

OCTOBER 2024

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

# Endocrine news

## Reproductive ENDOCRINOLOGY

### Endocrine science and its impact on reproduction

- **TEXAS NEXUS:**

**Shumei Meng, MD, PhD**, details how a new syndromic association and a multidisciplinary provider team may have saved a pregnant patient's life

- **NEW PERSPECTIVES ON PCOS:**

Recent *Journal of Clinical Endocrinology & Metabolism* studies add to the evidence base of this "neglected, yet common" condition

- **ORAL ARGUMENTS:**

Getting the word out about oral testosterone replacement therapy

### SHOULDERING RESPONSIBILITY:

Could a male contraceptive gel be a birth control game changer?

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## 14 | Texas Nexus

### A Multidisciplinary Healthcare Team Finds a Lifesaving Link Between Research and Clinical Practice

Shumei Meng, MD, PhD, from the Baylor University Medical Center and the Texas A&M School of Medicine, discusses a remarkable case study from *JCEM Case Reports* detailing how endocrinologists may have discovered a new syndromic association that may have saved a pregnant patient's life.

BY KELLY HORVATH

## 20 | Peak Performance

### Previewing the Endocrine Society's AI in Healthcare Virtual Summit

As Artificial Intelligence (AI) finds its way into all aspects of daily life, soon it could be an important component of scientific research, patient care, and the ins and outs of clinical practice. On November 8 and 9, the Endocrine Society will host the **AI in Healthcare Virtual Summit** that will cover a variety of topics that will inform, educate, and, most importantly, prepare today's practicing endocrinologist for tomorrow.

BY DEREK BAGLEY

## 26 | New Perspectives on PCOS

### As the incidence of polycystic ovary syndrome grows, so does an increased awareness.

Statistics show that nearly 10% of women have polycystic ovary syndrome (PCOS), making it one of the leading causes of infertility, and new research indicates that it seems to be on the rise. Three recent studies from *The Journal of Clinical Endocrinology & Metabolism* add to the evidence base of this "neglected, yet common" condition.

BY ERIC SEABORG

## 32 | Oral Arguments

### Getting the Word Out About Oral Testosterone Replacement Therapy

Injectable and gel versions of testosterone replacement therapy have long been considered cumbersome by both patients and providers, for a litany of reasons from being difficult to administer to an overwhelming insurance burden. However, research from **ENDO 2024** revealed that a new oral therapy could potentially eliminate these barriers and be a safer option.

BY KELLY HORVATH

## 36 | Shouldering Responsibility

### Could a male contraceptive gel be a birth control game changer?

When a presentation at **ENDO 2024** highlighted a male contraceptive gel that suppresses sperm production faster than other hormone-focused methods of male birth control, the Boston Convention Center was abuzz. Containing segesterone acetate and testosterone and applied to both shoulders, this groundbreaking new birth control could prove revolutionary.

BY DEREK BAGLEY

## 2 | PRESIDENT'S VIEWPOINT

Don't Forget to Renew Your Society Membership.

## 4 | FROM THE EDITOR

A Closer Look at Reproductive Endocrinology

## 6 | IN TOUCH

Members in the News: Antonio Bianco, MD, PhD, takes on a new role. Endocrine Society members Received 2024 Lasker~DeBakey Clinical Medical Research Award

## 10 | TRENDS & INSIGHTS

Review examines cardiometabolic aspects of CAH; and girls may start puberty early due to chemical exposure

BY DEREK BAGLEY

## 12 | ENDOCRINE ITINERARY

Scientific meetings of interest to endocrinologists from around the world

## 42 | ADVOCACY

Endocrine Society endorses Right to IVF Act; Society joins the 12th Annual Rally for Medical Research Hill Day, advocates for NIH funding; Endocrine Society advocates on Capitol Hill for SDP, extension of Medicare telehealth waivers, and increased physician payment; and Endocrine Society co-leads NIEHS Hill Day

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## Don't Forget to Renew Your Society Membership

I've been a proud member of the Endocrine Society for more than two decades. Each year as October comes around, I renew my membership, and I really encourage you to do so too.

If you haven't already done so, now is the perfect time to renew for 2025. Maintaining your membership allows you to continue tapping into the wealth of benefits our Society provides. Some of the big ones can be seen in the recent, and upcoming, flurry of educational activities.

### Discounts on Meetings and Conferences

Membership allows you to save big on meetings!

Take, for example, registration to **ENDO 2025**, from July 12 to 15 in San Francisco, Calif. Your yearly membership dues more than offset the price of attending this seminal meeting as a nonmember.

After the annual **ENDO** conference, our next two largest meetings are Endocrinology Board Review (EBR) and Clinical Endocrinology Update (CEU). EBR has helped thousands of rising endocrinologists to pass their board exams over the years, while CEU provides updates to working clinicians on how to treat endocrine conditions using the latest expert guidelines in hormone care.

Both EBR and CEU — which took place in September — provided members with registration discounts of up to several hundred dollars off the nonmember attendance price. Renewing for 2025 allows you to capture the savings on these meetings next year.

Members also can save hundreds of dollars on two upcoming meetings: the 1st International Conference on Steroid Hormones and Receptors (SHR 2024), October 16 – 18 in Albuquerque, N.M. ([www.endocrine.org/SHR2024](http://www.endocrine.org/SHR2024)), and

the Artificial Intelligence (AI) in Healthcare Virtual Summit, November 8 – 9 ([www.endocrine.org/ai-summit](http://www.endocrine.org/ai-summit)), detailed in “Peak Performance,” on page 20.

### Member-Only Events

But the advantages of renewing your membership go far beyond simply cost savings. Membership unlocks multiple member-only benefits that can enhance your career and professional network.

One of my favorites is the Society's Special Interest Groups (SIGs), ([www.endocrine.org/SIGs](http://www.endocrine.org/SIGs)), which allow you to engage with members who share your endocrine interests.

Much of the SIG engagement takes place on EndoForum, an online platform where you can share clinical and scientific cases and research, coordinate study groups, and simply connect with peers and experts, among other things.

Currently, the Society offers eight SIGs covering a wide range of clinical and research interests:

- ▶ Adrenal and Pituitary SIG;
- ▶ Bone & Mineral SIG;
- ▶ Early Career SIG;
- ▶ Endocrine-Disrupting Chemicals SIG;
- ▶ Endocrine Cancers SIG;
- ▶ Entrepreneurship SIG;
- ▶ Oncoendocrinology SIG; and
- ▶ Transgender Research and Medicine SIG.

The Society is preparing to launch SIGs in new topic areas by the end of 2024, with more to follow.

## Celebrating Excellence

Remaining a Society member also is the best way to stand out in our field. Nowhere is this more evident than in our prestigious Laureate Awards. The Society recently announced 14 leading endocrinologists as winners of the 2025 Laureate class. ([www.endocrine.org/awards/laureate-awards/2025-laureate-recipient](http://www.endocrine.org/awards/laureate-awards/2025-laureate-recipient))

The highest honor — the Fred Conrad Koch Lifetime Achievement Award — was awarded this year to Daniel Drucker, MD, who has made significant contributions to the field of glucagon-like peptide (GLP) biology, leading to the development of GLP-agonists for the treatment of diabetes mellitus, obesity, and short bowel syndrome.

Dr. Drucker and the other 2025 Laureate winners will be recognized at **ENDO 2025**. We look forward to celebrating their achievements with our community.

## Refer a Friend and Sign Up for Auto-Renewal

Like many things in life, renewing your membership is more fun when others join you. The Society's Refer a Friend program ([www.endocrine.org/membership/renew-your-membership/refer-a-friend](http://www.endocrine.org/membership/renew-your-membership/refer-a-friend)) allows you to receive a 10% discount on your renewal if two to three friends join, and up to 30% if eight or more join. And if keeping track of renewal deadlines is too much effort in our busy lives — which I totally understand — the Society has an excellent option. Members can enroll in the Society's auto-renewal program. (<https://ams.endocrine.org/eweb/DynamicPage.aspx?WebCode=MyMemberships>)

## Contributing as a Member — A Personal Journey

While I have been a member for more than 20 years, my affiliation with the Society goes back further. I remember attending my first ENDO in 1995 as a junior fellow and giving my first oral presentation. I was nervous but quickly put at ease

by the support and interest that I received from the Society's renowned senior members.

I knew right then that this would be my professional home. As a member, I've been fortunate to have been able to be involved in some of the many opportunities the Society has offered to help further our field and the organization itself including serving

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**While contributing to the Society, I too have benefited greatly. The experience of working with amazingly talented colleagues and staff has been so rewarding, and back at my own institution this has made me a far better endocrinologist, researcher, teacher, and administrator.**

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on writing groups to develop clinical practice guidelines, on JCEM's editorial board, on governance taskforces, as chair of ENDO's annual meeting steering committee, on the Board of Directors, and now as your president.

While contributing to the Society, I too have benefited greatly. The experience of working with amazingly talented colleagues and staff has been so rewarding, and back at my own institution this has made me a far better endocrinologist, researcher, teacher, and administrator.

I plan to stay a member for years and years to come. I hope you will join me!

If you have membership questions, please feel free to reach out to the Society's friendly staff at [info@endocrine.org](mailto:info@endocrine.org) or +1 (202) 971-3646 Monday – Friday, 8:30 a.m. – 5:00 p.m. EST. 

*John Newell-Price, MD, PhD, FRCP  
President, Endocrine Society*



FROM THE **EDITOR**

OCTOBER 2024

# Endocrine news

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

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*Endocrine News* informs and engages the global endocrine community by delivering timely, accurate, and trusted content covering the practice, research, and profession of endocrinology.

## A Closer Look at Reproductive Endocrinology

**T**his month's focus is in an area that has actually been in the mainstream media quite a bit in the past few years: reproduction. However, we are putting an endocrinology-focused spin on it with several stories about the impact endocrine science has made on human reproduction.

For our cover story, "**Texas Nexus: A Multidisciplinary Healthcare Team Finds a Lifesaving Link Between Research and Clinical Practice**" on page 14, Kelly Horvath talked to Shumei Meng, MD, PhD, from the Baylor University Medical Center and the Texas A&M School of Medicine, who discusses a remarkable case study published in *JCEM Case Reports*. The case detailed how endocrinologists, working with several other specialists on a variety of teams, may have discovered a new syndromic association that may have saved a pregnant patient's life. However, Meng credits the Endocrine Society for playing a large role in helping practitioners more easily connect research to patient care. "For any scientist or physician, I don't think at any moment we feel like we know enough," Meng says. "But the point of scientific curiosity and research is bringing that knowledge to patient care. It's making an impact on patients' lives. That's exactly what the [Endocrine] Society has done. You have to link the research to the clinical practice to make that impact."

In "**Shouldering Responsibility**" on page 36, Senior Editor Derek Bagley looks at research presented at **ENDO 2024** that could be a game changer in the world of contraception. While there have been several false starts through the years about the latest male birth control, this one does indeed show promise. This contraceptive gel applied to the man's shoulders — hence the article's title — has been shown to suppress sperm production faster than other hormone-focused methods of male birth control. The gel contains both segesterone acetate and testosterone and could finally be the solution many couples have been seeking.

Another article also focuses on male reproductive health, at least as it pertains to testosterone replacement therapy (TRT). In "**Oral Arguments**" on page 32, Kelly discusses an **ENDO 2024** presentation that looks at the viability of an oral version of TRT that could possibly replace injectable and gel versions, often considered less than optimal by both patients and providers. Adrian Dobs, MD, professor of medicine and oncology at Johns Hopkins School of Medicine in Baltimore, Md., presented the results of a survey that polled more than 300 physicians, seeking their perspectives on



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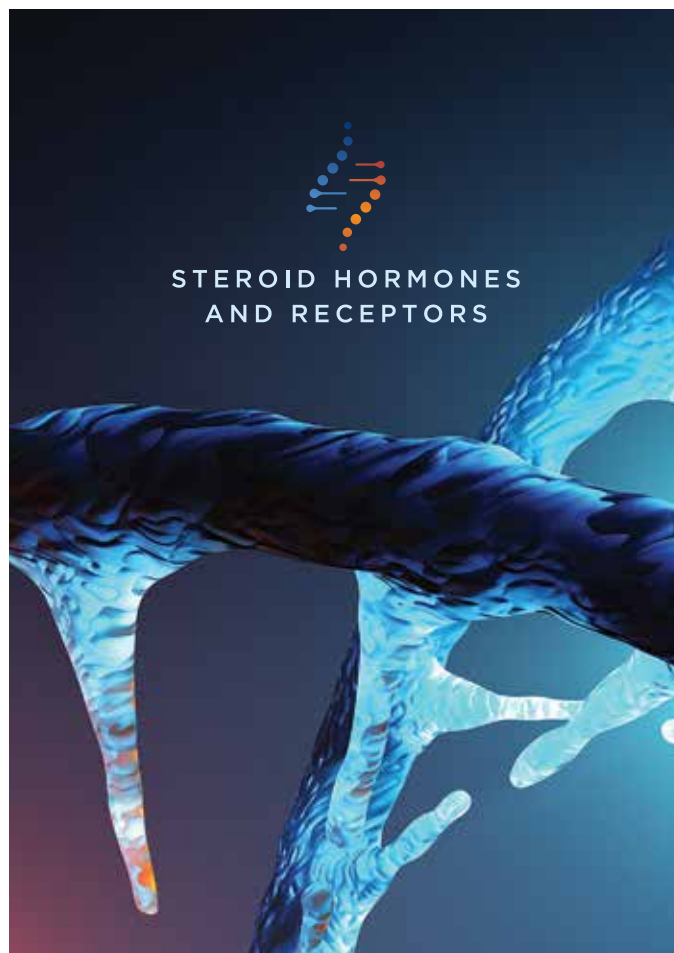
barriers to effective TRT treatment, among other points of interest including prescribing preferences and unmet patient needs. “As physicians, sometimes we’re really quite blinded to the fact that there are obstacles to patients,” Dobs explains. “In reality, there are several problems that cause them to switch to other testosterone products. Sometimes it’s insurance, sometimes it’s tolerance — injectables are painful; gels are messy. That was an important finding.”

Eric Seaborg looks at some recent studies from *The Journal of Clinical Endocrinology & Metabolism* that have recently added to the evidence base of polycystic ovary syndrome (PCOS) in “**New Perspectives on PCOS**” on page 26. With nearly one in 10 women dealing with PCOS, it has become one of the leading causes of infertility among women of child-bearing age, and research seems to indicate that PCOS diagnoses are on the rise. While the reasons for this increased incidence are up for debate, according to Richard S. Legro, MD, and who chaired an Endocrine Society committee that published a PCOS guideline in 2013, added that a “broader diagnostic criteria probably increased the incidence, and there has also been greater public and medical awareness of the disorder. Nonetheless, as the authors note, the disorder is still likely underdiagnosed in the population.”

We’re also giving you a preview of an exciting new meeting that the Endocrine Society is sponsoring in early November that delves into the phenomenon of artificial intelligence or, as it’s more commonly referred to: AI. In “**Peak Performance**” on page 20, Derek gives us a preview of the Society’s “AI in Healthcare Virtual Summit” taking place on Nov. 8 and 9, which promises to be quite an eye-opening experience for anyone either curious about how AI could impact his or her practice, as well as hopefully assuage the fears of those concerned about any negative components of this new technology in the healthcare field. Like it or not, AI is here to stay so it behooves us all to have a better understanding of what could be in store for the future. If I were you, I would go ahead and register for this virtual summit, if you haven’t already: <https://www.endocrine.org/meetings-and-events/ai-summit/ai-summit-registration>.

Be sure to let me know what you think of this month’s focus on reproductive endocrinology, or if you have any suggestions for future stories or other ideas. As always, you can contact me at: [mnewman@endocrine.org](mailto:mnewman@endocrine.org). 

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



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Antonio Bianco, MD, PhD

## Bianco Named Vice President and Vice Provost for Research, Chief Research Officer

**A**ntonio Bianco, MD, PhD, has joined the University of Texas Medical Branch (UTMB) as vice president and vice provost, research, and chief research officer, effective Sept. 1.

A renowned physician-scientist, scholar, and research leader, Bianco possesses an impressive academic career that includes influential contributions to the field of thyroid diseases and an enduring commitment to education and mentorship.

Bianco says that it is a privilege to lead the research enterprise at UTMB, home to the Galveston National Laboratory, which is one of the largest high-containment laboratories in the U.S. “This lab plays a critical role in national biodefense, focusing on dangerous pathogens such as SARS, anthrax, and smallpox,” he tells *Endocrine News*. “UTMB’s scientists and physician-scientists maintain an ambitious portfolio that spans microbiology, infectious diseases, and vaccine development. In addition, UTMB hosts one of the few residency programs in aerospace medicine and leads the field in human microbiome and aging research.”

Bianco earned his MD at the Santa Casa Medical School and PhD in human physiology at the University of São Paulo, both in São Paulo, Brazil. In 1998, he was recruited to Brigham and Women’s Hospital in Boston, where for 10 years he studied the cell and structure biology of deiodinases. After he served as chief of the Thyroid Section, he moved to Miami to lead the Division of Endocrinology at the University of Miami. In 2014, he was appointed the Charles A. Weaver Professor of Cancer Research, senior vice president, and vice dean of clinical affairs, and president of the Rush University Medical Group in Chicago. Since 2018, he has served as professor in the Department of Medicine, Section of Adult and Pediatric Endocrinology, and director of the Thyroid Study Unit at the University of Chicago.

“In today’s increasingly complex research landscape, managing budgets that total hundreds of millions of dollars while ensuring efficiency and user-friendliness is crucial,” Bianco says. “As a physician-scientist and administrator, I’ve worked on both sides of this equation for years, and I believe I am well-positioned to support the brilliant scientists at UTMB in advancing their groundbreaking work.”

Bianco has published extensively in the area of thyroid hormone metabolism and action. His findings have significant clinical implications and have shaped the treatment of patients with hypothyroidism. His research career has focused on how T3 (triiodothyronine) initiates or terminates critical biological steps while maintaining relatively stable plasma levels. Most recently, his laboratory has focused on the epigenetic mechanisms of T3 action and their implication for children with congenital hypothyroidism.

His involvement with the Endocrine Society includes serving on the AECD Discussion Group (2014 – 2015), a member of the Research Affairs Core Committee (2016 – 2019), and the Annual Meeting Steering Committee (2019 – 2022), as well as serving on the editorial board of the *Journal of the Endocrine Society* (2016 – 2019).

“I have dedicated my career to studying the thyroid gland. My most recent research focuses on clinical trials and the analysis of large patient datasets and clinical outcomes,” Bianco says. “I have also placed a strong emphasis on bioinformatics, epigenetics, and the impact of 3D chromatin modifications by thyroid hormones. My goal is to streamline access to these advanced tools at UTMB, ensuring that our scientists and physician-scientists remain at the forefront of health sciences research.”

Bianco will also serve as faculty in the Department of Internal Medicine, Division of Endocrinology, holding the Nelda C. and H. J. Lutcher Stark Distinguished Chair in Internal Medicine.





Joel F. Habener, MA, MD



Lotte Bjerre Knudsen, DMSc



Svetlana Mojsov, PhD

## Endocrine Society Members Receive 2024 Lasker~DeBakey Clinical Medical Research Award

**T**hree Endocrine Society members have taken home the 2024 Lasker~DeBakey Clinical Medical Research Award. Joel F. Habener, MA, MD, chief of Laboratory of Molecular Endocrinology, Massachusetts General Hospital; Lotte Bjerre Knudsen, DMSc, chief scientific advisor and head of the GLP-1 Centre of Excellence at Novo Nordisk; and Svetlana Mojsov, PhD, research associate professor at Rockefeller University in New York, were honored for their roles in the discovery and development of GLP-1-based drugs that have revolutionized the treatment of obesity.

In the 1970s, Habener became interested in how the hormone glucagon fits into the puzzle of how the body regulates blood sugar levels. When Habener cloned the gene for glucagon, he discovered that it encodes not only glucagon itself, but also another molecule that resembles glucagon-like-peptide-1.

“These are diseases with a high morbidity and mortality and are attracting greater research efforts to understand the pathophysiology and to develop effective therapies to combat them,” Habener told *Endocrine News* in a 2020 interview when he won the Warren Alpert Foundation Prize alongside Daniel J. Drucker, MD. “Obesity and its ensuing constellation of ensuing disorders known as the metabolic syndrome include diabetes, steatohepatitis,

hypertension, and even dementia and certain types of cancer.”

Mojsov identified and synthesized the physiologically active form of GLP-1 and developed innovative research methods and reagents that detected GLP-1 in the intestines. Collaborating with other scientists, she drew unambiguous conclusions about essential aspects of GLP-1 biology.

“It is a tremendous honor to receive the Lasker~DeBakey Clinical Medical Research Award, which recognizes my discovery in the 1980s that GLP-1(7-37) is an incretin with therapeutic potential to treat type 2 diabetes and obesity,” Mojsov says.

Mojsov says that when she was in the Endocrine Unit at Massachusetts General Hospital, she used synthetic chemistry — solid phase peptide synthesis — to obtain large quantities of synthetic GLP-1(7-37) and used it in all studies. First, she developed sensitive and specific radioimmunoassay for GLP-1 and chromatographic methods that allowed her to detect GLP-1(7-37) in rat intestines, a tissue where incretin is secreted.

“I then began a very productive collaboration with Dr. Gordon Weir from the Joslin Diabetes Center in Boston to show that GLP-1(7-37) stimulates insulin release from the perfused rat pancreas at very low picomolar concentration, the same

one that is found in blood,” Mojsov says. “My studies at the Endocrine Unit and collaborative studies with Gordon Weir proved that GLP-1(7-37) is the long sought after incretin.”

Mojsov goes on to say that in contrast, experiments in cell lines were inconclusive. For example, she says, GLP-1(7-37) stimulated insulin release from the RIN 1046-38 cells only at very high micromolar concentration. “This is five orders of magnitude higher concentration than the ones in

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**I’m very happy for GLP-1 to get this incredible recognition, and for me personally I am extremely grateful that the science we do in the pharmaceutical industry, and that I have focused on for 30 years, is recognized in this regard.**

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— LOTTE BJERRE KNUDSEN, DMSC, CHIEF SCIENTIFIC ADVISOR AND HEAD OF THE GLP-1 CENTRE OF EXCELLENCE AT NOVO NORDISK

Weir’s experiments. It is not physiological concentration. At very high micromolar concentration, glucagon and other peptides in the glucagon family of peptides also stimulate insulin secretion. The biological effect of GLP-1(7-37) was not specific,” she says. “Collaborative clinical studies with David Nathan at the Massachusetts General Hospital showed that GLP-1(7-37) stimulates insulin release in healthy individuals and patients with type 2 diabetes and established its therapeutic potential.”


Beginning in the 1990s, Knudsen and her team transformed these breakthroughs into treatments to fight diabetes (Ozempic) and obesity (Wegovy), advancing the duration of the drug’s therapeutic effects from a few hours to more than a week.

“I’m very happy for GLP-1 to get this incredible recognition, and for me personally I am extremely grateful that the science we do in the pharmaceutical industry, and that I have focused on for 30 years, is recognized in this regard,” Knudsen says.

Knudsen was responsible for inventing the first long-acting GLP-1RA. “I suggested as early as 1996 that it should be prioritized for obesity, based on initial promising animal data, as well as the increasing prevalence of obesity,” she says. “I have continued to lead in obesity with early publications documenting effects on a broad range of neurons involved with both homeostatic and hedonic aspect of energy homeostasis.”

Both Mojsov and Knudsen point to the potential of GLP-1-based drugs beyond obesity and diabetes. “We found that identical GLP-1 receptors exist in the human pancreas, the brain, and the heart, suggesting that the same drug could be used to treat multiple disorders of human health: in the pancreas, in the brain, and in the heart,” Mojsov says.

“Other than diabetes and obesity, we are witnessing right now unfolding of the GLP-1RA potential in cardiovascular and kidney disease,” Knudsen says. “It will be important for the field of endocrinology to understand how these medicines work in different diseases, and for that to happen it is important to understand that GLP-1RAs have many separate effects that can impact outcomes in different combinations.”

*TIME Magazine* recognized Habener and Mojsov in its 100 Most Influential People of 2024 earlier this year for their involvement in the development of GLP-1 anti-obesity medications. Through their discoveries and dedicated efforts, Habener, Mojsov, and Knudsen have introduced a new era of weight management, dramatically improving the well-being and health prospects for hundreds of millions. Their work has opened up a burgeoning field of studies about the numerous health benefits seen during GLP-1 therapy, including those related to cardiovascular disease, chronic kidney disorders, fatty liver disease, Alzheimer’s and Parkinson’s diseases, and addiction. 

– Derek Bagley

# AI IN HEALTHCARE VIRTUAL SUMMIT

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**BY DEREK BAGLEY**  
Senior Editor

## TRENDS & INSIGHTS

# Review Examines Cardiometabolic Aspects of Congenital Adrenal Hyperplasia



**A** paper recently published in *Endocrine Reviews* takes a look at the cardiometabolic risk in patients with congenital adrenal hyperplasia (CAH), since patients with CAH who are being treated still face numerous complications and increased mortality.

The authors of the review (Krysiak, et al.) write that the aim of their article is to create an authoritative and balanced review concerning the cardiometabolic risk in patients with CAH. For this paper, the authors searched all major databases and reviewed and scanned reference lists of all potentially eligible articles to find eligible articles published between January 1966 and October 2023 and compared the cardiometabolic risk in CAH to other forms of adrenal insufficiency.

“The reviewed articles, most of which were published recently, provided conflicting results, which can be partially explained by differences in the inclusion criteria and treatment, small sample sizes and gene-environmental interactions,” the authors write. “However, many studies showed that the presence of CAH is associated with an increased risk of weight gain, worsening of insulin sensitivity, high blood pressure, endothelial dysfunction, early atherosclerotic changes in the vascular wall, and left ventricular diastolic dysfunction.”

The authors make the distinction between classic CAH (C-CAH) and non-classic CAH (NC-CAH) and point out that the complications listed above were more consistently reported in patients with C-CAH. The authors start by concluding that analysis of the reviewed articles does show an association between CAH and cardiometabolic complications.

The authors go on to write that CAH is associated with an increased risk of developing overweight

and obesity. Patients with CAH also have reduced insulin sensitivity, which, according to the authors, can only partially be explained by increased body weight. “They are also determined by the degree of 21OH deficiency, are partially related to imperfections of the glucocorticoid replacement and may improve after treatment with insulin-sensitizing drugs,” the authors write. “Some subjects with CAH may, however, develop morning, nocturnal, and maybe also exercise-induced hypoglycemia, with potential negative cardiovascular consequence.”

The review covers a lot, from the complex relationship between CAH and blood pressure, inconsistent results in prior studies related to adipose tissue hormones, CAH’s effect on the heart itself, advances in treatment, and more. The authors conclude the paper by stating that the increased cardiovascular risk in patients with CAH is likely multifactorial: glucocorticoid overtreatment, imperfect adrenal hormone replacement therapy, androgen excess, and adrenomedullary failure.

The authors end by calling for future studies in middle-age and older adults with CAH (since the risk of cardiovascular complications increases with age), studies related to the cardiometabolic aspects of NC-CAH, and for partially updating the current recommendations of the Endocrine Society, especially as they relate to counseling.

“In our opinion, routine counseling concerning lifestyle choices should be part of the follow-up of each patient with CAH,” the authors write. “All necessary questions should be discussed with the parents, and with the affected child when able to comply. Moreover, we advise that all individuals with C-CAH require metabolic and cardiovascular follow-up.”

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**In our opinion, routine counseling concerning lifestyle choices should be part of the follow-up of each patient with CAH. All necessary questions should be discussed with the parents, and with the affected child when able to comply. Moreover, we advise that all individuals with C-CAH require metabolic and cardiovascular follow-up.**  
”

# Girls May Start Puberty Early Due to Chemical Exposure

**G**irls exposed to certain endocrine-disrupting chemicals (EDCs) may be more likely to start puberty early, according to new research published in *Endocrinology*.

Researchers led by Menghang Xia, PhD, from the National Center for Advancing Translational Sciences (NCATS) in Bethesda, Md., point out that there has been an alarming trend toward early puberty in girls, suggesting the influence of chemicals in our environment. “Over the past decade, a worldwide secular trend of earlier breast development, or thelarche, in girls has emerged,” the authors write. “This trend has important health implications, as earlier puberty is associated with an increased risk of psychosocial problems, obesity, diabetes, cardiovascular disease, and breast cancer. While the timing of puberty is determined both by genetics and the environment, the rapid pace of the current trend precludes a genetic etiology and instead, points to environmental factors.”

The authors go on to write that while several studies have attempted to identify potential environmental triggers, these studies suffer from a number of limitations, including the use of blood or urine samples, which only reflect recent exposures, and they do not reflect exposure in the hypothalamus. “To overcome the limitations inherent to observational studies in pediatric research participants, we used a quantitative high-throughput screening (qHTS) approach to identify environmental compounds that may activate the neuroreproductive axis,” the authors write.

“We conducted a comprehensive screen of 10,000 environmental compounds with extensive follow-up studies using human brain cells that control the reproductive axis, and our team identified several substances that may contribute to early puberty in girls,” says study author Natalie Shaw, MD, MMSc, of the National Institutes of Health’s (NIH) National Institute of Environmental Health Sciences (NIEHS) in Durham, N.C.

Those substances include musk ambrette, which is a fragrance used in some detergents, perfumes, and personal care products, and a group of medications called cholinergic agonists.

“More research is needed to confirm our findings,” says Shaw. “But the ability of these compounds to stimulate key receptors in the hypothalamus — the gonadotropin-releasing hormone receptor [GnRHR] and the kisspeptin receptor [KISS1R] — raises the possibility that exposure may prematurely activate the reproductive axis in children.”

According to the research team, musk ambrette is potentially concerning because it can be found in personal care products, and some rat studies have suggested it can cross the blood-brain barrier. Children are less likely to encounter cholinergic agonists in their daily lives.

As part of the study, the research team screened a Tox21 10,000-compound library of licensed pharmaceuticals, environmental chemicals, and dietary supplements against a human cell line overexpressing GnRHR or KISS1R. They conducted follow-up analysis using human hypothalamic neurons and zebrafish, finding that musk ambrette increased the number of GnRH neurons and GnRH expression.

“In conclusion, by using the Tox21 10K library and a qHTS method followed by confirmatory and secondary testing in relevant cell types (i.e., mHypoA-GnRH/GFP, L $\beta$ T2, and iPSC-derived hypothalamic neurons) and a zebrafish reporter line of GnRH neuronal development, we discovered novel GnRHR and KISS1R agonists that may, in part, contribute to the secular trend of early puberty in girls,” the authors write. “Future epidemiological investigations of pubertal timing should pay particular attention to synthetic nitro-musks and to cholinergic agonists, as well as to other chemicals with similar structures.” <sup>EN</sup>



“

**Earlier puberty is associated with an increased risk of psychosocial problems, obesity, diabetes, cardiovascular disease, and breast cancer. While the timing of puberty is determined both by genetics and the environment, the rapid pace of the current trend precludes a genetic etiology and instead, points to environmental factors.**

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## FROM THE ENDOCRINE SOCIETY

## 1st International Conference on Steroid Hormones and Receptors (SHR 2024)

Albuquerque, New Mexico

October 15 – 18, 2024

SHR 2024 will be held at the University of New Mexico Comprehensive Cancer Center and will be chaired by Eric Prossnitz (University of New Mexico) and Endocrine Society President-Elect Carol Lange (University of Minnesota). SHR 2024 is an international biomedical conference that builds on a 25-year legacy of highly successful conferences: the Steroid Hormones and Receptors in Health and Disease Conference hosted by FASEB Science Research Conferences (SRC) and the Rapid Responses to Steroid Hormones (RRSH) International Meetings hosted by the International RRSB Committee. A joint FASEB-RRSH conference held in 2021 recognized the evolution of the field in which



### STEROID HORMONES AND RECEPTORS

physiological and cellular effects of steroid hormones are frequently the result of the combined effects of rapid and genomic signaling. These advances in steroid hormone and receptor biology highlighted the need for a new series of international meetings. The SHR conferences will explore state-of-the-art advances in steroid hormone and receptor functions, both rapid and genomic, in various aspects of biology and medicine in terms of normal physiology and pathophysiology.

<https://www.endocrine.org/meetings-and-events/shr-2024>

## Artificial Intelligence in Healthcare

Virtual Meeting

November 8 – 9, 2024

The Endocrine Society's AI in Healthcare Virtual Summit is an innovative two-day virtual event designed to inform providers, healthcare professionals, researchers, technologists, industry stakeholders, and educators on the capabilities of artificial intelligence in the healthcare



field. This summit offers a unique opportunity to delve into the transformative potential of AI in revolutionizing patient care and shaping the future of medicine. Attendees will discover how AI technologies are redefining diagnostics, treatment planning, and patient outcomes in healthcare in addition to exploring the latest advancements in AI-driven healthcare, from predictive analytics to machine-learning algorithms. The summit will be held in conjunction with Matchbox Virtual, which provides an innovative user experience that mimics attendance at a physical conference site. Major content areas include Diagnosis and Prediction, Drug Discovery and Development, and Natural Language Processing (NLP).

<https://www.endocrine.org/meetings-and-events/ai-summit>

## Neuroscience 2024

Chicago, Illinois

October 5 – 9, 2024

Each year, scientists from around the world congregate to discover new ideas, share their research, and experience the best the field has to offer. Attend so you can present research, network with scientists, attend sessions and events, and browse the exhibit hall. Join the nearly half a million neuroscientists from around the world who have propelled their careers by presenting an abstract at an SfN annual meeting – the premier global neuroscience event.

<https://www.sfn.org/meetings/neuroscience-2024>

## National Conference on Women's Health and Sex Differences Research

Colorado Springs, Colorado

October 23 – 25, 2024

The three-day meeting offers unparalleled opportunities for senior investigators and early-career scientists alike to learn about current research, make strategic connections, and contribute to discovery and innovation in women's health and sex differences research. In addition to the scientific sessions, the conference also features a special community session where expert scientists translate their research to the public, helping our community learn about the real-world implications of issues affecting women's health.

<https://web.cvent.com/event/13b086e5-d335-4e87-880b-c0e63dead627/summary>

## American Thyroid Association 2024 Annual Meeting

Chicago, Illinois

October 30 – November 4, 2024

The ATA Annual Meeting is the world's preeminent event for those interested in thyroid diseases and disorders and provides an opportunity for peer-to-peer learning and collaboration through lectures, interactive discussions, meet-the-professor sessions, and abstracts. This year, the ATA will celebrate its centennial anniversary with a culmination of the celebration and the

largest gathering of thyroidologists in the world. Whether you're an endocrinologist, a surgeon, an advanced practice provider, a fellow in training, or a medical student, the topics covered during the meeting will provide in-depth information about thyroid diseases and disorders. With a diverse program planned, attendees can customize their experience by attending sessions that are most important to their professional development.

<https://www.thyroid.org/>

## ObesityWeek 2024

San Antonio, Texas

November 3 – 6, 2024

The preeminent international conference for obesity researchers and clinicians, ObesityWeek® is home to the latest developments in evidence-based obesity science: cutting-edge basic and clinical research, state-of-the-art obesity treatment and prevention, and the latest efforts in advocacy and public policy. Overcoming obesity requires multidisciplinary approaches. This is the conference that encompasses the full spectrum of obesity science: from basic science research to translational research and clinical application, to public policy; from diet, exercise, lifestyle, and psychology to medical and surgical interventions; from pediatric to geriatric to underserved populations.

<https://obesityweek.org/>

## 26th Davidson Mestman Intensive Course

Miami, Florida

December 11 – 14, 2024

Presented entirely in Spanish, the main objective of this intensive course is to provide physicians with specialized and advanced training in the diagnosis, treatment, and comprehensive management of patients with endocrine disorders, diabetes, and associated cardiovascular diseases, obesity, and endocrine cancers. The program will focus on updating and honing participants' clinical skills, enabling them to deliver cutting-edge, personalized medical care in these specialized areas.

<https://www.cursodavidsonmestman.com/>

## INTERNATIONAL ITINERARY



### EndoBridge 2024

Antalya, Turkey

October 18 – 20, 2024

EndoBridge will be held in English with simultaneous translation into Russian, Arabic, and Turkish. This three-day scientific program includes state-of-the-art lectures delivered by world-renowned faculty and interactive sessions covering all aspects of endocrinology. EndoBridge® provides a great opportunity for physicians and scientists from around the world to interact with each other, share their experience and perspectives, and participate in discussions with global leaders of endocrinology.

[www.endobridge.org](http://www.endobridge.org)

### What's New in Diabetes and Endocrinology?

London, U.K.

November 4, 2024

Join us in-person to hear experts in their fields examine the latest updates in endocrinology and diabetes in 2024. Speakers will highlight what has been recently shown to influence practice and how this can change management, with frequent panel discussions throughout the event enabling tricky issues and practical points to be explored. Additionally, participants will learn from specialists about new publications, examine data from clinical trials and basic science and their effect on current management, and gain an update on treatment strategies. This meeting is an association with the Society for Endocrinology (SfE) and the Association of British Clinical Diabetologists (ABCD).

<https://www.rsm.ac.uk/events/endocrinology-and-diabetes/2024-25/edt01/>



# TEXAS

# *Nexus*

A Multidisciplinary Healthcare Team Finds a Lifesaving Link  
Between Research and Clinical Practice





**BY KELLY HORVATH**

**S**ometimes in medicine, everything aligns, and patients with unusual presentations who might otherwise experience negative outcomes beat the odds. That serendipity starts with the medical team and their use of expert clinical reasoning. In “An Unusual Case of Pheochromocytoma Associated with von Hippel-Lindau

Disease and Lynch Syndrome During Pregnancy,” published in June in *JCEM Case Reports*, Shumei Meng, MD, PhD, clinical associate professor at the Texas A&M School of Medicine, in Bryan, Texas, and the chief of endocrinology at the Baylor University Medical Center in Dallas, shares just such a story.



“

For any scientist or physician, I don't think at any moment we feel like we know enough. But the point of scientific curiosity and research is bringing that knowledge to patient care. It's making an impact on patients' lives. That's exactly what the Society has done. You have to link the research to the clinical practice to make that impact.

”

— SHUMEI MENG, MD, PHD, CLINICAL ASSOCIATE PROFESSOR, TEXAS A&M SCHOOL OF MEDICINE, BRYAN; CHIEF OF ENDOCRINOLOGY, BAYLOR UNIVERSITY MEDICAL CENTER, DALLAS, TEXAS

## Case History

In 2023, Meng and her team at Baylor University Medical Center were referred a 25-year-old patient who was 22 weeks' pregnant with suspected preeclampsia from an outside hospital — a decision that likely saved the patient's life. At just nine weeks of pregnancy, she began experiencing hypertension, dizziness, nausea, and vomiting, common symptoms of pregnancy. Although these symptoms initially improved with medication, they later progressed. At 20 weeks, symptoms concerning for preeclampsia appeared, including tongue swelling, weakness, and vision loss in addition to higher blood pressure, and she was started on preeclampsia medications. When magnetic resonance imaging (MRI) revealed a mass in the medulla of her brain, the hospital swiftly transferred her to Baylor University Medical Center and endocrinology was consulted.

“For this case, she was so symptomatic at the outside hospital,” explains Meng. “When a young pregnant patient presents with sudden vision changes and higher blood pressure, they may think about common pregnancy complications, like gestational diabetes and preeclampsia. But preeclampsia is highly unusual at nine weeks. With that initial brain MRI, they realized it's more complicated, so they were able to transfer her to us.”

There, further imaging revealed pancreatic cysts, a renal cyst, and hemangioblastoma in the brainstem with associated syrinx formation in the thoracic spine, raising the suspicion for von Hippel-Lindau (VHL) disease. Initial genetic testing with next-generation sequencing was negative, but the team continued to pursue VHL on the differential due to high clinical suspicion.

Laboratory testing with fractionated serum metanephrines provided additional clues in the form of more than twofold higher normetanephrine levels, suggesting the presence



Accurate diagnosis of pheochromocytomas and paragangliomas is more difficult in pregnancy because many tests are contraindicated.

of pheochromocytomas (PCCs) and paragangliomas (PGLs), which had not initially been identified on imaging. But the team then considered that some subtypes of VHL predispose to PCCs and PGLs, prompting further treatment in lieu of certain tests that are harmful in pregnancy. Meng credits the radiologists' expertise here for seeing the possibility of something atypical, potentially VHL, and wanting the "whole picture." "Generally speaking," she says, "PCCs and PGLs are rare, and if they are not diagnosed before pregnancy, they can lead to very catastrophic outcomes."

Management consists of first an  $\alpha$ -blocker (e.g., doxazosin) then a  $\beta$ -blocker (e.g., labetalol in pregnancy) and volume expansion to control symptoms (a sequence Meng emphasizes is important to follow to negate first vasoconstriction then effect heart rate control), followed by postpartum surgery. Because this patient's condition was not diagnosed prior to pregnancy, and, in fact, pregnancy potentiated her symptoms (possibly due to the known interaction of VHL with female hormones, which pregnancy would amplify), her management was adjusted to allow for antepartum surgery to avoid an adrenergic crisis. At 24 weeks, the hemangioblastoma was resected, but she experienced respiratory failure from aspiration, a common postoperative complication, especially in someone so ill, requiring emergent management. Her pregnancy consequently ended at 27 weeks. After a three-month hospital stay, she was discharged to inpatient rehabilitation, which she has subsequently successfully completed and returned to normal life, but with some caveats.

## Outcomes and Implications

Meng says: "For this young patient who was completely healthy, recently married, and then pregnant, we would expect a happy outcome. Then, all of a sudden something like this happens. I think she is traumatized not just from the loss of the pregnancy, but also in terms of how long she was in the hospital. She also has anxiety, probably from not being able to breathe when she developed respiratory failure. In terms of future pregnancy, she is also concerned about genetic defects."

It turns out, during follow-up, the team performed RNA analysis, a type of genetic testing with better sensitivity, and that this time was positive for both VHL disease and Lynch syndrome, the latter of which was unexpected. "Gene mutations don't typically change over time, but the methods we use to detect them do evolve," Meng says. "Some of the genetic methods we use check only a few genes and maybe even miss some of the deletions and duplications, but nowadays we have much better screening and technology to pick up things we missed using the older methods." In other words, the team was connecting the dots between the patient's cysts and her neuroendocrine tumor, which pointed them to VHL disease, despite the first negative genetic test.

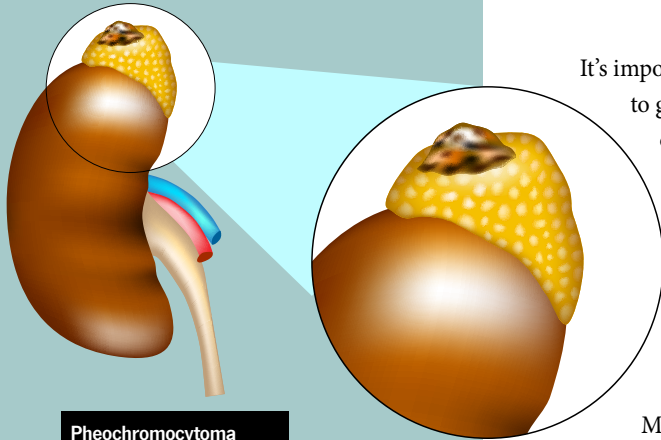
"PCCs and PGLs can be a common phenotype of VHL, and there are several different subtypes," Meng says. "Some subtypes are more correlated with big adrenal PCCs, some are more associated with PGLs, either sympathetic or parasympathetic gangliomas, and some have less risk for either. However, Lynch syndrome was a surprising finding. Its gene is a DNA mismatch repair gene, so if a mutation happens, you can have other tumors. With the typical Lynch phenotype, we think about gastrointestinal and uterine endometrium malignancies, which this patient did not exhibit at presentation."

“

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—SHUMEI MENG, MD, PHD, CLINICAL ASSOCIATE PROFESSOR, TEXAS A&M SCHOOL OF MEDICINE, BRYAN; CHIEF OF ENDOCRINOLOGY, BAYLOR UNIVERSITY MEDICAL CENTER, DALLAS, TEXAS



**Pheochromocytoma  
(Adrenal Medulla Tumor)**

## AT A GLANCE

- ▶ **Pheochromocytomas and paragangliomas can mimic other conditions and cause extreme morbidity during pregnancy if not recognized early; at the same time, accurate diagnosis is more difficult in pregnancy because many tests are contraindicated.**
- ▶ **Medical management with the correct sequence of an  $\alpha$ -adrenergic blocker and then a  $\beta$ -adrenergic blocker is crucial to avoid adrenergic crises.**
- ▶ **Many genetic conditions are associated with these neuroendocrine tumors, and knowing their association can help with earlier diagnosis and close follow-up.**

It's important to note here that the team had only half of the patient's family history to guess her genetic makeup — her father's information is unknown. That they continued pursuing VHL disease and arrived at the diagnosis attests to their clinical acumen. They do not know whether these two genetic syndromes may have been inherited from which parent, but they do know that the two conditions occurring together is exceedingly rare, and this patient endured a very heavy clinical burden as a result. It's also rare that either condition is diagnosed during pregnancy.

"The question is, is the VHL associated with the Lynch syndrome or not?" Meng says. "We don't really know for sure because there are not many cases reported — if at all — so we're trying to accumulate data, and maybe over time we start putting things together. Maybe this association is a new discovery."

### Takeaways and Future Impacts

Meng and team have three key points to make for clinicians: awareness, surveillance, and referral. "The number one is awareness of the possibility of this co-occurrence because early diagnosis can result in much better outcomes," Meng says. "It's not hard to screen for them, but if you don't know about or think about them, you wouldn't screen for them." Secondly, Meng emphasizes that newer genetic tests helped the team screen for other things. "For future follow-ups, I definitely keep eyes on what could develop over time with more targeted surveillance," she says. Finally, Meng's advice for the general practitioner or obstetrician/gynecologist is: "If something looks very unusual, refer the patient to a bigger, more specialized center."

Indeed, while the patient in Meng's team's care was unfortunate to have two genetic syndromes that combined to make her very ill, she was simultaneously very fortunate to have been referred to Meng and team and receive the exceptional care that facilitated her recovery. The patient herself expressed as much to Meng. The multidisciplinary makeup of the team was also critical, with one specialist after the next making the right call and ensuring steady progress to diagnosis and treatment. They continue to stand behind her, seeing her for follow-up in clinic as well as supporting her efforts also for emotional recovery from her ordeal. They want the best for her in all ways.

Meng also appreciates the Endocrine Society for providing resources and support within the field. She attended **ENDO 2024** and enjoyed it very much for not just "elevating her knowledge level," but also for delivering both sides of the knowledge coin. "For any scientist or physician, I don't think at any moment we feel like we know enough. But the point of scientific curiosity and research is bringing that knowledge to patient care. It's making an impact on patients' lives. That's exactly what the Society has done. You have to link the research to the clinical practice to make that impact." This patient's case may well be an exemplar of that synergy. <sup>EN</sup>

HORVATH IS A FREELANCE WRITER BASED IN BALTIMORE, MD. IN THE SEPTEMBER ISSUE, SHE WROTE ABOUT SOME OF THE WOMEN'S HEALTH RESEARCH PRESENTED AT **ENDO 2024** IN BOSTON.



# FLARE

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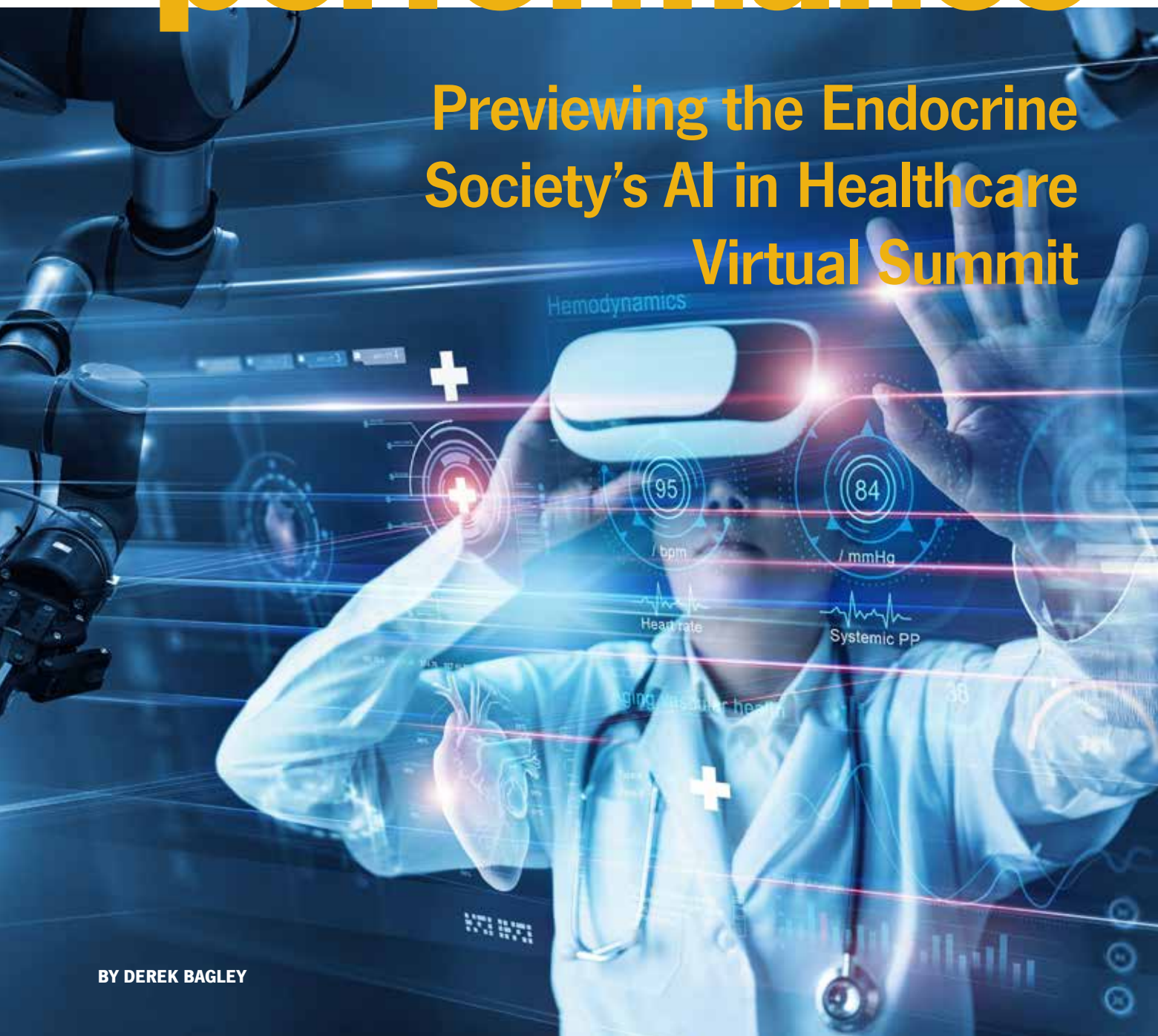
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# peak performance

Previewing the Endocrine Society's AI in Healthcare Virtual Summit



BY DEREK BAGLEY

As Artificial Intelligence (AI) finds its way into all aspects of daily life, soon it could be an important component of scientific research, patient care, and the ins and outs of clinical practice. On November 8 and 9, the Endocrine Society will host the **AI in Healthcare Virtual Summit** that will cover a variety of topics that will inform, educate, and, most importantly, prepare today's practicing endocrinologist for tomorrow.



**I**n 2024, artificial intelligence (AI) is somehow involved in almost every facet of life, but people still seem murky on exactly how it works or what it even is. The problem is that most people — even healthcare professionals — get their news about AI when someone generates a fake picture of a celebrity or uses AI to write an academic paper that turns out to be wildly inaccurate.

On November 8 and 9, the Endocrine Society is hosting the AI in Healthcare Virtual Summit, a two-day virtual event designed to inform providers, healthcare professionals, researchers, technologists, industry stakeholders, and educators on the capabilities of artificial intelligence in the healthcare field.

“A lot of physicians hear about AI in healthcare from the news or vendors or commercials,” says Jeffrey Moon, MD, MPH, assistant chief medical officer at the University of Pennsylvania in Philadelphia and one of the presenters at the summit. “They don’t hear it from their fellow doctors and healthcare providers who are unbiased and have a scientific background. That’s my role, and I will be able to provide that to like-minded colleagues, an objective assessment on where we are today and where we’ll be in the future.”

The AI Summit agenda is robust and diverse, from using the technology in diabetes



**NIKITA POZDEYEV,  
MD, PHD,**

ASSISTANT PROFESSOR,  
BIOMEDICAL  
INFORMATICS,  
UNIVERSITY OF  
COLORADO

ANCHUTZ SCHOOL OF  
MEDICINE,  
AURORA, COLORADO

**“ We believe that learning from the data responsibly can improve clinical care for patients with thyroid cancer and other thyroid diseases. My interest in using AI methods has grown since the invention of convolutional neural network technology, when computers began outperforming humans in comprehending visual data, including medical images.”**

treatment to diagnosing thyroid cancer to using AI to guide decision making. *Endocrine News* caught up with a few of the presenters to find out a little about their presentations and their thoughts on the current state of AI in healthcare.

## AI and Thyroid Cancer

Nikita Pozdeyev, MD, PhD, is assistant professor of biomedical informatics at the University of Colorado Anschutz School of Medicine and an endocrinologist specializing in the diagnosis and treatment of thyroid diseases, including thyroid cancer. He runs a “dry” laboratory focusing on data analysis.

“We believe that learning from the data responsibly can improve clinical care for patients with thyroid cancer and other thyroid diseases,” Pozdeyev says. “My interest in using AI methods has grown since the invention of convolutional neural network technology, when computers began outperforming humans in comprehending visual data, including medical images.”

Pozdeyev’s talk, “Artificial Intelligence and Statistical Genetics for Diagnosing Thyroid Cancer,” will, as the title suggests, focus on AI and machine learning for thyroid cancer diagnosis. He says that deciding which nodules need biopsy is complex and subjective.





## Artificial Intelligence in Healthcare

November 8 – 9, 2024

The Endocrine Society's AI in Healthcare Virtual Summit is an innovative two-day virtual event designed to inform providers, healthcare professionals, researchers, technologists, industry stakeholders, and educators on the capabilities of artificial intelligence in the healthcare field. This summit offers a unique opportunity to delve into the transformative potential of AI in revolutionizing patient care and shaping the future of medicine.

### Friday November 8, 2024

#### ***The Impact of AI in Transforming Care in Cardiometabolic Disease***

— Evan D. Muse, MD, PhD, FACC, FAHA, associate clinical professor, associate program director, MCTI Scripps Research Translational Institute

***Endocrinology and Hypertension*** — Maria-Christina Zennaro, MD, PhD, Inserm, Université Paris Cité, Paris Cardiovascular Research Center-PARCC

***Ambient and Wearable Devices, Biomedical Signal Processing, and Health Monitoring*** — Edward Sazonov, PhD, University of Alabama, Computer Laboratory of Ambient and Wearable Systems

***AI for Diabetes Treatment, T1D Patients, Nutrition Estimation, and Glucose Control*** — Yao Qin, PhD, assistant professor, UC Santa Barbara; co-director, REAL AI Initiative; senior research scientist, Google Deep Mind

### Saturday November 9, 2024

***AI for Bone Health*** — Christopher White, MBBS, PhD, FRACP, endocrinologist, Prince of Wales Hospital in Randwick, Australia

***AI for Healthcare in Action: What You Need to Know as a Decision Maker*** — Wuraola Oyewusi, data scientist and AI technical instructor, LinkedIn Learning

***Artificial Intelligence and Statistical Genetics for Diagnosing Thyroid Cancer*** — Nikita Pozdeyev, MD, PhD, assistant professor, Biomedical Informatics, University of Colorado, Anschutz School of Medicine

***Gen AI in Clinical Practice: Promise, But Much to Improve*** — Jeffrey Moon, MD, MPH, assistant chief medical information officer, University of Pennsylvania

Held in conjunction with Matchbox Virtual, attendees will all receive an innovative user experience that mimics attendance at a physical conference site.

<https://www.endocrine.org/meetings-and-events/ai-summit>



**WURAOLA  
OYEWUSI**  
DATA SCIENTIST  
AI TECHNICAL  
INSTRUCTOR  
LINKEDIN LEARNING

**“The concerns [about AI] are valid, and it’s important for people to ask questions. Like with any other tool, it’s our responsibility as professionals to become informed and engage with AI, rather than viewing it as some kind of magic.”**

“Because of this difficulty, clinicians biopsy too many thyroid nodules, which increases healthcare costs and frequently leads to additional testing, diagnostic surgery, and patient stress,” Pozdeyev says. “AI can streamline the interpretation of thyroid ultrasound images, but it has limitations that I will highlight in the talk. We work to augment AI predictions using alternative thyroid cancer risk assessments, such as by quantifying the inherited risk of developing the disease.”

Pozdeyev says he will make his presentation as entertaining as possible but adds that the main takeaway will be that “AI is a machine-learning tool that is very powerful. It is now able to perform tasks previously thought to be doable by humans only. However, AI does not reason or feel, and we should use it to augment but not replace clinical providers.”

Pozdeyev says that we are at the “Peak of Inflated Expectations” of the Gartner hype cycle. “I do not mean this in a negative sense; it is a necessary step that will ultimately result in the safe and productive use of AI in medicine,” he says.

## AI in Decision Making

Wuraola Oyewusi is a data scientist and AI technical instructor at LinkedIn Learning, previously held roles in AI Research as a researcher (data science and data curation) at Imperial College London and led Research and Innovation at Data Science Nigeria.

“I started my career as a pharmacist before transitioning into data science and AI,” Oyewusi says. “My interest in AI was somewhat incidental. I came across a job description related to analytics and thought I could do most of the tasks listed, except for SQL (a language used to retrieve data from databases in the way you need). So, I decided to take an online course on SQL, and it made sense to me.”

Oyewusi says that from there, she discovered data science and AI, and she found them fascinating. “This led me to dive deeper into learning everything I needed, from programming to linear algebra and machine learning (I treated it like a school schedule),” she says. “Once I had a solid grasp of these concepts, I found it easy to apply them within the context of my healthcare background.”



Oyewusi's presentation, "AI for Healthcare in Action: What You Need to Know as a Decision Maker" will home in on the fact that AI is an important technology that everyone will be using, and that it's not some sort of fantastical nightmare. "Now that AI is here, I understand that not everyone will become a coder," she says. "However, we'll focus on the key things you need to know in order to make informed decisions about AI systems, without resorting to fear mongering.

"The concerns [about AI] are valid, and it's important for people to ask questions," Oyewusi continues. "Like with any other tool, it's our responsibility as professionals to become informed and engage with AI, rather than viewing it as some kind of magic."

## AI in Clinical Practice


And speaking of concerns, Moon agrees that the hesitation some might feel about AI is well founded, but he says he has not seen anything dangerous regarding safety or hallucinations (when the AI produces inaccurate information that's presented as fact) or a perpetuation of bias. "These are big things we have been watching like a hawk for," he says.

But while AI hasn't been dangerous, it hasn't been all that great either, Moon says. "If you ask it to help with patient messages that they send to their doctors, the responses are B-plus at best,"

he says. "They're not dangerously wrong, but they're not that good. If the goal is to help doctors with all the patient messages, it hasn't really done that."

Moon is an emergency physician and has a particular interest in discovering and sharing artificial intelligence applications that improve diagnostics, achieve provider well-being, automate tasks, and enhance the EMR experience, and his talk "Gen AI in Clinical Practice: Promise, But Much to Improve," will cover how physicians can leverage AI to relieve burnout, especially with the electronic medical records.

"There is great interest among doctors about how AI might affect them," Moon says. "There's great interest among healthcare leaders about making purchases of this expensive software, but you want to get the right one. And there's a lot of promise by vendors that what they have is the next big thing. But they've been promising home runs, and all we've seen are singles and doubles at best."

Moon says that for now, with AI there is greater potential than there are results, but he's cautiously optimistic. "Artificial intelligence is in its worst state right now," he says. "It's only going to get better, and two, three, maybe five years from now it will be something quite impressive." 

— BAGLEY IS THE SENIOR EDITOR OF *ENDOCRINE NEWS*. IN THE SEPTEMBER ISSUE, HE WROTE ABOUT THE ONGOING EFFORTS TO FUND WOMEN'S HEALTH RESEARCH.

# New Perspectives on PCOS

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**AS THE INCIDENCE OF POLYCYSTIC OVARY SYNDROME GROWS, SO DOES AN INCREASED AWARENESS.**

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**Statistics show that nearly 10% of women have polycystic ovary syndrome (PCOS), making it one of the leading causes of infertility, and new research indicates that it seems to be on the rise. Three recent studies from the *Journal of Clinical Endocrinology & Metabolism* add to the evidence base of this “neglected, yet common” condition.**

**BY ERIC SEABORG**



**A**lthough polycystic ovary syndrome (PCOS) is the most common endocrine disorder among reproductive-age women, the evidence base for diagnosis and treatment remains relatively weak for this “neglected” condition, according to the most recent international guideline.

Three new studies published in *The Journal of Clinical Endocrinology & Metabolism* have added to that evidence base, with one reporting a rise in incidence of the condition in the past two decades, a second tying disease phenotypes to particular co-morbidities, and a third confirming the increased risks of eating disorders among women with PCOS.

### Increased Incidence

The first study, “Rising Incidence, Health Resource Utilization, and Costs of Polycystic Ovary Syndrome in the United Kingdom,” by Berni, et al., examined data from U.K. health records and found that reported PCOS incidence increased “significantly” from 1.22 per 1,000 person years in 2004 to 1.77 in 2012 and 2.20 in 2019. Point prevalence increased from 1.02% in 2004 to 2.2% in 2012 and 3.5% in 2020, with significant differences by ethnicity. The highest rates occurred among those of Asian ethnicity. The researchers also reported that healthcare costs were significantly higher for patients with PCOS compared with matched controls.

The researchers noted that the reported prevalence of PCOS seems to vary in part due to diagnostic criteria. The Rotterdam criteria published in 2003 are less strict than the previous National Institutes of Health and Androgen-Excess-PCOS Society criteria.

“The reasons for this rising incidence are subject to debate,” says Richard S. Legro, MD, chair of the Department of Obstetrics and Gynecology at Pennsylvania State College of Medicine. Legro chaired an Endocrine Society committee that published a PCOS guideline in 2013 and reviewed the three recent studies at the request of *Endocrine News*. “Broader diagnostic criteria probably increased the incidence, and there has also been greater public and medical awareness of the disorder. Nonetheless, as the authors note, the disorder is still likely underdiagnosed in the population.”





**Leanne M. Redman, MD**

professor of reproductive  
endocrinology and women's health,  
Pennington Biomedical  
Research Center,  
Baton Rouge, Louisiana



Without giving  
PCOS dedicated  
research resources  
the prevalence will  
only continue to  
increase; people  
affected will continue  
to suffer with few  
effective treatments;  
and families,  
communities, and  
societies will bear  
increased healthcare  
costs and  
financial burdens.



The 2023 international guideline for PCOS assessment and management offers the most recent diagnostic criteria, which the authors say build on the 2018 international guideline and the 2003 Rotterdam criteria. The 2023 guideline bases a PCOS diagnosis on the presence of at least two of three indicators: (1) clinical/biochemical hyperandrogenism, (2) ovulatory dysfunction, and (3) polycystic ovaries as assessed on ultrasound or by an anti-Müllerian hormone blood test.

## Phenotypes Affect Sequelae

The second study, “Risk of Type 2 Diabetes, MASLD, and Cardiovascular Disease in People Living with Polycystic Ovary Syndrome,” by Henney, et al., used U.K. Biobank data to examine the incidence of type 2 diabetes, metabolic dysfunction associated steatotic liver disease, cardiovascular disease (CVD), hormone-dependent cancers, and dementia between PCOS patients compared with controls matched by age and body mass index. The researchers found no differences between the groups for cancer and dementia, but PCOS patients had a higher incidence of diabetes, all-cause cardiovascular disease, and steatotic liver disease.

In addition, the researchers examined multiorgan magnetic resonance imaging data of PCOS patients and compared the effects of normoandrogenic versus hyperandrogenic phenotypes. They found that normoandrogenic PCOS patients had a greater incidence of all-cause CVD, whereas hyperandrogenic patients were more likely to have hepatic steatosis.

The researchers conclude that “people with PCOS are at an increased risk of metabolic disease and CVD, with a potential divergence of risk according to PCOS phenotype. Hyperandrogenism may confer opposing metabolic and cardiovascular effects, with a potentially amplified risk of metabolic dysfunction associated steatotic liver disease despite a lower risk of CVD. These results suggest more precise phenotype classification may benefit ongoing risk stratification for patients with PCOS.”

Legro notes that this phenotypic classification could be “important for identifying women with PCOS at risk for these disorders. The diagnostic criteria for PCOS remain an expert-based opinion, not evidence-based, and linking specific phenotypes to long-term sequelae are important both for long-term management and the further development of evidence-based diagnostic criteria.”

## Eating Disorders Linked to PCOS

The third study — “Increased Prevalence of Binge Eating Disorder and Bulimia Nervosa in Women with Polycystic Ovary Syndrome: A Systematic Review and Meta-analysis” — reviewed and analyzed 20 cross-sectional studies in nine countries that was done in support of the 2023 international PCOS guideline.

The study shows that women with PCOS are at higher risk for eating disorders, including bulimia nervosa, binge-eating disorder, and disordered eating. “This analysis is the first time we’ve been able to confirm this increased risk of specific eating disorders,” says the study’s lead author, Laura Cooney, MD, associate professor at the University of Wisconsin in Madison. “Many women with PCOS experience weight stigma, and that can be detrimental to mental health generally and contribute to disordered eating.”

“Our findings emphasize the importance of screening women with PCOS for eating disorders before clinicians share any lifestyle advice,” Cooney says. “The lifestyle modifications we often recommend for women with PCOS — including physical activity, healthy diet, and behavior modifications — could hinder the recovery process for eating disorders. Healthcare providers need to be vigilant about screening for eating disorders in this population.”

## A Need for More Research

All three studies and the 2023 international guideline emphasize the need for more research. The guideline notes that “the evidence has generally improved over the past five years [since the 2018 international guideline] but remains of



**Laura Cooney, MD**

associate professor,  
University of Wisconsin, Madison,  
Wisconsin



Our findings emphasize the importance of screening women with PCOS for eating disorders before clinicians share any lifestyle advice. The lifestyle modifications we often recommend for women with PCOS — including physical activity, healthy diet, and behavior modifications — could hinder the recovery process for eating disorders. Healthcare providers need to be vigilant about screening for eating disorders in this population.



## AT A GLANCE



- ▶ The incidence of polycystic ovary syndrome has risen over the past two decades, according to U.K. health records data.
- ▶ Different PCOS phenotypes may pose different risks: Patients with normal androgen levels have a greater cardiovascular risk, while those with high androgen levels have higher rates of hepatic steatosis.
- ▶ Women with PCOS have higher odds of eating disorders, such as bulimia nervosa, binge-eating disorder, and disordered eating.



**Richard S. Legro, MD**

chair, Department of  
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Pennsylvania State College of  
Medicine,  
Hershey, Pennsylvania



The reasons for this rising incidence are subject to debate. Broader diagnostic criteria probably increased the incidence, and there has also been greater public and medical awareness of the disorder. Nonetheless, as the authors note, the disorder is still likely underdiagnosed in the population.



low to moderate quality, requiring significant research investment into this neglected, yet common condition.”

Berni, et al. write: “Our data emphasize the importance of recognizing PCOS as a public health priority and underscore the need for greater investment and research funding for this historically under-resourced disorder. Although our data confirm a rise in prevalence of a recorded diagnosis of PCOS, suggesting a possible improvement in diagnostic awareness over time, the true prevalence is likely to be much higher. Improved education is therefore still needed to improve the gaps that are apparent in physician knowledge.”

“These three articles underscore the dire need for more research funding to understand identification, prevention, and treatment of polycystic ovary syndrome,” agrees Leanne M. Redman, MD, professor of reproductive endocrinology and women’s health at Pennington Biomedical Research Center, part of the Louisiana State University System, who was a contributor to the international guideline. “Without giving PCOS dedicated research resources the prevalence will only continue to increase; people affected will continue to suffer with few effective treatments; and families, communities, and societies will bear increased healthcare costs and financial burdens.” <sup>EN</sup>



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– SEABORG IS A FREELANCE WRITER BASED IN CHARLOTTESVILLE, VA. IN THE AUGUST **ENDO 2024** HIGHLIGHTS ISSUE, HE WROTE ABOUT “EUROPEAN SOCIETY OF ENDOCRINOLOGY AND ENDOCRINE SOCIETY JOINT CLINICAL GUIDELINE: DIAGNOSIS AND THERAPY OF GLUCOCORTICOID-INDUCED ADRENAL INSUFFICIENCY,” THE FIRST NEW PRACTICE GUIDELINE TO BE CO-AUTHORED BY BOTH THE ENDOCRINE SOCIETY AND EUROPEAN SOCIETY OF ENDOCRINOLOGY.





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# ORAL arguments

According to Sandeep Dhindsa, MBBS, “Intramuscular injections are painful, and they have some limitations, specifically the peaks and the troughs.” The associated pain and the highs and lows can lead to patient nonadherence.



## Getting the Word Out About Oral Testosterone Replacement Therapy

Injectable and gel versions of testosterone replacement therapy have long been considered cumbersome by both patients and providers, for a litany of reasons from being difficult to administer to an overwhelming insurance burden. However, research from **ENDO 2024** revealed that a new oral therapy could potentially eliminate these barriers and be a safer option.

BY KELLY HORVATH

**A**lthough testosterone replacement therapy (TRT) has been around for decades, a recent survey jointly undertaken by pharmaceutical company Tolmar, Inc., and the online physician community Sermo found that many patients who could benefit from TRT may not be effectively treated, for a variety of reasons.

The survey polled more than 300 physicians in February, seeking their perspectives on barriers to effective treatment, among other points of interest including prescribing preferences and unmet patient needs. The results from this survey were presented at **ENDO 2024** in June by Adrian Dobs, MD, professor of medicine and oncology at the Johns Hopkins School of Medicine, in Baltimore, Md., and Sandeep Dhindsa, MBBS, director of the Division of Endocrinology, Diabetes, and Metabolism at the St. Louis University School of Medicine in Missouri.

Tolmar is the maker of Jatenzo®, an oral TRT approved by the U.S. Food and Drug Administration in 2019. “Tolmar wanted to understand the current landscape of TRT among physicians who write a lot of TRT prescriptions a month,” Dhindsa says, “and they wanted a good representation of endocrinologists and urologists, the two relevant specialties. In the end, they had 100 endocrinologists, 100 urologists,

and 103 other specialties. To disseminate the findings of this comprehensive survey, they chose to do so at ENDO 2024, and they contacted Dr. Dobs and me who are both interested in clinical andrology to present at the product theater.”

Jatenzo® is testosterone undecanoate (TU) unlike the previous formulation of oral TRT, methyltestosterone, which was found to cause liver damage. “TU is a different kind of esterified testosterone, and it is absorbed through the lymphatic system, where it goes directly into the peripheral circulation,” Dobs explains. “The oral preparation that was available many years ago had a methylated group to improve absorption. But the problem was, it was directly absorbed through the portal vein into the liver, and that caused abnormal liver function.” The pharmacokinetic profile of this drug has shown that liver monitoring is not required, and TU’s safety has been rigorously tested.

## Barriers to Treatment and Unmet Patient Needs

The importance of having a new oral TRT available cannot be overstated. This is where the unmet patient needs and barriers to treatment come in as well as, as Dobs puts it, “how physicians make prescribing decisions and what they think is important in making recommendations to patients.” Moreover, the barriers and unmet needs are inextricably intertwined, thus compounding each other.

One barrier to treatment is insurance. Despite the number of TRT products now on the market, including injections,

gels, patches, and (now) oral, as well as various routes of administration, insurance generally covers inexpensive generic formulations, which, in the realm of TRT, usually means injectables or, more recently, gels. “Intramuscular injections are painful, and they have some limitations, specifically the peaks and the troughs,” Dhindsa says. The associated pain and the highs and lows can lead to patient nonadherence. Although gels do not have the same administration challenges, some patients and physicians nevertheless would not opt for them either, given the choice.

Dhindsa explains: “In the survey, we asked physicians what they prescribe and why. They responded that injections and gels are a lot of what they prescribe, and the number one reason is to avoid insurance hassles. When, in a follow-up question, we asked what they would prescribe if insurance was removed completely, their preference for gels and injections went way down.” Moreover, when asked if they thought their patients would prefer an oral option, 70% not only said yes, but also that adherence would improve dramatically.

Dhindsa and Dobs both found something surprising in the survey related to barriers and unmet needs: that so many patients switch TRT formulations. “As physicians, sometimes we’re really quite blinded to the fact that there are obstacles to patients,” Dobs says. “In reality, there are several problems that cause them to switch to other testosterone products. Sometimes it’s insurance, sometimes it’s tolerance — injectables are painful; gels are messy. That was an important finding.”



“As physicians, sometimes we’re really quite blinded to the fact that there are obstacles to patients. In reality, there are several problems that cause them to switch to other testosterone products. **Sometimes it’s insurance, sometimes it’s tolerance — injectables are painful; gels are messy. That was an important finding.**”

— ADRIAN DOBS, MD, PROFESSOR OF MEDICINE AND ONCOLOGY, JOHNS HOPKINS SCHOOL OF MEDICINE, BALTIMORE, MARYLAND

In a survey, physicians stated that they often prescribed testosterone replacement therapy in gel form since there were typically fewer insurance hassles. However, there is often an issue with patient adherence since the gels can be messy.

Dhindsa explains it this way: “[We] typically would not expect that switching from one TRT product to another would improve adherence because it’s just a different testosterone product. But clearly administration makes a difference in this case. We were surprised to know that 25% of patients don’t take the TRT prescribed to them, and 17% don’t even come back to the doctor to follow up. They give up because it’s just too cumbersome for them to do.”

Insurance creates other problems besides restricting patient/provider choices (again, leading to nonadherence), namely, the hoops the provider and their staff have to jump through to ensure that coverage. Dhindsa says that the survey asked how much time staff spend on obtaining prior authorizations as well as on following up with insurance companies when a particular formulation is not serving a patient, and it’s on the order of 11 hours per month — just for paperwork — none of which is reimbursable to the physician.

Another physician perspective that is pertinent here relates back to the TRT switching already described. Physicians would prefer to be able to start a patient on the TRT that is going to work for them, not to have to work up to that status by trial and error, both because that is obviously better for the patient, but it’s better for the physician trying to provide care for that patient also. “When I start a patient on TRT, I do a



blood test to see what the levels are, then titrate the dose and get them where they need to be to have symptomatic benefit,” Dhindsa says. “If I have to change it and start the process all over again, we are losing weeks if not months in the process, and it may be six months before the patient can expect any benefit. Some of them may give up at that time because they don’t think it is worth the hassle. So, we lose patients.” The implication is clear: An oral TRT would circumvent many of these issues (e.g., administration challenges, burdens associated with TRT switching) for many patients.

So, if oral TU is both safe and well tolerated, why aren’t more patients using it? Perhaps the most surprising finding to come out of the survey for both Dobs and Dhindsa was the lack of physician (and patient) awareness about oral TRT — its existence in some cases, its safety profile in others. “Many physicians did not realize that there was an oral preparation available. Even though patients wanted to use an oral preparation, they didn’t know that it was available,” Dobs says.



“We typically would not expect that switching from one TRT product to another would improve adherence because it’s just a different testosterone product. But clearly administration makes a difference in this case. **We were surprised to know that 25% of patients don’t take the TRT prescribed to them, and 17% don’t even come back to the doctor to follow up. They give up because it’s just too cumbersome for them to do.**”

— SANDEEP DHINDSA, MBBS, DIRECTOR, DIVISION OF ENDOCRINOLOGY, DIABETES, AND METABOLISM, ST. LOUIS UNIVERSITY SCHOOL OF MEDICINE, ST. LOUIS, MISSOURI

“This really suggests to me as well that physicians don’t do a good job of explaining to patients what options are out there and their pros and cons.”

Says Dhindsa: “Although there has been no liver toxicity, this point has to be made again and again, because one of the findings in our survey is that there were some physicians still concerned about toxicity with oral testosterone because of the baggage from the prior version of oral testosterone. This was one of the key points we really focused on during the presentation at **ENDO 2024**.”

## Need for Education

Dobs and Dhindsa agree that education is needed on this score. “It takes a long time for patients and for physicians to understand a new product, how it’s given, and how to make sure that the patient is obtaining a sufficient level,” Dobs says. “So some of that is general to all medications, and some specific for testosterone, which has had a sort of a bumpy course altogether. There have always been lots of discussions about who should be treated and when they should be treated, and that has created controversy in the field. So put this all together, and it’s not easy for physicians to discuss this with patients and really be impartial on one of the various options that they have.”

Physicians can also help dispel myths surrounding testosterone, Dhindsa says. Patients are lured by promises that over-the-counter TRT supplements will boost their levels, for example. “So, it is necessary to make sure that doctors are well educated because they are the number one resource for patients.”

Then again, further physician training is still needed, given that the surveyed physicians themselves still expressed so many reservations about the safety of oral TRT. Both Dobs and Dhindsa mentioned concerns about blood pressure and hematocrit elevations with oral TU, but Dobs says evidence suggests this is a class effect and not specific to TU. They recommend blood pressure and hematocrit monitoring with oral TU treatment.

Ultimately, improving patient care is at the heart of this matter, and having various formulations and routes of administration will increase the ability of patients to adhere to one or the other. Oral TU that is taken twice daily with meals, explains Dobs, will likely work well for a patient with a regular daily routine, for example, while it might not be the best choice for a patient who does not keep regular mealtimes. “But that’s what we want — adherence to the medication because if they’re not adhering to the treatment, it’s hard to determine whether or not the patient is improving. We have to make sure that patients need to be treated, that they adhere to treatment, that they’re getting better with treatment, and that it’s safe over time,” she says. Dhindsa adds that oral TU’s multiple dosing options also may improve adherence and therefore care.

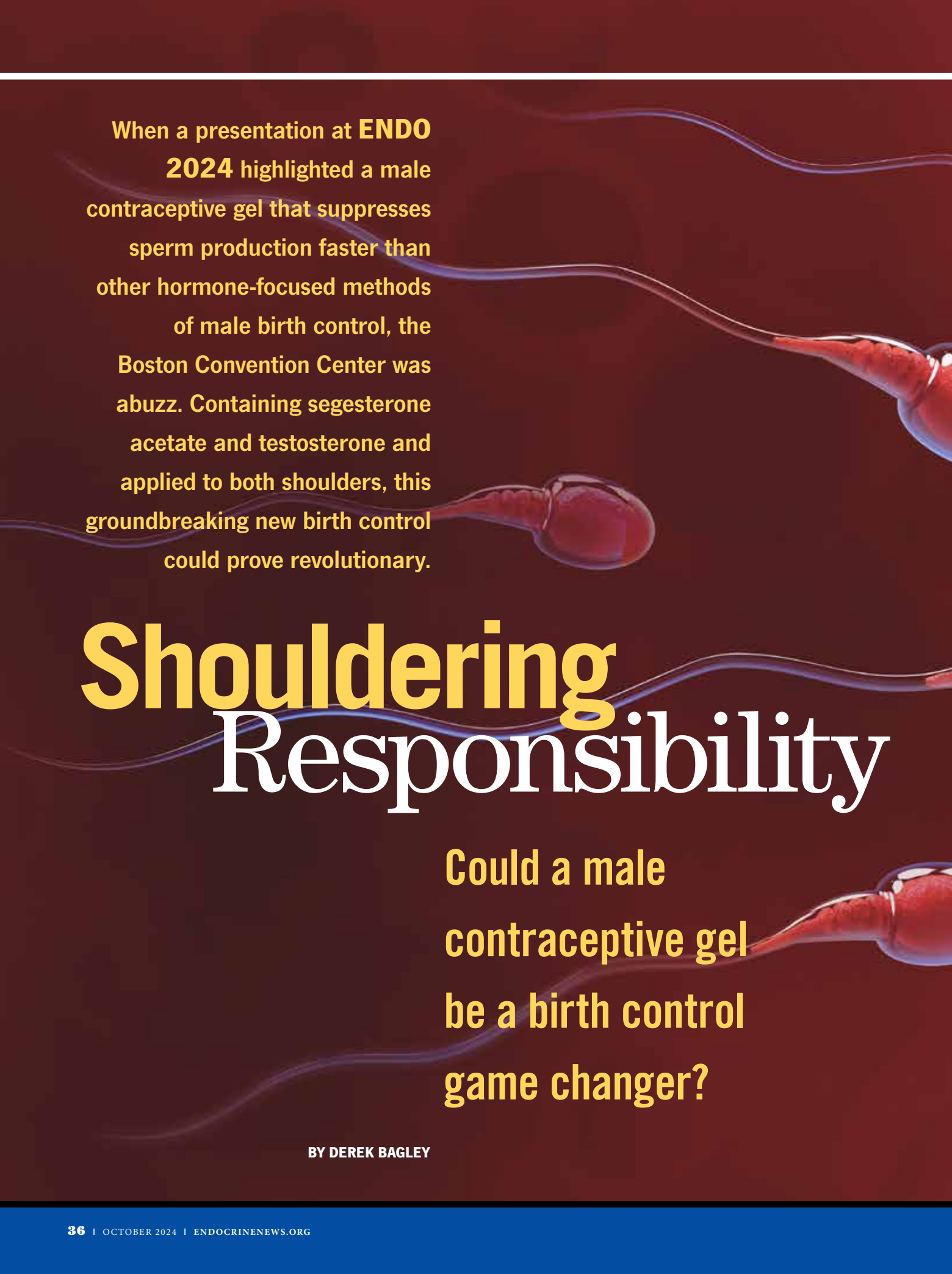
But, continuing to get the word out about oral TU is the first step because, as Dobs says, “the key takeaway is really talking to patients, making sure that they’re aware of the various options that are out there, and that oral therapy is available.” In order to accomplish that aim, says Dhindsa, “we have to continue the work that has started with the Endocrine Society presentation and disseminate these findings,” Dhindsa says. “There was good involvement from the audience, and quite a few people came up to us after the presentation to discuss their experiences.” He believes the survey of physicians was probably the first in an annual series of surveys and hopes that he and Dobs will be presenting further iterations in future meetings. **EN**



## AT A GLANCE

- ▶ Two thirds (66%) of patients taking testosterone replacement therapy (TRT) switched therapy in the past year, largely driven by insurance and undesirable routes of administration.
- ▶ Among both patients and physicians, there is a lack of awareness of newer and potentially more convenient treatment options, like oral TRT, that may improve patient care.
- ▶ Testosterone undecanoate (TU) is absorbed through the lymphatic system and does not have a first pass through the liver, making it a safe oral TRT option.

— HORVATH IS A FREELANCE WRITER BASED IN BALTIMORE, MD. IN THE SEPTEMBER ISSUE, SHE WROTE ABOUT SOME OF THE WOMEN’S HEALTH RESEARCH PRESENTED AT **ENDO 2024** IN BOSTON.

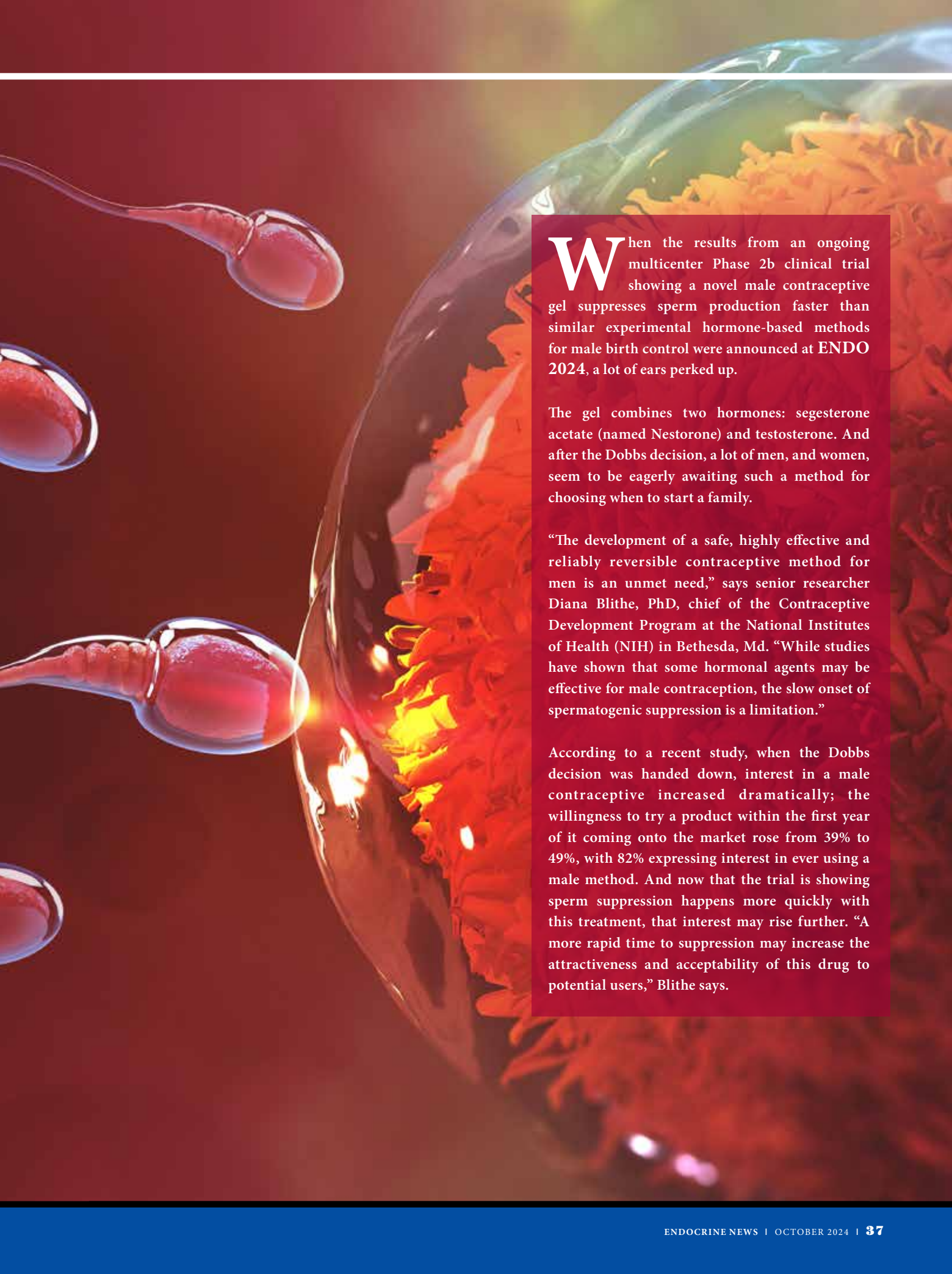
A background image showing several sperm cells in motion against a dark red background. The sperm heads are bright red, and their tails are long and thin, with some appearing to have a blueish glow. The cells are scattered across the frame, with some in the foreground and others in the background, creating a sense of depth and movement.

When a presentation at **ENDO 2024** highlighted a male contraceptive gel that suppresses sperm production faster than other hormone-focused methods of male birth control, the Boston Convention Center was abuzz. Containing segesterone acetate and testosterone and applied to both shoulders, this groundbreaking new birth control could prove revolutionary.

# Shouldering Responsibility

Could a male  
contraceptive gel  
be a birth control  
game changer?

BY DEREK BAGLEY



**W**hen the results from an ongoing multicenter Phase 2b clinical trial showing a novel male contraceptive gel suppresses sperm production faster than similar experimental hormone-based methods for male birth control were announced at ENDO 2024, a lot of ears perked up.

The gel combines two hormones: segesterone acetate (named Nestorone) and testosterone. And after the Dobbs decision, a lot of men, and women, seem to be eagerly awaiting such a method for choosing when to start a family.

“The development of a safe, highly effective and reliably reversible contraceptive method for men is an unmet need,” says senior researcher Diana Blithe, PhD, chief of the Contraceptive Development Program at the National Institutes of Health (NIH) in Bethesda, Md. “While studies have shown that some hormonal agents may be effective for male contraception, the slow onset of spermatogenic suppression is a limitation.”

According to a recent study, when the Dobbs decision was handed down, interest in a male contraceptive increased dramatically; the willingness to try a product within the first year of it coming onto the market rose from 39% to 49%, with 82% expressing interest in ever using a male method. And now that the trial is showing sperm suppression happens more quickly with this treatment, that interest may rise further. “A more rapid time to suppression may increase the attractiveness and acceptability of this drug to potential users,” Blithe says.



“ The sperm production stays shut off, but everything else functions normally because the blood is not seeing any kind of lower testosterone levels. It’s the differential between the concentration of testosterone that’s needed locally in the testes to recruit stem cells to make sperm and the testosterone that’s needed in the blood to support all the other functions that androgens support.”

— DIANA BLITHE, PHD, CHIEF, CONTRACEPTIVE DEVELOPMENT PROGRAM, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND

## Goldilocks of Testosterone

The results presented at **ENDO 2024** in Boston, Mass., included data from 222 men who completed at least three weeks of daily treatment with the contraceptive gel. The gel contained 8 mg of segesterone acetate and 74 mg of testosterone. Segesterone acetate is an ingredient of the Annovera vaginal birth control ring. Men applied the gel once daily to each shoulder blade (to reduce the risk of exposing the gel to others).

The treatment acts on the endocrine feedback loop between the pituitary and the gonads — secretion of luteinizing hormone (LH) from the pituitary causes the testes to make testosterone, and follicle-stimulating hormone (FSH) is involved in sperm maturation. The segesterone acetate in the gel stops the pituitary from secreting LH and FSH, shutting down the production of testosterone. Local testosterone concentration in testes is higher than levels that circulate in the blood; when testosterone falls below a threshold, the testes stop producing sperm. But men would like to maintain a normal libido and muscle mass, so the gel replaces testosterone in the blood without it accumulating in the testes.

“The sperm production stays shut off, but everything else functions normally because the blood is not seeing any kind of lower testosterone levels,” Blithe says. “It’s the differential between the concentration of testosterone that’s needed locally in the testes to recruit stem cells to make sperm and the testosterone that’s needed in the blood to support all the other functions that androgens support.”

Blithe explains that they found that Nestorone is a pure progestin — not a so-called “promiscuous” hormone like levonorgestrel that’s commonly used in female contraception. “[Levonorgestrel] binds to the progesterone receptor very strongly, but it also binds to the androgen receptor pretty strongly,” she says. “Those off-target effects, including other hormones that impact the glucocorticoid pathway, can impact mood and things. It’s the off-target effects of hormones that might cause some bad side effects. Nestorone, we think, binds to the progesterone receptor and not so much to other receptors, so it’s good because we’re not seeing the





kinds of side effects that we would worry about if it were impacting some of these other pathways.”

“Nestorone is the progestin. That shuts down the pituitary LH and FSH,” Blithe continues. “Testosterone is the second component, and that maintains everything in the normal functional range. We’re not too high, not too low, just the Goldilocks amount of testosterone that makes everything work well.”

Eighty-six percent of participants reached this sperm count by week 15, the researchers report. Among those men, sperm production was suppressed at a median, or midpoint, time of fewer than eight weeks of segesterone-testosterone treatment. Blithe says prior studies of male hormonal contraceptives given by injections showed a median time between nine and 15 weeks for sperm output to become suppressed.

“What we actually are seeing is by eight weeks, half the men are already fully suppressed. That was a surprise,” she says. “That’s where the publicity around this came out when we released that information to say, ‘This is working faster than we expected.’”

## Family Time

The sperm suppression stage of the international Phase 2b trial of segesterone-testosterone gel is complete. The study continues to test the contraceptive’s effectiveness, safety, acceptability, and reversibility of contraception after treatment stops.

Once the subjects stop using the product, they go into recovery and Blithe and her team take sperm samples to show how long it takes for the sperm to come back. “Once you start seeing them, then they go up to normal range pretty quickly,” she says.

Couples who completed the trial and decided it was the right time for them to start a family have done so successfully. “We’re not aware of anybody who’s trying and not able to, and there’s no reason to think that would be the case if it wasn’t the case before they started the study because their sperm come back,” Blithe says. “Their sperm parameters are normal when they leave us.”

## Male Contraception: A Women’s Health Issue

Blithe says that the development of a male contraceptive is a women’s health issue, since women are the ones who get pregnant if they don’t have a contraceptive. And

# AT A GLANCE

- ▶ A presentation at **ENDO 2024** showed a novel male contraceptive gel suppresses sperm production faster than similar experimental hormone-based methods for male birth control.
- ▶ The treatment, a topical gel applied to both shoulders, contains segesterone acetate and testosterone.
- ▶ Researchers see male contraception as a women’s health issue since women are the ones who get pregnant if they don’t have a contraceptive, and women don’t always have the best experiences with certain contraceptives.

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“ The development of a safe, highly effective, and reliably reversible contraceptive method for men is an unmet need. While studies have shown that some hormonal agents may be effective for male contraception, the slow onset of spermatogenic suppression is a limitation.”

— DIANA BLITHE, PHD, CHIEF, CONTRACEPTIVE DEVELOPMENT PROGRAM, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND


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some women don't always have the best experiences with certain contraceptives. "Lots of women really love their contraceptive methods and don't want something else, but lots of women don't love theirs and would love to have a hormone-free interval, or in some cases they actually can't use hormonal methods. That really limits their options," she says. "A male contraceptive for them is really critical."

Blithe says some of the investigators have spent their careers developing contraception methods for women, which provided a perspective for the researchers who have worked on developing methods for men. "I think one of the things that our study in couples has taught me that I didn't appreciate when we started was how much it means to a female partner to be able to be in a situation where she has a really effective method that doesn't require her to use products that she doesn't want or can't use," she says.

Blithe says that the communication between investigators working on female contraception and their counterparts developing a male contraceptive has been crucial. She tells *Endocrine News* that she doesn't see the study participants personally, but she hears from her teams that some female partners experience anxiety as they get to the end of the year of efficacy. The male partner stops using the gel and goes into recovery. The anxiety that some women experience at that point is much greater than the anxiety the women in the female method studies face for the same choice.

"That is probably something that none of us really thought about much ahead of time but see in practice in a way that it makes it more palpable that this is a method for women as well as potentially a method for men, who might not be in a relationship but might want to control their fertility," she says. "It's really two different aspects of trying to look at this progress in the field: who it benefits and how much it means to the people who are in the study."

Blithe goes on to say that the study seems to mean a lot to the people participating in it. The participants are already eager for Phase 3. "I always say my favorite comment when we ask about acceptability is, 'Can I re-enroll?' Because it's almost a two-year commitment. That indicates, again, a great deal of acceptability of this method for many of the participants," she says. 

— BAGLEY IS THE SENIOR EDITOR OF *ENDOCRINE NEWS*. IN THE SEPTEMBER ISSUE, HE WROTE ABOUT THE ONGOING EFFORTS TO FUND WOMEN'S HEALTH RESEARCH.



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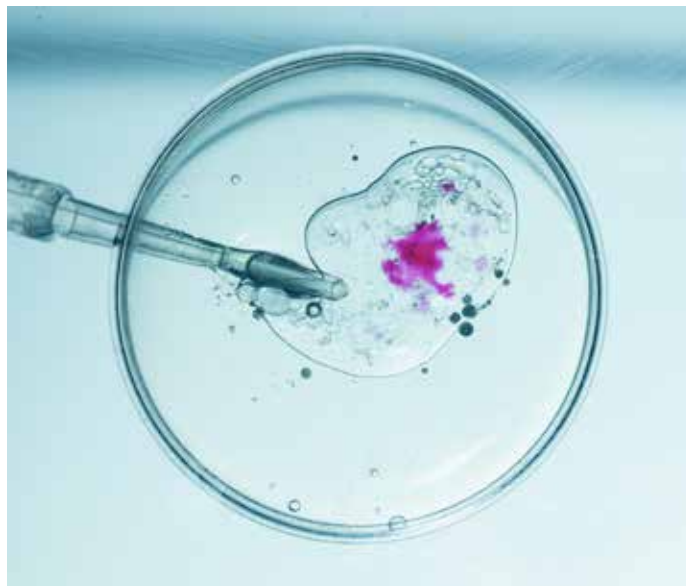
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## Endocrine Society Endorses Right to IVF Act



**I**n June 2024, the Endocrine Society endorsed the Right to IVF Act, introduced by Senators Cory Booker (D-NJ), Patty Murray (D-WA), and Tammy Duckworth (D-IL) to protect and expand nationwide access to fertility treatment, including in vitro fertilization (IVF).

The Right to IVF Act would help individuals and families impacted by infertility by establishing a statutory right to access IVF for all Americans who need it to start or grow a family and expanding access to coverage for IVF and fertility treatments. On September 17, 2024, Senate Majority Leader Chuck Schumer (D-NY) tried to proceed with a Senate vote on the bill, but Senate Republicans voted to block the bill. The 51 – 44 vote fell short of the 60-vote threshold needed to pass.

The Society has been a leading voice in advocating for access to IVF and fertility treatment. In some states, access to IVF is limited, and many states have banned or restricted access

to reproductive medical services, in some cases including IVF. In June, members of the Endocrine Society attended the American Medical Association's (AMA's) annual meeting in Chicago to advocate for IVF treatment. We co-authored a resolution with

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**The Society has been a leading voice in advocating for access to IVF and fertility treatment. In some states, access to IVF is limited, and many states have banned or restricted access to reproductive medical services, in some cases including IVF.**

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the American Society of Reproductive Medicine (ASRM) to oppose legislation, ballot measures, or court rulings that would restrict access to IVF treatment.

Endocrinologists are essential to IVF care, and we support access for all families across the country seeking safe and effective IVF treatment. The Society will continue to urge congressional leaders on both sides of the aisle to address access to IVF and other assisted reproductive technologies and will continue to advocate for our members who treat and research infertility and other hormone health conditions. For more information, please see our statement on our website ([endocrine.org/news-and-advocacy/news-room/2024](https://endocrine.org/news-and-advocacy/news-room/2024)).



As part of the 12th Annual Rally for Medical Research, Roy Jensen, MD, and Kristy Brown, PhD, did their parts to urge Congress to provide \$51.3 billion for the NIH.

## Society Joins the 12th Annual Rally for Medical Research Hill Day, Advocates for NIH Funding

**M**ore than 200 scientists, patients, and researchers visited Capitol Hill on Thursday, September 19, to advocate for funding increases for the National Institutes of Health (NIH) as part of the Rally for Medical Research Hill Day.

Endocrine Society members Drs. Kristy Brown, Lorenzo Smith, Patricia Morris, Shannon Whirledge, Nico West, and Aime Franco urged Congress to provide at least \$51.3 billion for the NIH and emphasized the need for leaders to work in a bipartisan manner to complete the funding process for Fiscal Year 2025 (FY 2025).

During our visits, we shared that the importance of steady, sustained investments are essential to research progress. Cuts to the NIH prevent groundbreaking discoveries that advance our understanding of and treatments for diabetes, obesity, endocrine-related cancers, osteoporosis, reproductive health, and other endocrine conditions.

In September, Congress passed a temporary spending bill to keep the government funded until December 20 before it recessed to campaign ahead of the November elections. While this move averted a government shutdown, funding for all federal programs, including the NIH, remains in jeopardy until Congress completes funding bills for FY 2025. The Endocrine Society will continue to urge Congress to complete the appropriations process for FY 2025 when it returns to Washington in November.

Check [www.endocrine.org/advocacy](http://www.endocrine.org/advocacy) for the latest updates for NIH funding.

## Endocrine Society Advocates on Capitol Hill for SDP, Extension of Medicare Telehealth Waivers, and Increased Physician Payment

Endocrine Society members Sara Rose MacLeod, DO, MPH; Natalia Chamorro-Pareja, MD; Whitney Goldner, MD; and Leslie Eiland, MD; visited Capitol Hill to advocate for the reauthorization of the Special Diabetes Program, extension of Medicare telehealth waivers, and increased Medicare physician payment.



**O**n Monday, September 9, Endocrine Society clinicians from across the country traveled to Capitol Hill to advocate for some of our top policy priorities: reauthorization of the Special Diabetes Program (SDP), extension of Medicare telehealth waivers, and increased Medicare physician payment.

In all of our meetings, we urged Congress to extend the SDP and Medicare Telehealth Flexibilities before they expire on December 31, 2024.

We also spent time discussing Medicare physician payment issues. We encouraged Congress to take action to avert the scheduled 2.8% cut to the Medicare Conversion Factor in 2025 and to provide an annual inflationary update in the Medicare Physician Fee Schedule. We also highlighted the Society's support of a provision of the Pay PCPs Act that would create a Technical Advisory Committee to improve the accuracy of values of reimbursement codes commonly used by endocrinologists.

As a result of our close relationships with leadership in the House and Senate, we also had meetings with the Senate Finance Committee to discuss the need for Medicare to cover anti-obesity medications and with the Senate Majority Leader and House Minority Leader to discuss a path forward for legislation that would expand the \$35/month cap on insulin for Medicare beneficiaries to people with private insurance and the uninsured.



Endocrine Society member Gabriel Castano, MD (right), with Sen. Chuck Grassley (R-IA) when several Society members were on the Hill in September to advocate for a variety of topics important to the field of endocrinology.

## Endocrine Society Co-Leads NIEHS Hill Day

As one of the lead organizations for the Friends of the National Institute of Environmental Health Sciences (NIEHS), the Endocrine Society works with a broad coalition of organizations to educate Congress about the important role the NIEHS plays within the broader biomedical research enterprise and how endocrine science advances the NIEHS mission.

On September 26, we joined scientific leaders from the NIEHS Environmental Health Science Core Centers to visit congressional representatives and share the latest discoveries and scientific advancements made possible through NIEHS-funded research, including in the field of endocrine-disrupting chemicals (EDCs). While requesting increased funding for the NIEHS as part of an overall increase in funding for the National Institutes of Health (NIH), we described the unique strengths of the NIEHS core program and their focus areas including advancing scientific research, promoting community engagement, advancing translational research, and training new researchers.

With our comprehensive approach to advocacy for biomedical research, we will continue to ask for steady and sustainable increases to NIH funding across all NIH Institutes and Centers to advance endocrine research throughout the NIH. <sup>EN</sup>



As a resident of Bethesda, Md., that makes Mihail Zilbermint, MD, a constituent of Rep. Jamie Raskin (D-MD), so he popped by for a quick photo op amid his advocacy duties on Capitol Hill.

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