 annual meeting of the



American Urological Association,” Haider says. “Up to now we have not seen an increase in the risk of cardiovascular events during therapy although it was added by the FDA as a warning. On the contrary, we saw a much higher mortality and incidence of major adverse cardiovascular events in the untreated control group.”

Hypogonadism: Lifelong Treatment

Haider credits the fact that medication adherence in the testosterone group was 100% as one of the most important explanations of their results, since all injections were performed in the clinic and all patients continuously have stable serum-testosterone levels. He also warns against stopping testosterone treatment in men who have lost weight or whose comorbidities have improved. Haider points to another study in which patients stopped treatment after more than five years for approximately 18 months and then continued treatment again.

“The results were drastic worsening in every measurable parameter throughout the time without therapy, even worse than at baseline, and again an improvement when continuing the therapy,” Haider says. “Similar results had been observed by various other researchers who tried stopping the treatment. Just like hypothyroidism, hypogonadism is a chronic disease which therefore requires lifelong treatment.” **EN**



New research presented at ENDO 2019 in New Orleans has reignited anticipation of a potential novel male hormonal contraceptive. After recent scientific breakthroughs, how long before men are “on the pill” or another means of hormonal contraceptive?



One Step CLOSER:

BY KELLY HORVATH

IS MALE HORMONAL CONTRACEPTION FINALLY WITHIN REACH?

Unintended pregnancy is a global public health problem. The health and economic impacts on women and their children can be enormous. Unplanned children are at risk for suboptimal prenatal care, premature birth, and future health problems. In addition to coping with the stress of an unintended pregnancy, women are less likely to attain higher education and find lucrative employment, which, in turn, can negatively impact children.

Although rates worldwide have been on the decline in the last 30 years, still, around 44% of pregnancies are unplanned, with rates in developing countries tending to be higher than in developed countries. The U.S. is an exception, however, with an estimated 45% of pregnancies being unplanned. The need for contraceptive options and family planning is all too clear.

That's where a team working jointly from the Los Angeles Biomedical Research Institute (LABiomed) in Torrance, Calif., and the University of Washington (UW) School of Medicine, in Seattle, Wash., in association with and sponsored by The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) come in. "Our lab, and all the people in this field I think I can safely say, feel that developing a male contraceptive is important because of the global problem of unplanned pregnancy, despite the fact that there are many contraceptive choices for women," says Stephanie Page, MD, PhD, University of Washington and a co-senior investigator. "While contraceptive access remains an issue here and across the globe and needs to be addressed, we feel that providing more options for men, who currently have very limited options in terms of contraceptives, could help to make a dent in the problem of unplanned pregnancy."



“While contraceptive access remains an issue here and across the globe and needs to be addressed, **we feel that providing more options for men, who currently have very limited options in terms of contraceptives, could help to make a dent in the problem of unplanned pregnancy.**”

—STEPHANIE PAGE, MD, PHD, UNIVERSITY OF WASHINGTON, SEATTLE

Co-senior investigator Christina Wang, MD, from LABiomed agrees wholeheartedly: “We have been pursuing this for a few years, and it’s just coming to the time when we can see real results. We noted a lot of interest from the general population that more men may be interested in male hormonal contraception and feel that there’s a need for them to participate in family planning. That’s all good.”

Oral Hormonal Contraception

Her enthusiasm is well warranted. The team is concurrently undertaking studies of three different modes of administration of five different prototype products. The biggest recent news is that their second oral modified testosterone compound has just completed a one-month safety test, an early step in the U.S. Food and Drug Administration (FDA)’s evaluation of new drugs, and a three-month trial should follow based upon their positive findings.

► 11-Beta-MNTDC

11-Beta-methyl-19-nortestosterone dodecylcarbonate (11-beta-MNTDC) has both androgenic and progestational activity and successfully and reversibly suppressed testosterone, luteinizing hormone (LH), and follicle-stimulating hormone (FSH) in a preclinical study of 40 healthy men. Male hormonal contraceptives use both androgen and progestin because adding the progestin suppresses sperm production more quickly, and requires less androgen than when testosterone is given alone. The actions of these two hormones, which regulate LH and FSH, are present in 11-beta-MNTDC. By shutting down the regulators of testicular function, sperm production as well as the production of testosterone is ablated. Because

11-beta-MNTDC performs like a male hormone in the body, however, the lack of testosterone is not noticeable, and libido and sexual activity were not significantly affected.

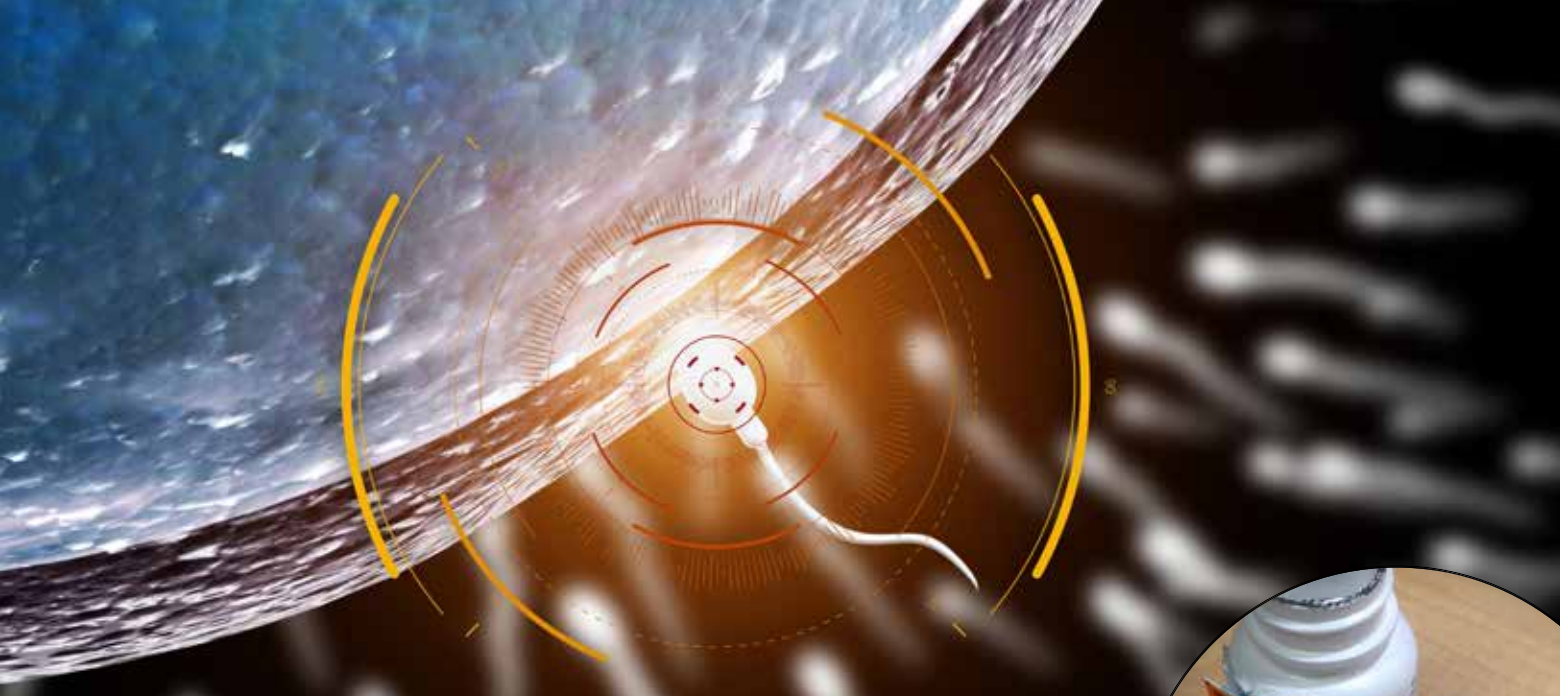
In the randomized, placebo-controlled, double-blind study, 10 men were given placebo, 14 men were given 200 mg of 11-beta-MNTDC, and 16 were given 400 mg of 11-beta-MNTDC. All participants took the capsules daily with a large breakfast to facilitate absorption and per FDA recommendations.

“Since this trial passed the safety tests, appears to be well tolerated in men, and achieved the actions that we were anticipating it to show, our next step has to be to demonstrate that it can suppress sperm production,” Wang explains. “Because we have only given 11-beta-MNTDC for 28 days, we have yet to show that the sperm count will suppress to very low levels. For a drug that works by suppressing sperm production, it will take about 90 days (three months) to demonstrate this. If the dose is adjusted right, we want to see at least 90% of men having their sperm count suppressed to a very low level to prevent pregnancy in the female partner.”

The team has conducted a six-month rodent toxicology study and is now conducting a six-month primate toxicology study, with the results to be available at the end of this year. Once these demonstrate safety, the longer trial of 11-beta-MNTDC in humans can begin.

► DMAU

As mentioned, 11-beta-MNTDC is not the only male hormonal contraceptive the team is working on. Like 11-beta-MNTDC, oral dimethandrolone undecanoate (DMAU) looks promising in terms of efficacy and safety and is farther



In the randomized, placebo-controlled, double-blind study, 10 men were given placebo, 14 men were given 200 mg of 11-beta-MNTDC, and 16 were given 400 mg of 11-beta-MNTDC. “Since this trial passed the safety tests, appears to be well tolerated in men, and achieved the actions that we were anticipating it to show, our next step has to be to demonstrate that it can suppress sperm production,” Wang explains.

along in the development cycle. “We think of them as sister compounds,” Page says. “We wanted to have multiple compounds in the pipeline, and that’s why we are developing and testing these in parallel. You never know when you’re going to encounter a hiccup during drug development. The compounds are very closely related, and we are trying to ensure that we have something that moves forward.”

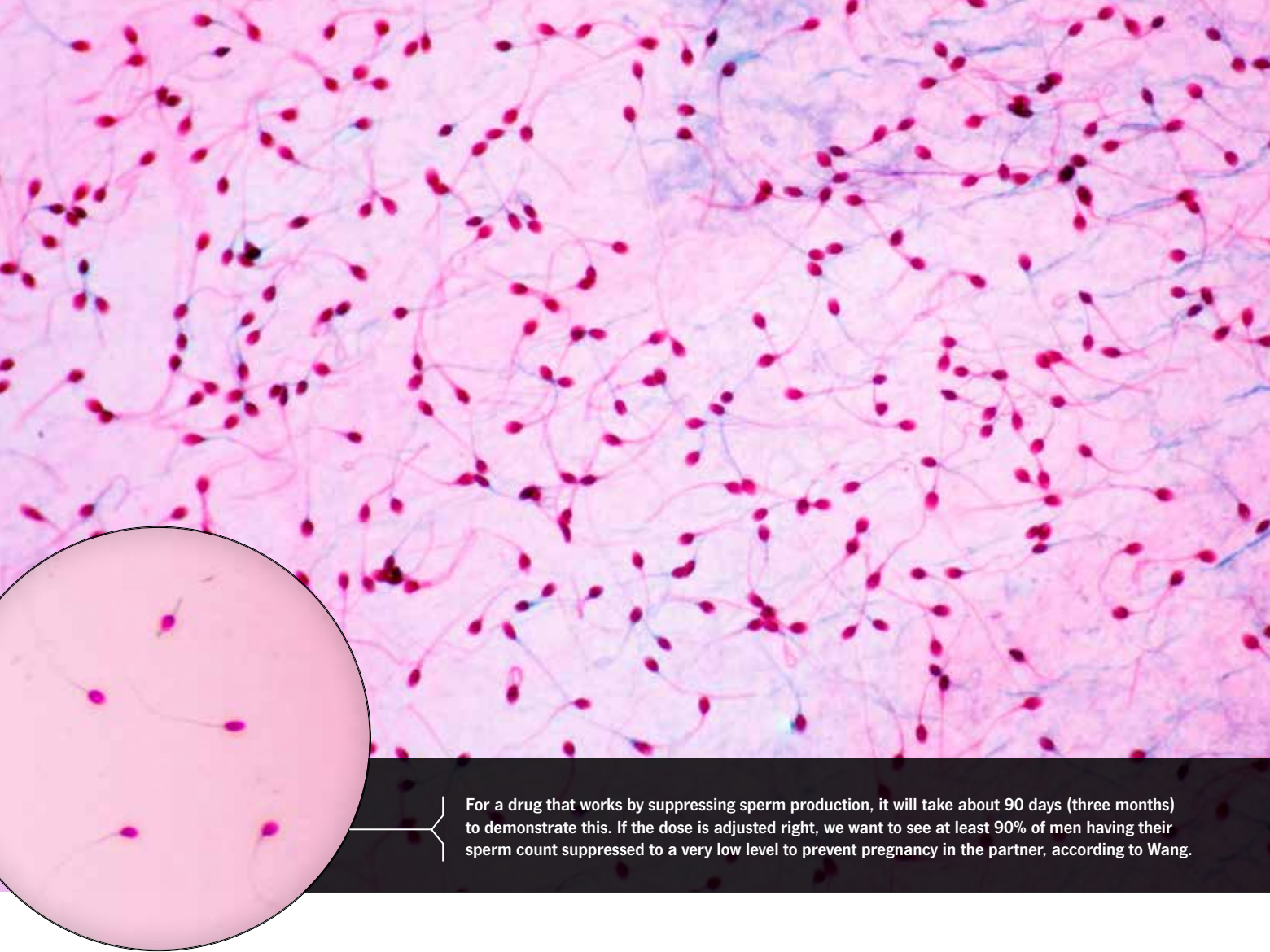
Both compounds are built on a backbone of 19-nortestosterone and both have androgen and progestin actions, but there are slight chemical differences between the two, including that DMAU is a bit more androgenic. “Until we do human trials, we don’t know for certain whether those in vitro differences will translate into clinical differences,” Page says. “For example, we know that giving oral androgens is going to have some effects on cholesterol. So, it may be that one of our compounds will have less impact than the other. Or one of them has an effect that may be more beneficial than the other, or is better absorbed, or lasts longer in the blood. That’s where those slight differences could translate into something that is clinically important for a contraceptive as the project moves forward.”

So far, up to a 5-kg weight gain has been seen across studies, although some participants did not gain any weight. Researchers are not sure yet whether the weight gain is related to the compound itself or to the fact that it had to be taken with a fatty meal; however, more weight gain was seen in the groups taking the compounds than in the control groups. “We are going to work on what types of foods these compounds can be taken with down the line. It may be that we can reduce the fat content that was required for these early clinical trials,” Page says.



AT A GLANCE

- ▶ A team from University of Washington and Los Angeles Biomedical Research Institute has five prototype male hormonal contraceptive products in various stages of development: Two oral capsules, two injectables, and a transdermal gel.
- ▶ The latest product, 11-beta-MNTDC, was well tolerated and effectively suppressed serum gonadotropins and testosterone in study participants and is approved for the next phase of testing.
- ▶ Like its sister compound, DMAU, 11-beta-MNTDC is expected to provide both an oral and a long-acting injectable means of reversible contraception.



For a drug that works by suppressing sperm production, it will take about 90 days (three months) to demonstrate this. If the dose is adjusted right, we want to see at least 90% of men having their sperm count suppressed to a very low level to prevent pregnancy in the partner, according to Wang.

Intramuscular Injectable Contraception

As of April 2019, trials of both oral administration and intramuscular (IM) injections of DMAU in rats and monkeys have been completed. The next step for DMAU is to see which oral dose most effectively suppresses sperm production in humans in a three-month trial. "Once that is done," Wang says, "we can decide whether we need to have more studies to make sure that this compound is safe and tolerated when delivered orally, or can we go into a study that can prevent pregnancy in the female partner. We're about halfway through the recruitment for this study."

Study of IM injection of DMAU is also underway. "Because it appears to last a long time in men, progress is a bit slow," Wang explains. "We have a safety review as we increase each of the test doses to make sure that all subjects recover before we go to the next dose in the current Phase 1 study."

The team anticipates that both DMAU and 11-beta-MNTDC will work as long-acting reversible injectable contraception. Additionally, the absorption and bioavailability of both 11-beta-MNTDC and DMAU appears to be better after the IM injection. Oral absorption is lower. "So, as far we know, you can use much less of the drug with the IM injection," Wang says.

Transdermal Gel Contraception

In association with the Population Council, the team also developed a transdermal gel that began testing in couples at the end of 2018. A previous test of Nestorone® (segesterone acetate) and testosterone (N/EST) showed that, for men applying the gel for six months, sperm count was suppressed to a very low concentration in about 90% of study participants. A total of 420 couples will be enrolled in the new late phase 2 trial with the primary endpoint being prevention of pregnancy.

In addition to UW and LABiomed, other testing sites will include the University of Kansas in Overland Park; the University of Edinburgh in Scotland; the University of Manchester in the U.K.; the Karolinska Institute in Stockholm, Sweden; Kenyatta National Hospital in Nairobi, Kenya; the Chilean Institute of Reproductive Medicine in Santiago; and the University of Bologna, Italy.

“Suddenly everything began developing, so that we have a study that is in late phase 2, and one going after another,” Wang says.

Team Science

Male hormonal contraception has been a long time coming. “Unplanned pregnancy is a big problem,” Page says, “and 50% of the population is less engaged than they could be in combating it — and that’s in part because men don’t have very many contraceptive choices.”

That could be changing very soon, however. When researchers asked men from across the globe what form of reversible birth control they would prefer, the number one response was a pill. They also know from female contraception that there is likely to be demand for longer-acting male contraceptives. “What we are trying to do is develop many methods for men,” Wang says. “Different products will be appealing to different men and to different couples, just as is the case for women. And, different products might be appealing to the same person at a different stage in his life,” echoes Page. “Just as a woman might take an oral contraceptive for a while, then switch to an IUD, for example, there’s no reason to think that men wouldn’t similarly want to change their methods or the methods they share with their partners across the lifespan.”

These eagerly awaited options for effective, reversible male contraception have something else in common: They came to be from team science.

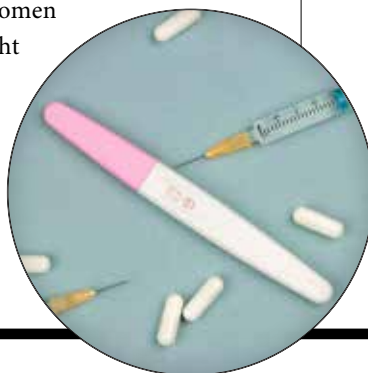
“We all work as a team toward developing effective male contraceptives — team science is so important in accelerating development of novel solutions to health problems,” Page says. “Dr. Wang and I work very closely together, and we were honored that our DMAU paper (“Effects of 28 Days of Oral Dimethandrolone Undecanoate in Healthy Men: A Prototype Male Pill,” published in JCEM in February) was recognized by the Endocrine Society’s “Women in Endocrinology” organization. It’s always great to highlight how collaborative science can move things forward.” 

— HORVATH IS A FREELANCE WRITER BASED IN BALTIMORE, MD. SHE WROTE ABOUT THE LATEST BREAKTHROUGHS IN OBESITY RESEARCH IN THE APRIL ISSUE.



“We have been pursuing this for a few years, and it’s just coming to the time when we can see real results. **We noted a lot of interest from the general population that more men may be interested in male hormonal contraception and feel that there’s a need for them to participate in family planning.** That’s all good.”

— CHRISTINA WANG, MD,
LABIOMED, LOS ANGELES, CALIF.



Q&A:

Derek LeRoith, MD, PhD

Endocrine News talks with Derek LeRoith MD, PhD, chair of the guideline writing committee that created the latest Endocrine Society Clinical Practice Guideline on Treatment of Diabetes in Older Adults.



“Diabetes is more common in the elderly, and they require treatment similar to the younger diabetic population with special care regarding acute complications in addition to preventing the long-term complications.”

Simplifying medication regimens and tailoring glycemic targets in older adults with diabetes improves adherence and avoids treatment-related complications, according to the latest clinical practice guideline released by the Endocrine Society during **ENDO 2019** in New Orleans in March.

Entitled “Treatment of Diabetes in Older Adults: An Endocrine Society Clinical Practice Guideline,” the guideline was published online in March and appeared in the May 2019 print issue of *The Journal of Clinical Endocrinology & Metabolism*.

Derek LeRoith MD, PhD, director of research, Division of Endocrinology, Diabetes, and Bone Diseases, Icahn School of Medicine at Mt. Sinai, New York, is the chair of the writing committee that authored this guideline. “The guideline encourages clinicians to consider available evidence, a patient’s overall health, their likelihood to benefit from interventions, and their personal values when considering treatment goals such as glucose, blood pressure, and cholesterol,” says LeRoith. “Our framework prioritizes blood glucose targets over the hemoglobin A1c test when managing diabetes in older adults.”

LeRoith shares his thoughts with *Endocrine News* about how this new guideline will impact treating this patient population and how it could impact other medical specialties.

ENDOCRINE NEWS: What was the main reason for the publication of the diabetes in older adults guideline. What drove the decision and why now?

DEREK LEROITH: The incidence of diabetes in the older population (over the age of 65 years) is much greater than those in the younger age group. It was therefore important to us as endocrinologists to highlight the need for more attention to this age group, both in making the diagnosis and instituting the correct therapies.

EN: What are your hopes for the impact of the guideline on endocrine standards of care for older patients with diabetes?

DL: We believe that the guidelines will enable the health professional to pay more attention to the elderly patient with diabetes, both therapeutically and to avoid many of the hazards and complications that occur with this population.

EN: How do you expect other medical specialties to be affected by this guideline's recommendations?



DL: The guidelines not only address the general medical health providers but other subspecialties that deal with diabetic complications, including nephrologists, eye specialists, surgeons, etc.

EN: What are the key take-home messages for patients in this guideline?

DL: The key take-home messages are diabetes is more common in the elderly and they require treatment similar to the younger diabetic population, with special care regarding acute complications, in addition to preventing the long-term complications. ^{EN}

ESSENTIAL POINTS

from the “Treatment of Diabetes in Older Adults: An Endocrine Society Clinical Practice Guideline.”

- ▶ Prediabetes is highly prevalent in older people, however, interventions to delay progression from prediabetes to diabetes are especially effective in this age group.
- ▶ The prevalence of type 2 diabetes increases as individuals age and exaggerates the incidence of both microvascular and macrovascular complications.
- ▶ Clinicians should perform regular screening for prediabetes and diabetes in the older population and implement interventions as indicated in this guideline.
- ▶ Given the heterogeneity of the health status of older people with diabetes, the guideline emphasizes shared decision making and provides a framework to assist healthcare providers to individualize treatment goals.
- ▶ The problems that older individuals with diabetes face, in contrast to younger people with the disease, include sarcopenia, frailty, and cognitive dysfunction. Such complications can lead to an increased risk of poor medication adherence, hypoglycemia (from certain medications), falls, and loss of independence in daily living activities.
- ▶ The guideline presents evidence for the various effects of diabetes in older patients and the relevant therapies for glycemic control, hyperlipidemia, and hypertension.
- ▶ Guideline recommendations also address common comorbidities such as renal impairment, which affects the pharmacokinetics and pharmacodynamics of specific agents, and concomitant heart disease.



GREENER LABS

Considering your lab probably consumes more energy than your entire home, it might be time to consider these energy-saving options.

BY GLENDA FAUNTLEROY SHAW

“I think researchers have always been interested in reducing their environmental impact, particularly with regard to waste, they just haven’t known how or where to start.”

— ALLISON PARADISE, CEO, MY GREEN LAB

Did you know laboratories consume five times more energy than your average home? And that small water baths can use as much energy as a dishwasher every hour? U.S. laboratories, on average, use far more energy and water per square foot than office buildings and other facilities because their activities are energy intensive and their health and safety requirements are more stringent, according to the U.S. Department of Energy.

The good news is that many lab researchers are now taking the necessary steps to reverse this wasteful trend and make their spaces more energy efficient.

The idea of “green labs” is increasingly more mainstream, says Allison Paradise, CEO of My Green Lab, a California nonprofit run “for scientists, by scientists” to improve the sustainability of scientific research.

“When we started our nonprofit six years ago, there were fewer than 10 research organizations, such as universities and biotech companies, with programs dedicated to laboratory sustainability and today there are nearly 100,” Paradise says.

“I think researchers have always been interested in reducing their environmental impact, particularly with regard to waste, they just haven’t known how or where to start,” she adds. “This is where My Green Lab has been particularly influential. Our mission is to build a culture of sustainability through science. In doing so, we work directly with scientists and research organizations to improve environmental health and resource utilization.”

My Green Lab has initiated several programs designed to meet its mission. One popular competition is its Freezer Challenge that’s designed to promote best

practices in cold storage management. Labs get points for taking actions such as properly maintaining freezers and refrigerators and discarding old samples. Last year, more than 175 labs representing 28 organizations around the world competed, and the University of Illinois, Urbana-Champaign claimed first place by saving an estimated 260,000 kWh/year.

Fume Hoods: A Big Offender

The large equipment used in laboratories are classic energy wasters and the fume hood — a necessity in any lab — is one of the worst offenders. A fume hood (“the cabinet”) provides a contained work space that is ducted outside of the building for researchers to handle materials such as volatile organic compounds and solvents. The user can adjust the hood’s movable window (“the sash”) to access the cabinet, and air is then driven away from the user at a proper rate to reduce exposure risk.

Fume hoods place tremendous pressure on a building’s HVAC system because they are constantly exhausting newly conditioned air out of the building. A recent “Fume Hood Strategy” white paper published by Harvard University cited

that 44% of the energy used at one institution’s labs was directly related to ventilation. The paper analyzed Harvard’s Shut the Sash Program that was launched to encourage lab workers to shut fume hood sashes to reduce the amount of air exhausted from labs. The program resulted in the university saving an estimated \$200,000 – \$250,000 in utilities per year, according to the report.

Turning Green

Making environmentally smart changes in your lab can start with simple observations.

“The single most important action lab managers can take is to start asking, ‘Why,’” explains Paradise. “As you enter the lab in the morning, query why the equipment has been left on overnight. As you start work, critically examine the chemicals and reagents you are using and ask if there are more sustainable/benign alternatives.”

“By asking ‘Why?’ you will start to see your lab from a whole new perspective, and with this new perspective it will become clear which actions will go the furthest toward reducing the environmental impact of the lab.” ^{EN}

MEANS TO GO GREEN

Make these greener habits a part of your lab’s routine to reduce your environmental impact:

- Unplug lab equipment when not in use;
- Keep fume hood sashes closed whenever possible;
- Defrost lab freezers;
- Partner with a recycling program, such as Corning Recycles, for lab materials such as Styrofoam containers and pipette tip boxes;
- Turn off air valves;
- Clarify lab and office recycling procedures, label bins, and hang signage;
- Use a power strip so groups of appliances can be powered down when not in use;
- Swap plastic and disposable pipettes for glass pipettes and wash them with a pipette washing rack; and
- Regularly check freezer door seals to be sure cold air is not escaping.



Power strips can reduce energy use by allowing groups of appliances to be powered down when not in use.

If certain lab equipment won’t be used for an extended period of time, simply unplug it to reduce the energy load.





Take Your Leave:

How to Handle a Medical or Parental Leave

Practicing clinicians know all too well that often life intervenes into a meticulously planned career path. *Endocrine News* shares a few tips on steps you can take if you have to be out of the office for a while.

BY CHERYL ALKON

For Sarah Hart-Unger, MD, a pediatric endocrinologist at Joe DiMaggio Children's Hospital at Memorial Healthcare System in Hollywood, Fla., having children and being a physician was always a priority.

"I never felt like I wanted to hold back on having kids for the sake of my career," Hart-Unger says. "I had fantastic role models who made it quite clear I could train in academic medicine and have children." She is the mother of three children: a five- and seven-year-old, and a 15-month-old.

Hart-Unger, who co-founded the *Best of Both Worlds* podcast about balancing work and family life with time-management author Laura Vanderkam, is upfront about fully using maternity time to welcome her new children. She also cites hiring help for childcare, family meals, house cleaning, and whatever other tasks needed to run a career and a family smoothly.

In the U.S., the Family Medical Leave Act (FMLA) allows employees to take up to 12 weeks of unpaid leave for maternity or sick leave, provided that the company has at least 50 employees and the employee has worked for that company for at least a year. Other employers may offer additional benefits (such as paid time off) for their workers who need to take time off from their jobs.

“Don’t skimp on your leave itself, whether it’s for a maternity leave, a medical reason, or something else,” Hart-Unger says. “Whether you are in training or are an attending, if you are able to, and feel like you will benefit from a full 12 weeks, probably no one else will care if you took the longer leave. You will probably never regret it. I know many residents rush their leave, but I 100% believe that a longer leave is worth it.”

Hart-Unger took 12 weeks of leave after each child was born, with one of them occurring six months after starting her first job. “I am very grateful that I had never had anything but support, as endocrinologists tend to be a supportive bunch,” she says.

Taking a leave from work — to care for a new child, to heal from an extended illness, to help with a family member’s medical or personal issues, for example — can require some planning and finesse. Working with your practice’s human resources department will help you fully understand what you are entitled to during a medical, sick, or disability leave, and how you can make the most of time away from the office.

Approaching the Human Resources Department

Reach out to your contact at your company’s human resources department and give them time to prepare the right information for your particular situation, says Suzanne Goulden, a spokesperson for the Society of Human Resource Management based in Alexandria, Va.

“It can be hard to prepare if someone approaches me and says, ‘I need FMLA’ [immediately], because there are certain disability claim forms to complete,” Goulden explains. “If somebody is pregnant and emails me and says they are due in July, then great. We can meet next week.”

For a more urgent need, such as a person learning he will need surgery within a few days, Goulden says she works as quickly

as she can to meet with the employee to set up the leave. Every company is different in terms of what paperwork needs to be completed. A maternity leave meeting will include information about how to add a newborn to an employee’s healthcare plan, for example, while a leave related to an injury that occurred while on the job requires working with the human resources department right away to ensure that worker’s compensation goes into effect at the right time. In this case, “go to human resources right away, as it is happening or after an immediate crisis,” says Goulden. “Sometimes with worker’s compensation, benefits can be delayed or denied if the employee goes to the wrong healthcare provider for care.”

Plan Ahead

If you are facing a leave, think about what you will need to function well. Financially, it can be hard to save money during your medical training when salaries are smaller and workloads are heavier, but doing so can help establish savings for the future. “It can be a challenge on a resident or fellowship salary, but you will eventually be an attending,” Hart-Unger says.



“

I never felt like I wanted to hold back on having kids for the sake of my career. I had fantastic role models who made it quite clear I could train in academic medicine and have children.” — SARAH HART-UNGER, MD, PEDIATRIC ENDOCRINOLOGIST, JOE DIMAGGIO CHILDREN'S HOSPITAL, MEMORIAL HEALTHCARE SYSTEM, HOLLYWOOD, FLORIDA

For a maternity leave, think about childcare as soon as possible; decide about what options work best so you can continue working, such as day care centers, home-based childcare settings, nannies, or au pairs. Research options by talking to others in similar situations (Hart-Unger recommends searching on Facebook for physician mom groups) as well as those in your area. “Look in your community; there are many other women and men in your position, and it’s great to network with others with young kids.”

If you’re facing a part-time disability leave where you will need to take time for multiple physician’s appointments, try to schedule appointments first thing in the morning if you need to return to work for a full day afterward, or at lunch time, when you can leave the office without attracting as much attention with your absence.

For medical leaves where you will be recovering at home, ask about what options your health insurance will cover, such as visiting nurses or partial or full payment for items needed at home, such as a knee scooter if you are on crutches. Can your local pharmacy deliver medications to your house if the prescriptions are called in from your doctor’s office?

Helping Hands

Once the leave has begun, don’t be shy about asking others for help. If you know you will need help with meal preparation or grocery shopping, let others know. When friends or family ask if they can help you with anything,

give them specific tasks, such as picking up groceries and bringing them home to help put them away. Consider online vendors as well; with companies like Instacart or Peapod, you can have groceries delivered to your house sometimes within a few hours of ordering. Sites like DoorDash or Grubhub can also deliver meals to your house for a fee — look for introductory rates for new customers that will offer free or reduced delivery costs.

Outsourcing can help offload the feeling that you have to do it all, especially if you have a partner.

“With all the challenges you have with a new baby, don’t let everything fall on you; share the load with others you created this situation with,” Hart-Unger says. “Make sure you are getting the help you need.”

Hiring help, even temporarily such as a food-delivery service or a taxi for getting to and from medical appointments if you cannot drive yourself, will help you get things done.

“Take stock of your life, and make sure you aren’t spending time doing things if you have the money to outsource,” Hart-Unger says. “You don’t need to be the only one to make dinner. Instead, think about how to make use of your limited time.” 

— ALKON IS A MASSACHUSETTS-BASED FREELANCE WRITER AND AUTHOR OF THE BOOK, *BALANCING PREGNANCY WITH PRE-EXISTING DIABETES: HEALTHY MOM, HEALTHY BABY*. SHE WROTE ABOUT PHYSICIAN NETWORKING WEBSITES IN THE OCTOBER 2017 ISSUE.



Society Advocates for Important Diabetes Research Programs, Access, and Affordability

The Endocrine Society is a leading advocate on several issues that would increase access to diabetes coverage and funding for important research. See below for recent highlights of our activities concerning the reauthorization of the Special Diabetes Program, insulin affordability, and diabetes testing supplies.

► **Special Diabetes Program** — Ensuring continuation of the Special Diabetes Program (SDP) is a top priority for the Endocrine Society. The lives of over 114 million Americans living with or at-risk for developing diabetes are being changed through the SDP; however, funding will expire on September 30 if Congress fails to act. The SDP is comprised of two programs — the Special Diabetes Program for Type 1 Diabetes and the Special Diabetes Program for Indians. Congress created these programs in 1997 to advance research for type 1 diabetes at the National Institute of Diabetes and Digestive and Kidney Disorders and to provide treatment and education programs for type 2 diabetes among American Indians and Alaska Natives. Together, these programs have proven to be a critical pathway to preventing and treating diabetes and its complications. The Society has been working with the Congressional Diabetes Caucus and the diabetes community to ensure that the SDP is reauthorized by the deadline. Through these efforts, more than 400 members of Congress signed onto a letter of support for these important programs.

Take Action

Help us advocate for these important diabetes issues today. Please join our online advocacy campaign at www.endocrine.org/takeaction to urge your members of Congress to renew the Special Diabetes Program.

You can also contact govt-prof@endocrine.org to learn more about how to get involved with our advocacy activities.

► **Insulin Pricing** — Ensuring access to affordable insulin is another key issue for the Endocrine Society. Since testifying before the Congressional Oversight & Investigations Subcommittee in April, we have been working with manufacturers to better understand how patients can benefit from various assistance programs offered by these companies. We also submitted testimony to the Food and Drug Administration (FDA), which held a hearing to discuss opportunities to increase competition for biosimilars, including insulin. In our testimony, the Society commended the FDA for holding the hearing and underscored our hope that the introduction of new biosimilar insulin products would lower costs for patients. The full testimony can be accessed at endocrine.org/testimony. In addition, the Society responded to a proposal by the Department of Health and Human Services that would eliminate rebates arranged between manufacturers and pharmacy benefit managers (PBMs). While we are supportive of efforts to eliminate rebates that artificially inflate drug prices, we shared concerns about how this change would impact patients and the drug pricing system overall. We are supportive of consumer protections to ensure that this proposal would reduce out-of-pocket costs to the patients and offered a number of questions for the administration to consider when finalizing the proposal.

► **Diabetes Test Strips** — We have also been working to address recent policy changes by the CVS drug store chain that prevents Medicare patients from accessing the diabetes testing supplies needed to manage their diabetes. In January, CVS issued a policy limiting the quantity of diabetes supplies for patients on insulin to no more than three per day. However, many patients, particularly those with type 1 diabetes, must test their blood sugar more than three times per day. The Centers for Medicare and Medicaid Services (CMS) covers additional test strips and lancets if the prescribing physician documents why it is medically necessary. This documentation has been difficult for CVS to access, resulting in extensive audits and leading to the policy change. The Society met with CVS requesting that they rescind this policy, and we plan to work with both the company and CMS to rectify the situation.

House Appropriations Subcommittee Delivers Wins for the Endocrine Society

In May, the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (LHHS) voted to approve an appropriations bill for fiscal year (FY) 2020 that included substantial increases in funding consistent with the Endocrine Society's requests for the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and Title X.

The bill proposes to deliver a \$2 billion increase for the NIH to a total of over \$41.1 billion, including \$500 million for research initiatives supported by the 21st Century Cures program. The CDC would see an increase of \$921 million, including a total of \$168 million to address diabetes and \$30 million for the Diabetes Prevention Program. Included in the increases for the Health Resources and Services Administration, the Title X Family Planning Program would receive \$400 million, or an increase of \$114 million.

These funding increases would address advocacy priorities for Endocrine Society members in the U.S. Additional funding for the NIH will support new endocrine research grants and

advance initiatives to recruit and retain the next generation of endocrine researchers. Additional funds for the CDC will help improve the accuracy and reliability of hormone testing and advance prevention efforts to reduce the prevalence of diabetes; and additional funding to Title X will ensure that reproductive health services are available to more of the over 4 million people who depend on Title X-funded centers.

Additionally, the report accompanying the bill included language the Society recommended to recognize the NICHD-led Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) and encourage implementation of Task Force recommendations with the aim of ensuring that "healthcare professionals and consumers have accurate information on the safety and efficacy of drugs taken by these populations." The Endocrine Society advocated for inclusion of this language in the appropriations report during our Researcher Hill Day this past February.

Attention now turns to the Senate, where the Senate Appropriations Subcommittees are working on their own FY

2020 appropriations bills. However, lawmakers in both chambers acknowledge that a comprehensive budget deal to raise austere caps imposed by the Budget Control Act will be necessary to ensure that any proposed increases for research and public health become a reality. Therefore, there is still much work that needs to be done, and we need your help to put more pressure on members of Congress to raise the budget caps and ensure that appropriators in the Senate achieve funding levels for Endocrine Society priorities that are at least as generous as the House. Visit the Society's Advocacy website at endocrine.org/takeaction to participate in our online advocacy campaign, and take advantage of our new easy-to-use tool to send a letter to your elected representatives today!



On Thursday, May 9, the Endocrine Society hosted a meeting with Diana Bianchi, MD, director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). The meeting was held for the Friends of NICHD, an independent coalition of over 100 organizations that advocate on behalf of the NICHD during the annual congressional appropriations and budget process. Joe Laakso, PhD, who is the director of science policy at the Endocrine Society, is the chair of the Friends of NICHD for 2019.

During the meeting, Bianchi shared an update on the fiscal year 2020 appropriations process and her experience testifying before the House Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee. She also commented on recent scientific advances achieved by NICHD-supported researchers, including results from the Nurses' Health Study II demonstrating that folic acid supplementation could reduce the risk of gestational diabetes.

The group discussed progress by the Institute in developing its new strategic plan. Currently, NICHD is in the process of refining the themes of the plan and incorporating stakeholder feedback. The Institute intends to release the final strategic plan in fall 2019. Bianchi ended with updates on several trans-NIH initiatives that the NICHD is leading or participating in. These include the Task Force on Research on Pregnant and Lactating Women (PRGLAC), a new Trans-NIH Pediatric Research Consortium (N-PeRC), a series of meetings to identify future research directions to address maternal mortality, and the HEAL (Helping to End Addiction Long-term) initiative, which will accelerate scientific solutions to address opioid addiction.

Coalition members appreciated the opportunity to discuss research priorities with Bianchi and gain insights into the Institute's plans for the coming year. For more information on the Friends of NICHD, please visit the coalition website at friendsofnichd.org.



NICHD Director Visits the Endocrine Society



Pictured are Joe Laakso, PhD, the Endocrine Society's director of science policy, and Diana Bianchi, MD, director of the *Eunice Kennedy Shriver* NICHD, at a meeting hosted at the Society's D.C. headquarters.

Endocrine Society Hosts Partnership for the Accurate Testing of Hormones (PATH) and Helps Identify Path Forward for Accurate Hormone Assays



A busy day for the PATH Steering Committee, which met May 3 at the Endocrine Society's Washington, D.C., headquarters to plan strategies for the coming year.

The Partnership for the Accurate Testing of Hormones (PATH) was established in 2010 to address the need for better hormone tests for use in healthcare and research to enable better patient care. PATH currently comprises 20 clinical, research, and public health organizations. It provides technical and scientific support to the Centers for Disease Control and Prevention (CDC) Clinical Standardization Programs and conducts educational activities on hormone measurements for physicians and other healthcare providers.

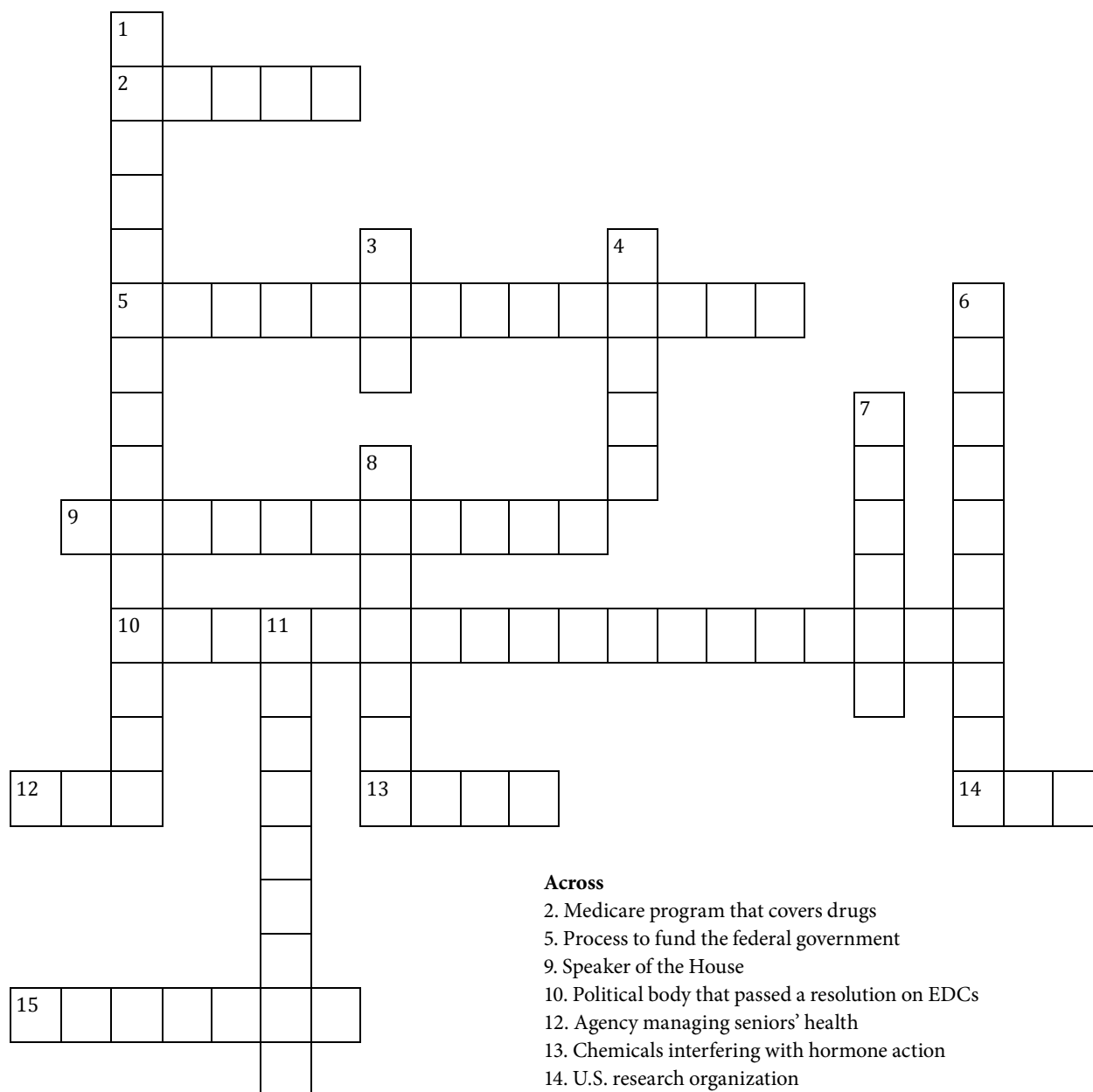
On May 3, the PATH Steering Committee met at the Endocrine Society headquarters for a strategy session. During the meeting, the Steering Committee heard a presentation from Hubert Vesper, PhD, director of the Clinical Standardization Programs at the CDC and co-chair of PATH on the CDC's activities to ensure laboratory measurements are accurate and reliable. During the year, PATH and PATH members have had many accomplishments from launching a new website to conducting

an educational briefing for congressional offices to sharing presentations at several conferences. The Steering Committee is excited to continue its work to seek universal use of standardized hormone tests.

In the coming year, PATH plans to continue advancing its agenda, including participating in an upcoming workshop to develop normal ranges for estradiol in postmenopausal women hosted by the North American Menopause Society (NAMS) in September and an effort led by PATH co-chair Alvin Matsumoto, MD, to develop training materials.

For more information about PATH and how you can participate, please visit the PATH website hormoneassays.org or contact Endocrine Society Chief Policy Officer Mila Becker at mbecker@endocrine.org.

Advocacy in Action: Crossword Edition



Across

- 2. Medicare program that covers drugs
- 5. Process to fund the federal government
- 9. Speaker of the House
- 10. Political body that passed a resolution on EDCs
- 12. Agency managing seniors' health
- 13. Chemicals interfering with hormone action
- 14. U.S. research organization
- 15. Where to buy \$25 insulin

Down

- 1. Program needing reauthorization by September 30
- 3. Medicare payment program
- 4. Diabetes research institution
- 6. ___ and management codes changing in 2020
- 7. Federal family planning program
- 8. Co-chair of Congressional Diabetes Caucus
- 11. Nickname for health reform law ^{EN}

(Answers on page 4.)



PennState Health
Milton S. Hershey Medical Center

ENDOCRINOLOGY CLINICAL INVESTIGATOR/SCIENTIST

The Division of Endocrinology, Diabetes, and Metabolism at **Penn State Health Milton S. Hershey Medical Center**, Penn State College of Medicine (Hershey, PA) is seeking an NIH-funded **Clinical Investigator/Scientist** with a focus on basic/clinical diabetes related research to join an expanding Diabetes program. A highly competitive departmental and institutional start-up package will supplement the candidate's extramural support to strengthen and expand the candidate's ongoing research with the goal of developing novel scholarly initiatives within the division and the institution in the field of diabetes. Joint appointments in Basic Science Departments are anticipated.

The Harrisburg-Hershey area includes the state capitol, a population of 500,000 and offers an excellent combination of low cost of living, excellent schools, cultural activities and attractions that bring millions of visitors each year. We're conveniently located within a short distance to major cities such as Philadelphia, Pittsburgh, NYC, Baltimore, and Washington DC.

Appropriate candidates must possess a MD, MD/PhD or foreign equivalent, NIH funding, the ability to obtain a medical license in the Commonwealth of Pennsylvania.

Qualified applicants should contact:

Andrea Manni, M.D.
Professor and Division Chief of Endocrinology
Diabetes, and Metabolism
c/o **Heather Peffley, PHR, FASPR**
Physician Recruiter
Penn State Health
hpeffley@pennstatehealth.psu.edu

Penn State Health is committed to affirmative action, equal opportunity and the diversity of its workforce. Equal Opportunity Employer – Minorities/Women/Protected Veterans/Disabled.



Endocrinologist

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HealthPartners Medical Group is one of the largest multi-specialty physician practices in the Upper Midwest. Our talented Endocrinology group has an exciting, full-time practice opportunity for a BC/BE Endocrinologist interested in serving a diverse patient population, treating a variety of endocrine disorders, participating in resident/fellow education and monthly educational forums, rounding at our Level 1 trauma center – Regions Hospital in St. Paul, and enjoying access to opportunities via our Research Institute and International Diabetes Center.

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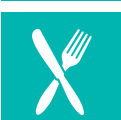
SPECIAL CONSIDERATIONS FOR OLDER ADULTS WITH DIABETES

Diabetes is very common in older adults. The approach to management should be unique to each individual in this age group. Diabetes in adults 65 years and older is associated with higher risks of complications and other harmful side effects than diabetes in younger people.

Older adults often have one or more co-existing conditions like cognitive impairment, cardiovascular disease and others that impact diabetes education and management.

FUNCTIONAL STATUS

A person's ability to perform normal daily activities required to meet basic needs, fulfill usual roles and maintain health and well-being. Functional status is complex and varies for everyone. Aging and diabetes can impair a person's functional status.

	VS	Instrumental Activities of Daily Living (IADLs) are activities related to independent living and for evaluating whether a person with an early-stage disease can care for oneself.	
		Ex: Shopping, cooking, housework, managing finances, driving, or using public transportation.	
			

Activities of Daily Living (ADLs) are every day personal activities that are fundamental to caring for oneself and maintaining independence.

Ex: Bathing, dressing, grooming, walking, and eating.

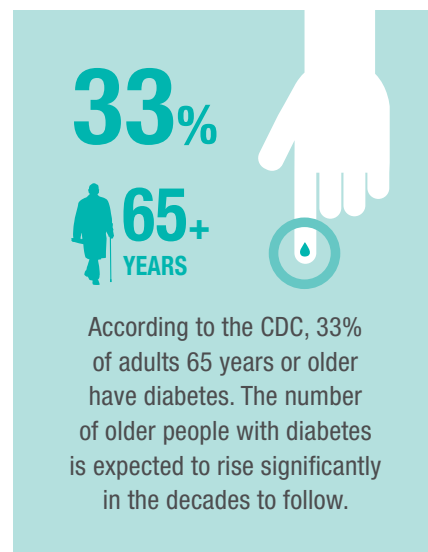
COLLABORATIVE CARE

Collaborative care is very important for all people living with diabetes. However, it is extremely critical for some older adults who have complex health care needs.

Some important care considerations include:

- Supporting “at home” needs
- Monitoring interactions between medications
- Preventing falls
- Family or community support
- Access to proper medications and food

Your primary care doctor, geriatrician, diabetes educator, endocrinologist, nutritionist, and social worker work together to make sure all aspects of care are carefully developed to achieve personal goals and to prevent short and long-term complications.



Visit hormone.org for more information.

Additional editing by Jeffrey B. Halter, MD, *University of Michigan, Ann Arbor*
Leonora Corsino, MD, MHS, FACE, *Duke University*

RECOMMENDED ASSESSMENTS AND SCREENINGS

The treatment of diabetes in adults 65 years and older should be based on the assessment of your overall health and other medical conditions. Glycemic targets should be a shared decision with your healthcare team and tailored to each individual.

General Health Assessments:

- ADLs** Functional Status (ADLs/IADLs)
- Mental Health Screening**
- Screening for Cognitive Impairment and Dementia**
- Frailty & Physical Exam**
- BMI** Body Mass Index (BMI)
- Lifestyle Assessment**
- Medication Review**
- Cancer Screening**
- Hearing Test**

General Health Tests:

- EKG** Electrocardiogram (EKG): used to evaluate the condition of your heart
- Lipid Panel:** measures the amount of cholesterol and fats in the blood
- Bone Mineral Density**
- Abdominal Aortic Aneurysm (AAA) Ultrasound:** an abdominal screening to help check for kidney stones, liver disease, tumors and many other conditions
- A1c** Hemoglobin A1C test, oral glucose tolerance test, and fasting blood glucose test are used to diagnose diabetes or prediabetes. These tests estimate your average blood glucose level over the past 3 months.

Diabetes-Specific Assessments:

- Eye Exam (Retinopathy)**
- Kidney Screening (Nephropathy)**
- Nerve Damage (Neuropathy)**
- Medical Nutrition Therapy**
- Diabetes Self-Management and Training**

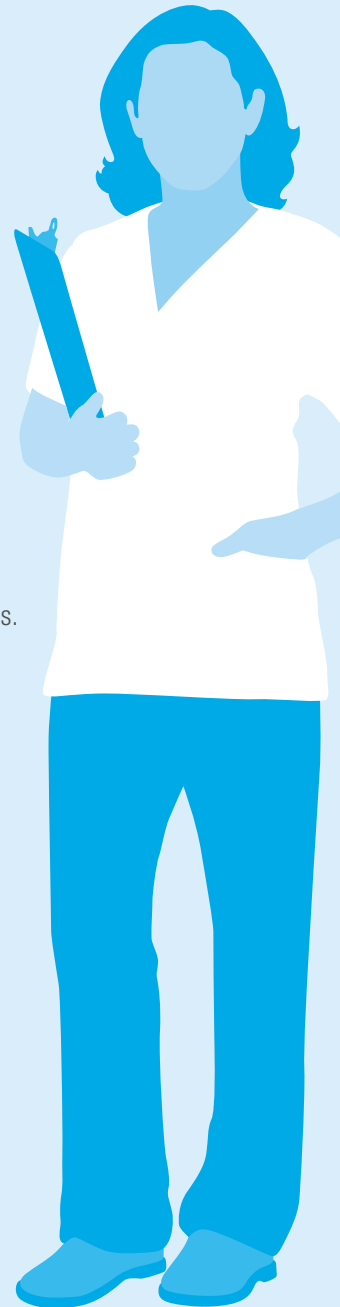
TIPS FOR DIABETES CARE

- Talk honestly with your healthcare team.
- Develop a healthy eating plan.
- Consistently monitor blood glucose levels to ensure you are reaching your recommended target range.
- If you are prescribed new medication or diabetes care management devices, make sure you ask your healthcare provider for the appropriate training.
- Communicate any small muscle (fine motor) issues like in hands or fingers with your healthcare team.
- Find exercises that match your level of activity or exercises that can be worked into your daily routines.

QUESTIONS TO ASK YOUR HEALTHCARE TEAM

Diabetes management goals will not be the same for everyone and may change over time. It is important to talk honestly with your healthcare team to have the best outcomes and prevent complications. Questions to ask your doctor may include:

- What should be my target goal for managing blood glucose and hemoglobin A1c?
- How can I prevent diabetes complications?
- How can I prevent low blood sugar?
- How often should I see an endocrinologist and other specialists?



65
YEARS

The medication regimen should be simplified for many adults 65 years and older to improve adherence and prevent treatment-related complications.

Patients have questions. We have answers.

The Hormone Health Network is your trusted source for endocrine patient education. Our free, online resources are available at hormone.org.

Developed for patients based on *Treatment of Diabetes in Older Adults:*
An Endocrine Society Clinical Practice Guideline



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