

JUNE 2017

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

Endocrine news

INTERNATIONAL



Washington D.C. is as divided as the rest of the country when it comes to healthcare reform. *Endocrine News* presents an in-depth analysis of the American Health Care Act and what it could mean for endocrinologists practicing in the United States.

FACE off

FUNCTIONAL HYPOTHALAMIC AMENORRHEA:

A new Society guideline promotes a multifaceted approach

GEARING UP:

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COVER STORY

22 | The Healthcare Reform Tug of War

When the U.S. House of Representatives passed health reform legislation in yet another attempt to repeal Obamacare, there were more questions than answers. *Endocrine News* examines the new bill to let you know what's in it, what's not, what's at stake, where the Endocrine Society stands, and what's next for you and your patients.

BY MILA BECKER

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Although it sounds like a plot from a sudsy melodrama, more and more people who were conceived via sperm donation are discovering their half siblings ... sometimes dozens of them! The Food and Drug Administration only regulates screening and testing donors for diseases, many feel there needs to be more rules governing the use of these donations.

BY GLENDA FAUNTLEROY

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30 | No Easy Answers

The Endocrine Society's new clinical practice guideline on treating patients with functional hypothalamic amenorrhea highlights the need for a multidisciplinary approach to care. However, in some cases the patient must undertake certain lifestyle changes and that poses an entirely new set of challenges.

BY ERIC SEABORG

PRACTICE RESOURCES

37 | Making the Grade: Should You Get Certified in Obesity Medicine?

As trends go, obesity continues its climb to epidemic levels. Likewise, over the past five years the number of physicians certified in obesity medicine has increased tenfold. For clinicians who treat obese patients, getting certified in this specialty is a viable option.

BY ERIC SEABORG



Our Strategic Plan Drives Us Forward into Our Second Century

I AM VERY EXCITED TO BEGIN MY PRESIDENTIAL year and look forward to working with colleagues and staff to position the Society to address the challenges and opportunities in endocrinology. We have made great strides this past year in many areas, particularly in advocacy and global outreach, and will continue our efforts moving forward.

In mid-May, just one month after **ENDO 2017**, I met with the Annual Meeting Steering Committee (AMSC) to begin planning next year's **ENDO**, which will be held in Chicago. This talented and diverse group of members gathered for two and a half days to design an exciting, vibrant program. The AMSC is in the process of finalizing the program; I will share more information with you in the coming months.

Last year, we celebrated the Society's centennial and highlighted all the discoveries and advances in our field over the past 100 years. This year we begin the first year of our second century, and we need to embrace it with an open mind, enthusiasm, and determination to raise awareness of our discipline.

One of the major initiatives for this year is developing our next strategic plan, which we call SP4. Every five years or so, we embark on a process to update our Society's strategic plan. Each of our three strategic plans built upon the previous plan to strengthen our governance structure, emphasize our scientific and clinical excellence, and enhance our advocacy and outreach efforts. This year, an SP4 Task Force has been established to work with Council, staff, and consultants to develop the next plan. Our consultants have conducted a member research survey, including reaching out to past members and non-members to gain a better understanding of their needs. At **ENDO** in Orlando, Fla., several focus groups

were convened to obtain additional member feedback. An environmental scan of new and emerging opportunities is being conducted to provide further background information to better inform our discussions.

Later in June, in conjunction with our Council meeting, there will be a two-day strategic planning retreat. In addition to our Council members and the SP4 Task Force, we have invited several guests to join us for the strategic planning discussions. The guests were chosen to add diversity to the group by bringing different perspectives, not only from their professional role (basic scientists, clinical scientists, and physicians in practice) but also ethnic and geographic diversity as well as members at different stages of their career. The strategic planning conversation will begin at the retreat but will continue throughout the year, with the SP4 Task Force leading the process. This planning process will enable us to identify new opportunities to provide value to members and remain a valuable resource for endocrine scientists and clinicians. The next strategic plan will provide direction on how to focus our resources for maximum impact, ensure relevance of future products and programming, and expand our opportunities to influence and attract those who are engaged in the practice and science of endocrinology. SP4 will provide an updated roadmap for our priorities and will position our Society to be successful as we enter our second century.

“
This year we begin the first year of our second century, and we need to embrace it with an open mind, enthusiasm, and determination to raise awareness of our discipline.
”

I would like to thank all the members who have participated in the surveys, focus groups, and strategic discussions; your feedback is very important to this process. I look forward to sharing our Strategic Plan 4 with you later this year. Feel free to send me your comments at president@endocrine.org 

— **Lynnette Nieman, MD**, President, The Endocrine Society

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Keeping the modern research lab up to date as the technology evolves can often be a full-time job. Since most scientists would rather be focused on their research, *Endocrine News* has compiled a few of the coolest gadgets to make your lab life a little easier.

BY GLENDA FAUNTLEROY

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Hormone Science to Health



FROM THE **EDITOR**

Help Make *Endocrine News* Even Stronger

OVER THE PAST FEW YEARS, IT HAS BEEN HARD NOT TO NOTICE the amount of change that has taken place with *Endocrine News*. From refocused editorial content to an entirely new design and layout, *Endocrine News* is not the same magazine it was back in 2012. And that's not even taking into account the revamped website, our presence on Twitter (@Endocrine_News), and the newly launched bimonthly electronic newsletter, *Endocrine eNews*.

One of the shifts of the editorial content has been to place more of a focus on the Endocrine Society's greatest strength: You. While there are other publications in the endocrinology-specific space, *Endocrine News* stands apart from these other magazines for a variety of reasons, but the most important reason is our membership. We have the luxury of drawing on the experience and expertise of the Endocrine Society's members for our content. Whether it's a Q&A about an upcoming event or Clinical Practice Guideline or an in-depth feature on a recent article from one of the Society's esteemed peer-reviewed journals, *Endocrine News* quite clearly stands on the shoulders of giants.

To that end, here's what we have in mind for new types of articles in which you can contribute or recommend others who would be interested in contributing:

- ▶ **"Second Opinion"** — This column would tackle a topic in either the research or treatment realm that has two distinct approaches or thought processes. Endocrinology is such a complex field that there are many different opinions on how to reach the same goals or on whether certain goals should even be considered. Think of it as the *Endocrine News* version of the "Point/Counterpoint" segment that used to appear on *60 Minutes*.
- ▶ **"Peer Review"** — This column will be written by professionals in other specialties telling our readers about how important it is for them to work with endocrinologists. Whether it's a researcher in another field who needed an endocrine scientist's expertise to solve a complex problem or a clinician in another specialty who finally solved a patient's treatment conundrum thanks to an endocrinologist's contributions, these are the stories we want to tell. We hope you can help us find these professionals via your own experiences.
- ▶ **"First Person"** — These articles detail your experiences in your practice or research and are told from your point of view. So far, we've had members write about using the EndoECHO program in rural New Mexico; an early-career member's experience in Ethiopia as part of the Ambassador Exchange Program; and next month two members detail their involvement in a diabetes camp for kids. These articles are some of my favorites because they are written with so much passion.

If you have an idea or a candidate for any of the above topics, send me an email at mnewman@endocrine.org. Together we can ensure that *Endocrine News* remains the No. 1 magazine in the endocrinology space! 

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

JUNE 2017

Endocrine news

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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.



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“ I got certified in obesity medicine because I wanted to push the field in an academic direction. I felt like there should be strong guidelines, structure, and certain criteria that a physician who treats patients with obesity should meet. Just the way we do in any other field. My typical patients have fairly complex hormonal issues, with some kind of obesity problem as well. Obesity medicine overlaps several subspecialties, so being board-certified kind of forces you to understand some diabetes guidelines, lipid management, and hypertension, and basically to go back to the basics of a lot of metabolic disease.”

— **REKHA KUMAR, MD**, an endocrinologist who is an assistant professor of medicine at Weill Cornell Medical College in New York City, discussing why she got certified in obesity medicine in “Making the Grade” on page 37.

FROM THE CENTURY OF
ENDOCRINOLOGY TIMELINE

1939:

Nobel Prize in Chemistry Awarded to A. Butenandt and L. Ruzicka



In 1939, the Nobel Prize in Chemistry was divided equally between Adolf Friedrich Johann Butenandt “for his work on sex hormones” and Leopold Ruzicka “for his work on polymethylenes and higher terpenes.” In 1931 Butenandt isolated androsterone in pure, crystalline form. From androsterone he, as well as Ruzicka, independently obtained testosterone in 1939, a compound which had been obtained from the testes in 1935 by Ernst Laqueur. Progesterone was isolated by Butenandt from the corpus luteum in 1934.

For more about the Century of Endocrinology, go to: www.endocrine.org/timeline.

\$220,000

The average annual compensation for endocrinologists, according to the Physician Wealth and Debt Report 2017 from Medscape. The only specialties that scored lower were family medicine doctors (\$209K) and pediatricians (\$202K).

97

The number of unique nominees for 2018 Laureate Awards received by the Laureate Awards Committee.

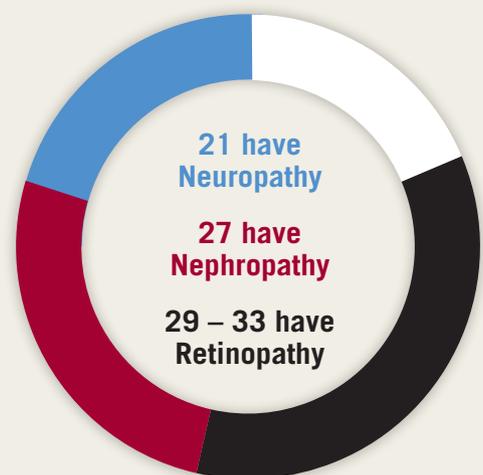
— **SOURCE:** JUNE 2017 ENDOCRINE SOCIETY COUNCIL REPORT

50%

The drop in personal bankruptcies from 2010 (1,536,799) to 2016 (770,846). This is believed to be linked to the implementation of the Affordable Care Act, which resulted in expanded healthcare accessibility.

— **SOURCE:** CONSUMER REPORTS

For Every 100 Americans with Diagnosed Diabetes



— **SOURCE:** ENDOCRINE FACT AND FIGURES: DIABETES. FIRST EDITION. 2015 (WWW.ENDOCRINEFACTS.ORG)

Society Applauds New Beauty Products Bill



The Endocrine Society praised the reintroduction of a Senate bill to ensure consumers are protected from hazards associated with exposure to chemicals in personal care products such as cosmetics and lotions.

The Personal Care Products Safety Act, co-sponsored by U.S. Sens. Dianne Feinstein and Susan Collins, would set a rigorous safety standard for personal care products and provide the public with more information about the chemicals in the products they are purchasing.

This is an area of concern for the Society and its 18,000 members, including researchers studying how endocrine-disrupting chemicals (EDCs) disrupt the body's hormones. There are more than 85,000 manufactured chemicals, of which thousands may be EDCs. EDCs are found in everyday products and throughout the environment.

The evidence is more definitive than ever before that EDCs disrupt hormones in a manner that harms human health. EDC-related health outcomes include male reproductive disorders, premature death, obesity and diabetes, neurological impacts, breast cancer, endometriosis, female reproductive disorders, immune disorders, liver cancer, osteoporosis, Parkinson's disease, prostate cancer, and thyroid disorders.

The Personal Care Products Safety Act calls for some chemicals found in shampoo, deodorant, cosmetics, and other personal care products to be reviewed for safety for the first time. The Society applauded the bill's inclusion of propyl paraben, a potential EDC linked to reproductive disorders, as one of the first five chemicals slated for review.

By providing the necessary authority and fees for the FDA to properly regulate personal care products, the Society believes



Sen. Dianne Feinstein (D-CA)



Sen. Susan Collins (R-ME)

that this legislation will effectively and efficiently ensure a safer marketplace for personal care products and reduce harms from exposure to EDCs and other toxic chemicals.

For more information on endocrine-disrupting chemicals, visit www.endocrine.org/topics/edc.

The Personal Care Products Safety Act amends the Federal Food, Drug, and Cosmetic Act and institutes new requirements for the FDA:

- ▶ Develop and implement cosmetic manufacturing standards that are consistent with existing national and international standards;
- ▶ Be allowed to inspect a company's cosmetic safety records;
- ▶ Recall a cosmetic that is likely to cause serious adverse health consequences; and
- ▶ Encourage cosmetic safety testing practices that minimize the use of animals.



Endocrine Reviews Debuts New Look in June

Readers of *Endocrine Reviews* will be pleasantly surprised when they receive their June issue and see the journal's new look, both inside and out.

The bimonthly journal, published by the Endocrine Society since 1980, has undergone an entirely new redesign to give the journal a more contemporary look and enhance readability.

This issue of *Endocrine Reviews* will introduce a new cover design and improved content format that will match the vitality of the published reviews within, according to the journal's editor-in-chief Len Wartofsky, MD, MACP, professor of medicine at Georgetown University School of Medicine, Washington, D.C. "A simple, straightforward eye-catching cover design will highlight the contents of each issue and other changes include new, more pleasing fonts and highly professional illustrations," he explains. "The quality of the cover illustrations will reflect refinements by our professional illustrators of the figures submitted with reviews."

Wartofsky adds that the revamped illustrations that will accompany the articles will be able to have a life beyond the pages of *Endocrine Reviews*. "All journal illustrations will be highly suitable for secondary use as teaching slides," he says. "The editors and publications staff hope that you will enjoy the fresh new look of *Endocrine Reviews*."

Endocrine Reviews publishes comprehensive, authoritative, and timely review articles balancing both experimental and clinical endocrinology themes and crystallizing the most significant clinical experience and current research in endocrinology and related areas such as cell biology, immunology, pharmacology, genetics, molecular biology, neuroscience, reproductive medicine, and pediatric endocrinology.

Access *Endocrine Reviews* online at <https://academic.oup.com/edrv> for articles, videos, and more.

MEMBERS
in the
NEWS



(L to R): Luigi Dei, rector, University of Florence, John K. Potts, Jr., MD, and Maria Luisa Brandi, professor, University of Florence, at the award ceremony in Florence, Italy, May 10, 2017.

Society Past President John Potts, Jr. Receives Honorary Degree

John Potts, Jr., MD, who served as president of the Endocrine Society from 1987 to 1988, was bestowed an honorary degree in medicine by the University of Florence, Italy, on May 10.

Potts, the Distinguished Jackson Professor of Clinical Medicine at the Massachusetts General Hospital (MGH) and Harvard Medical School in Boston, is an internationally recognized authority on calcium metabolism and the hormonal mechanisms that govern it. He is a pioneer in the chemistry and biology of parathyroid hormone (PTH) and its role in clinical disorders of bone and mineral ion metabolism. The author or co-author of over 500 scientific publications, Potts' accomplishments have been recognized worldwide, as this recent honor indicates.

The award that Potts received, the Laurea Honoris Causa in Medicine, is rarely given out by the University of Florence. In fact, the last time the honor was bestowed was over a decade ago. According to Maria Luisa Brandi, MD, PhD, professor of endocrinology, University of Florence, the process for awarding this honor is quite labor intensive and actually requires approval from Italy's Minister of Education.

Potts received the honor based on his innovative, transformative, and breakthrough research in the field of PTH as well as his research in calcium metabolism, his capability to build an incredible team of medical scientists, and his development of novel therapy to help patients affected by fractures. "For all these reasons, he represents a modern giant in medicine and I would certainly say in endocrinology — an ENDO-GIANT," says Brandi. "[He is] one of those people for whom a start comes to end in a circle, a Giotto circle! All of us admire him and consider his scientific life an example."

Potts is also a past recipient of the Endocrine Society's Fred Conrad Koch Laureate Award.

Society Members Elected to National Academy of Sciences

MEMBERS
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Endocrine Society members Barbara B. Kahn, MD, Mitchell A. Lazar, MD, PhD, and Christopher K. Glass, MD, PhD, have been elected to the National Academy of Sciences (NAS), which recognizes achievement in science and provides science, engineering, and health policy advice to the federal government and other organizations.



Kahn, an international leader in the field of diabetes, endocrinology and metabolism, is vice chair for research strategy in the Department of Medicine at Beth Israel Deaconess Medical Center (BIDMC) and the George R. Minot Professor of Medicine at Harvard Medical School.

In a career spanning nearly 30 years, she has made landmark contributions to the field of metabolic research, uncovering the complex mechanisms of insulin action, insulin resistance, and type 2 diabetes.

Kahn joined the Division of Endocrinology, Diabetes and Metabolism at BIDMC in 1986, and served as chief of the Diabetes Unit from 1990 to 2000 and Division Chief from 2000 to 2011 before becoming vice chair of research strategy in BIDMC's Department of Medicine. She has trained numerous outstanding scientists, who have gone on to successful careers in investigation worldwide.



Lazar is the Willard and Rhoda Ware Professor in Diabetes and Metabolic Diseases, founding director of the Penn Institute for Diabetes, Obesity, and Metabolism (IDOM) as well as chief of the division of Endocrinology, Diabetes, and Metabolism in the Perelman School of Medicine at the University of Pennsylvania.

His groundbreaking research has uncovered genetic and epigenomic mechanisms by which the environment interacts with the genome to regulate circadian rhythms

and metabolism, and how these impact the epidemics of obesity and diabetes. He has received awards from numerous international societies and universities, and has been elected to the American Society for Clinical Investigation, the Association of American Physicians, the National Academy of Medicine, and the American Academy of Arts and Sciences.



Glass, professor in the Departments of Medicine and Cellular and Molecular Medicine at University of California San Diego School of Medicine, serves as associate director of the Medical Scientist (MD/PhD) Training Program at UC San Diego School of Medicine.

His research focuses on how genes are turned on and off in macrophages, a type of immune cell, and how that influences macrophage development and function. His lab works to understand how the normally beneficial actions of the macrophage are subverted in inflammatory diseases, such as atherosclerosis, diabetes, and neurodegenerative disease. Their studies have uncovered basic mechanisms that regulate both protective and disease-causing functions of macrophages found in atherosclerotic lesions, fat tissue, and the brain.

In addition, Glass' team recently discovered how small genetic differences in regions of the genome that do not code for proteins can nonetheless influence the extent to which genes are turned on or off among different individuals and thereby influence risk of disease. These findings have implications for improved prediction, diagnosis, and treatment of a broad spectrum of human diseases.

Kahn, Lazar, and Glass join 84 new members and 21 foreign associates recently elected to NAS in recognition of their distinguished and continuing achievements in original research. The NAS is a private, nonprofit institution that was established under a congressional charter signed by President Abraham Lincoln in 1863.

MEMBERS
in the
NEWS

Teresa Woodruff, PhD

Teresa Woodruff Receives Multiple Honors

So far, 2017 has been a very rewarding year for Endocrine Society past-president Teresa Woodruff, PhD, who was honored by the John Simon Guggenheim Memorial Foundation, the American Institute for Medical and Biological Engineering, the Society of Endocrinology, and the Academy of Women's Health.

Woodruff, the Thomas J. Watkins Professor of Obstetrics & Gynecology, the vice chair of research (OB/GYN), the chief of the Division of Reproductive Science in Medicine, Feinberg School of Medicine, and Professor of Molecular Biosciences at the Weinberg College of Arts and Sciences at Northwestern University, was awarded the John Simon Guggenheim Memorial Foundation Fellowship in April. She was one of 173 fellows out of almost 3,000 potential applicants.

Through the Guggenheim fellowship Woodruff will generate an unprecedented view of germ cells across the globe — from ocean corals to humans. In her project, the Global Germ Cell Metallome, she will interrogate and catalogue the metal content and dynamics that comprise the inorganic signature of life in species that inhabit the most diverse corners of the world.

In March, Woodruff was inducted into the College of Fellows by the American Institute for Medical and Biological Engineering (AIMBE) for her outstanding contributions to ovarian biology and championship of policies that reduce

gender disparity in clinical research. She was one of 146 inductees that comprise the top 2% of medical and biological engineers in the country.

Woodruff's endocrinology colleagues across the Atlantic Ocean honored her with the 2017 Transatlantic Medal from the Society of Endocrinology. Each year, the Transatlantic Medal is given to a North American endocrinologist who has made significant contributions to the field of endocrine science. The medal was created to promote the relationship between endocrinology in the U.K. and North America.

Woodruff also received the 2017 *Journal of Women's Health* Award for Outstanding Achievement in Women's Health Research. *The Journal of Women's Health* is published by the Academy of Women's Health.

It should be noted that the first award Woodruff received this year was from the Endocrine Society; she received the 2017 Laureate Award for Outstanding Leadership in Endocrinology, which was covered in the January 2017 issue of *Endocrine News*. ^{EN}

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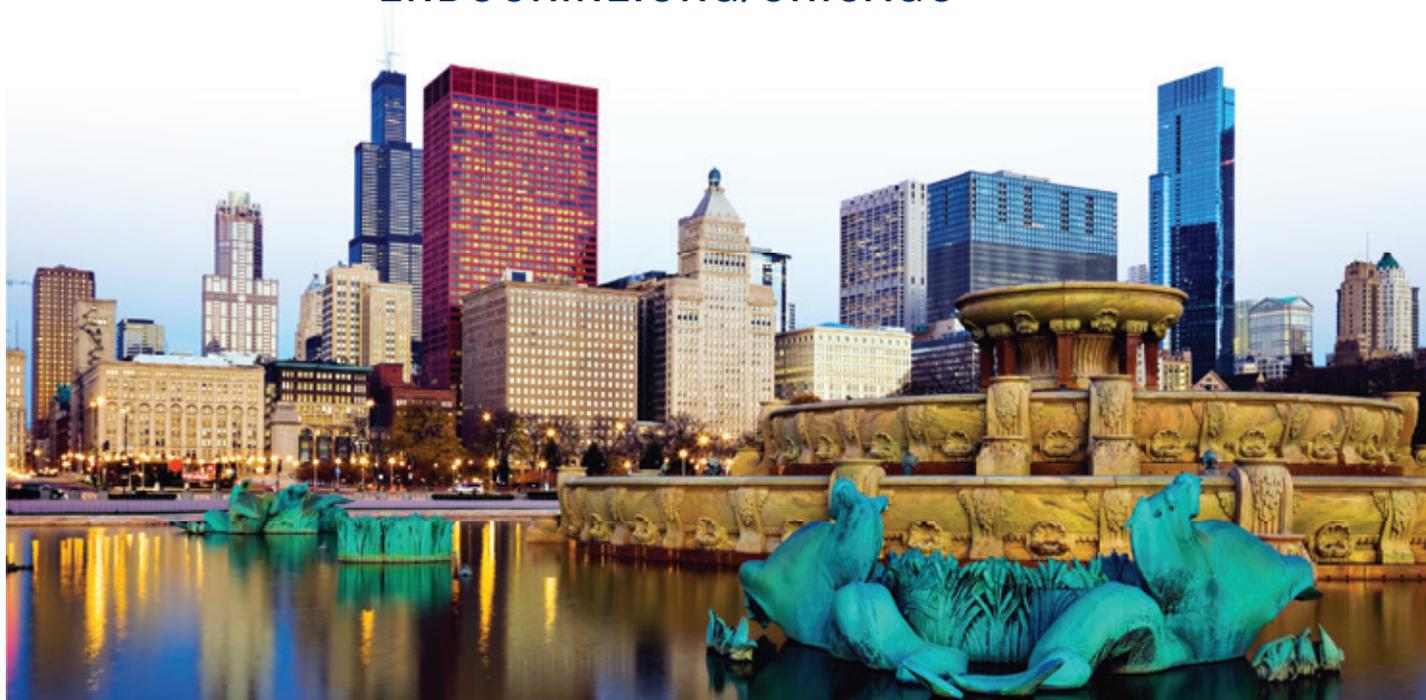
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SEPTEMBER 26-27

KEY DEADLINE

ADVANCED REGISTRATION—AUGUST 3, 2017

ENDOCRINE.ORG/CHICAGO



2017 Clinical Endocrinology Update/ Endocrine Board Review

Chicago, Ill.

September 23 – 27, 2017

www.endocrine.org/ceu

www.endocrine.org/ebr

Special discounts are available by registering for both meetings together.



The Chicago Marriott will be the location for the joint meeting of the 2017 Clinical Endocrinology Update (CEU)/Endocrine Board Review (EBR). Each year CEU brings together hundreds of endocrine clinicians for a unique learning experience and opportunities to network with expert faculty and colleagues. Attend the 69th CEU to receive the most trusted and clinically relevant information about recent advances in the field of endocrinology. The educational programming at CEU appeals to clinicians at all levels of practice, as well as fellows and other members of the clinical practice team.

Unlike other board preparation meetings, the EBR offers a comprehensive

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

Rapid Signaling & Genomic Hormone Action in Health & Disease

Snowmass, Colo., June 11 – 16, 2017

Hormone researchers from around the world will be attending the FASEB Science Research Conference focused on steroid hormone receptors. This five-day event will focus on nuclear and steroid hormone receptor and signaling pathway crosstalk in cancer, metabolism, neuroscience, immunology, and reproduction.

www.faseb.org/src/micro/Site/SteroidHormones/home.aspx

Dimensions in Diabetes

Mumbai, India, June 17 – 18, 2017

This annual program will bring high-quality clinical education to Indian endocrinologists. The goal of the program is to foster relationships with endocrinologists around India, while providing a clinical update in the field of diabetes. Supported by SunPharma, the two-day program brings in eight faculty members to present in-depth lectures on diabetes and its comorbidities.

www.endocrine.org

Santa Fe Bone Symposium

Santa Fe, N.M., August 4 – 5, 2017

This annual forum devoted to advances in the science and economics of osteoporosis, metabolic bone disease, and assessment of skeletal health is for healthcare providers, scientists, and researchers with a special interest in bone disease, and for bone densitometry technologists who seek a high level of knowledge in their field.

www.ofnm.org

EndoBridge 2017

Antalya, Turkey, October 19 – 22, 2017

Jointly organized by the Endocrine Society, the European Society of Endocrinology, and the Society of Endocrinology and Metabolism of Turkey, EndoBridge will provide a comprehensive update in the field of endocrinology. This meeting is designed for the clinical endocrinologist. The official language of the meeting is English, but simultaneous translation will be available in Russian, Arabic, and Turkish.

info@endobridge.org

19th ASEAN Federation of Endocrine Societies 2017

Yangon, Myanmar, November 9 – 12, 2017

ASEAN Federation of Endocrine Societies (AFES) is an association of seven endocrine societies in

Southeast Asia with a conference held every two years. With an extensive program covering a broad array of topics, various networking opportunities, poster sessions, continuing medical education, updates on new products and technologies at the AFES Expo, keynote speakers, and more, AFES 2017 is a “must-attend” event in Asia and one of the most recognized congresses among the clinicians and researchers in endocrinology.

www.afes2017myanmar.com

Translational Reproductive Biology and Clinical Reproductive Endocrinology 2017

New York, N.Y., November 16 – 19, 2017

The objective of this conference is to offer an authoritative 2017 update for reproductive clinicians and researchers, focusing on new translational developments in the field of reproductive biology and physiology, as well as clinically relevant patient-care issues. The conference aims to offer basic scientists and clinicians a unique and intimate framework for interactions and exchanges of ideas around paradigm changes and imminent new developments of significance.

www.afes2017myanmar.com

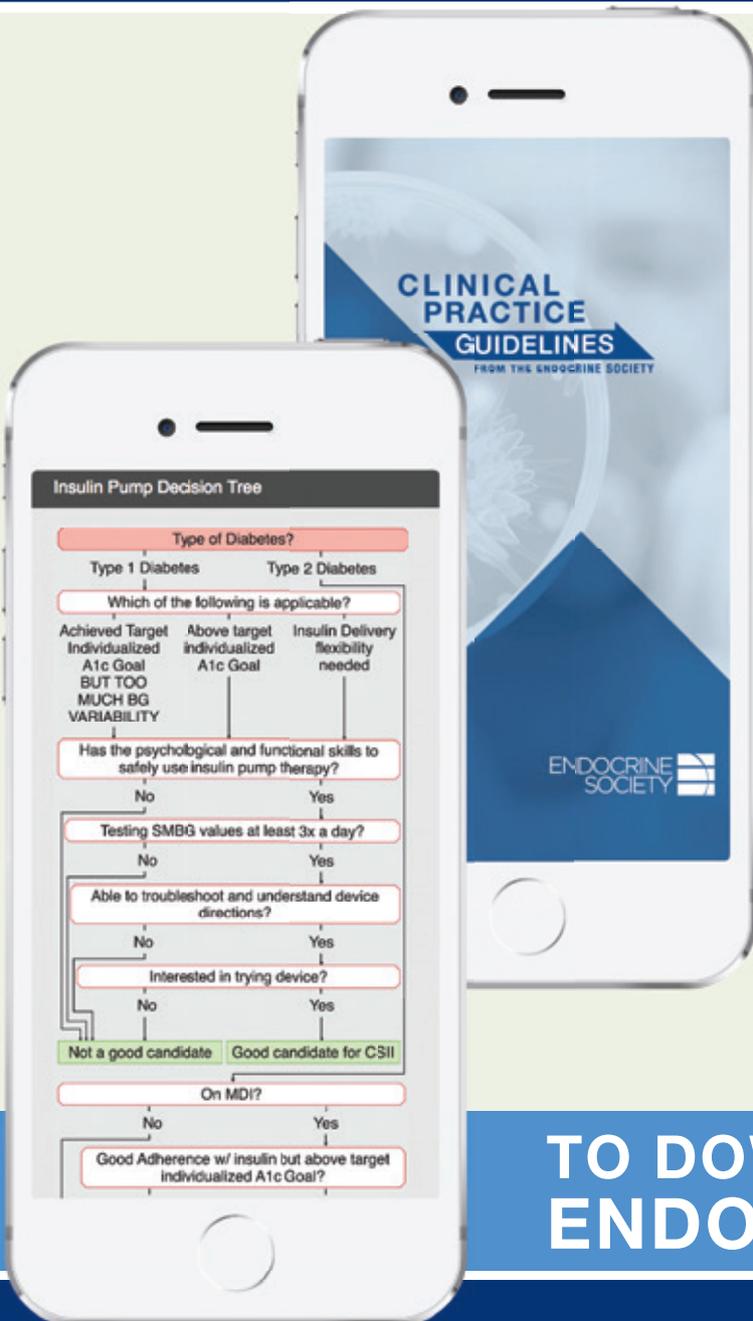
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BY DEREK BAGLEY



Childhood Obesity Quadruples Risk of Developing Type 2 Diabetes

Obese children have a fourfold greater risk of developing type 2 diabetes compared to their normal-weight counterparts, according to a study published in the *Journal of the Endocrine Society*.

Researchers led by Ali Abbasi, MD, PhD, of King's College London in London, U.K., point out that there is little known about the link between obesity and diabetes in children and young adults. The team developed a cohort study that used electronic health records from one of the largest primary care databases worldwide, the U.K. Clinical Practice Research Datalink, to pull data from 375 general practices. The researchers examined BMI measurements, diabetes diagnosis records, and other data for 369,362 children between the ages of 2 and 15 years. "The present study aimed to evaluate the incidence and temporal trends of type 1 and type 2 diabetes and to estimate the risk of developing diabetes associated with elevated BMI in a cohort of children and young adults with BMI recorded from 1994 through 2013," the authors write.

The researchers found 654 children and teenagers were diagnosed with type 2 diabetes and 1,318 were diagnosed with type 1 diabetes. Children and teenagers with obesity constituted nearly half of the type 2 diabetes cases — 308 in all. The study found no association between obesity and increased incidence of type 1 diabetes, which is linked to an underlying autoimmune disorder.

"As the prevalence of obesity and being overweight has rapidly risen, an increasing number of children and young adults have been diagnosed with diabetes in the United Kingdom since the early 1990s," says Abbasi. "A child with obesity faces a four-fold greater risk of being diagnosed with diabetes by age 25 than a counterpart who is normal weight."



Findings: The researchers conclude that increasing obesity rates are what's contributing to the rise in type 2 diabetes — but not type 1, and that children with obesity face a quadrupled risk of developing type 2 diabetes. "Diabetes imposes a heavy burden on society because the condition is common and costly to treat," Abbasi says. "Estimates indicate one in 11 adults has type 2 diabetes, or about 415 million people worldwide. Given that diabetes and obesity are preventable from early life, our findings and other research will hopefully motivate the public and policy makers to invest and engage in diabetes prevention efforts."



Low Body Mass Index Not Associated with Alzheimer's Disease

Low body mass index (BMI) is not associated with an increased risk of Alzheimer's disease after all, according to a recent study published in *The Journal of Clinical Endocrinology & Metabolism*.

Researchers led by Ruth Frikke-Schmidt, MD, DMSc, PhD, chief physician at Rigshospitalet in Copenhagen, Denmark, and associate research professor at the University of Copenhagen, point out that a recent study established that low BMI is associated with an increased risk of dementia, but Frikke-Schmidt's team wanted to clarify whether this observational association reflects a causal effect.

"Although prior studies found an association between Alzheimer's disease and low BMI, the new findings suggest this is not a causal relationship," Frikke-Schmidt says. "The association can likely be explained by the fact that individuals with Alzheimer's disease are more likely to have low BMIs due to loss of appetite and weight loss in the early stages of the disease."

The researchers studied 95,578 individuals from the Copenhagen General Population Study (CGPS) with up to 36 years of follow-up. Of the participants, 645 individuals developed Alzheimer's disease. The team also analyzed data from up to 249,796 individuals participating in the Genetic Investigation of ANthropometric Traits (GIANT) and the International Genomics of Alzheimer's Project (IGAP) consortium for the genetic variants closely linked to low BMI, using a Mendelian randomization approach. They analyzed the study participants' DNA for the presence of five genetic variants that have strong associations with BMI. Based on how many variants were found, participants were divided into four groups to reflect the likelihood of low BMI.

The analysis found that the presence of the genetic variants tied to low BMI was not associated with increased risk of Alzheimer's disease. For comparison, the researchers examined if individuals with genetic variants connected to high BMI were more likely to have type 2 diabetes and did find the expected causal relationship. The authors write: "The causal odds ratio for a 1 kg/m² genetically determined lower BMI was 0.98 (95% confidence interval: 0.77-1.23) for a weighted allele score in the CGPS. Using 32 BMI decreasing variants from GIANT and IGAP the causal odds ratio for Alzheimer's disease for a one standard deviation lower genetically determined BMI was 1.02 (0.86-1.22).

Corresponding observational hazard ratios from the CGPS were 1.07 (1.05-1.09) and 1.32 (1.20-1.46) for a 1 kg/m² and a 1 standard deviation lower BMI, respectively."

Findings: Based on these results, the authors conclude that low BMI is not a causal risk factor for Alzheimer's disease, "and that the corresponding observational association likely is explained by reverse causation or confounding." "We found individuals with lifelong low BMI due to genetic variation were not at increased risk of Alzheimer's disease," Frikke-Schmidt says. "Since genetic variants are not affected by other risk factors or diseases, this is a clean measure that can help to determine causality. The findings highlight that testing causality of a risk factor is pivotal before considering changing public health recommendations based on observational data alone."

Personalized Insulin Dosing Could Lead to Better Outcomes Following CABG Surgery



A study from Emory University published in the April 2017 issue of *Journal of Diabetes and Its Complications* observes a near-20% reduction in perioperative complications, a 1.2-day reduction in ICU stay, and a \$3,654 reduction in per-patient hospitalization costs for coronary artery bypass graft (CABG) surgery. The reported outcomes, which included no severe hypoglycemia less than 40 mg/dL, were derived from an intensive glycemic control protocol for personalized insulin dosing.

The study is a post-hoc cost analysis of the GLUCO-CABG trial published in the October 2015 issue of *Diabetes Care*. The GLUCO-CABG trial was a randomized open-label clinical study of CABG surgery patients with and without diabetes who experienced perioperative hyperglycemia (defined as a blood glucose greater than 140 mg/dL). A total of 302 patients between ages 18 and 80 were randomized to an intensive glycemic control group (target blood glucose of 100 to 140 mg/dL) or a conservative glycemic control group (target blood glucose of 141 to 180 mg/dL). Both groups were treated using intravenous insulin dosing while in the ICU.

“We observed a significant reduction in cost between those treated to the intensive target and those treated to the conservative target,” says a study author, Guillermo Umpierrez, MD, professor of medicine and director of Clinical Research for the Diabetes and Metabolism Center at Emory University. “This reduction, which was more than \$3,600 per patient, is the result of multiple factors. Not only did we reduce complications and length of stay, we reduced resource utilization across pharmacy, radiology, laboratory, consultations, and ICU.”

Study data indicate the mean blood glucose was 132.5 mg/dL among patients in the intensive glycemic control group and 154.4 mg/dL among patients in the conservative glycemic control group, which Umpierrez believes is the primary factor behind the reduction in perioperative complications (of near-

20%). Umpierrez also believes the reduction in complications contributed to the reduction in both ICU stay (of 1.2 days) and hospitalization costs.

“A measure advance in the treatment of inpatient hyperglycemia, especially in the intensive care area, has been the development of computer-guided algorithms for insulin dosing; also, alerts to help the nurses stay on top of glycemic indicators and blood glucose checks,” Umpierrez says.

The most important consideration in the improvement of glycemic control, Umpierrez says, is safety: “Hypoglycemia has been shown to be associated with higher morbidity, mortality, and hospitalization costs. Thus, physicians frequently avoid intensive glycemic control due to fear of hypoglycemia. To break treatment inertia, we need safe tools to improve glycemic control with minimal risk of hypoglycemia. I think the GLUCO-CABG trial and other studies recently published have clearly indicated that improving glycemic control with minimal risk of hypoglycemia results in improved outcomes.”

Findings: Another key observation from the post-hoc cost analysis of the GLUCO-CABG trial was the difference in economic outcomes when comparing patients with perioperative complications to patients without perioperative complications. “We found that patients with perioperative complications had a longer overall length of stay, by four days (10.7 days vs. 6.7 days; $p=0.001$), higher total hospitalization costs (\$48,299 vs. \$32,675; $p=0.001$), and more resource utilization units (2,745 vs. 1,710; $p=0.001$),” explains lead author Saumeth Cardona, clinical research coordinator IV in the Division of Endocrinology, Metabolism, and Lipids at Emory University.

Researchers Studying Novel Gestational Diabetes Screening Alternative



Researchers at Brigham and Women's Hospital (BWH) recently published a study demonstrating the potential clinical utility of glycated CD59 (GCD59) as a novel biomarker for the screening and diagnosis of gestational diabetes mellitus (GDM). The data from this study showed that a single blood test that measures plasma GCD59 at weeks 24–28 of gestation identified women with GDM with high sensitivity and specificity. The paper was published in *Diabetes Care*.

The study was completed by a team of investigators at BWH led by Jose A. Halperin, MD, associate professor of Medicine at Harvard Medical School in collaboration with researchers from Harvard T.H. Chan School of Public Health. Halperin is also the scientific co-founder of Mellitus — a company dedicated to advancing diabetes detection.

The protein known as CD59 is an inhibitor of the complement system that is inactivated by high glucose in diabetes to form glycated CD59 (GCD59). Inactivation of CD59 decreases its protective effect and promotes complement-mediated damage that reportedly plays a role in the processes leading to complications of diabetes such as nephropathy, neuropathy, and retinopathy.

Researchers evaluated levels of GCD59 in plasma samples from 1,000 women undergoing routine screening and diagnosis of GDM at weeks 24–28 of gestation at BWH. Five hundred of the samples were from women who had a normal GCT (controls) and another 500 were from women who had failed the GCT and completed a subsequent OGTT (cases). Of the cases, 127 were diagnosed with GDM. The primary objective of the study was to assess the accuracy of plasma GCD59 to predict the results of the GCT. Secondary aims were to assess the accuracy of plasma GCD59 in predicting the diagnosis of GDM by OGTT and the association of plasma GCD59 with the prevalence of large for gestational age (LGA) newborns.

The study found that, compared to controls, median levels of plasma GCD59 were 8.5-fold higher in women who failed the GCT and 10-fold higher in women diagnosed with GDM. Results also demonstrated that measurement of plasma GCD59 independently discriminated cases from controls with high sensitivity and specificity, even after adjustment for covariates such as maternal age, body mass index, race/ethnicity, multiplicity, gestational age, and previous history of diabetes.

An exclusive, worldwide license agreement with Harvard University covers Mellitus' development of the GCD59 technology for diagnostic applications and related therapeutics.

“The planned development of the GCD59 test by Mellitus supports our mission to foster innovation and collaborate with industry to translate new discoveries made at Harvard into useful products that are beneficial to society,” says Isaac T. Kohlberg, senior associate provost and chief technology development officer at Harvard University.

Findings: “This is the first study to demonstrate that a single measurement of plasma GCD59 can be used as a simplified method to identify women who would have failed a GCT and are at higher risk of GDM,” says Halperin. “These results indicate that measurement of this novel disease-associated biomarker may be a convenient and effective alternative to the cumbersome methods currently used to screen and diagnose GDM; the study opens the door to future multi-center studies to confirm the clinical utility of plasma GCD59 as a biomarker for detection and diagnosis of GDM.”

The Big CHILL

BY GLENDA FAUNTLEROY

Although it sounds like a plot from a sudsy melodrama, more and more people who were conceived via sperm donation are discovering their half siblings ... sometimes dozens of them! The Food and Drug Administration only regulates screening and testing donors for diseases, but many feel there needs to be more rules governing the use of these donations.

Her son was in preschool when he first asked about his *father*.



Ryan had more questions for his mother, Wendy Kramer, when he was six. When Kramer made the trip to the sperm bank in 1990 with her then-husband, she didn't realize answering her son's future questions would be so difficult.

"He was saying to me, 'I want to know who my biological father is,' and I'm thinking, well, of course you do," Kramer recalls.

Kramer later learned from the sperm bank that her son had half siblings from "donor 1050," and her son was anxious to meet them. So in 2000, Kramer started her search in a Yahoo group that soon grew into the Donor Sibling Registry after her story received national media attention, including an appearance on *Oprah* in 2002. Kramer was contacted right after the show aired by a mother who birthed two daughters with sperm from her same donor. And just like that her son suddenly had two half-sisters.

The Donor Sibling Registry now boasts nearly 53,500 members, including donors, parents, and donor-conceived people. But Kramer intends to do more than make matches between donors and offspring. She wants the Food and Drug Administration (FDA), the governing body in these matters, to institute more regulation in the sperm bank industry.

No one knows for sure how many individuals and couples seek sperm donation in the U.S. each year. The CDC's National Health Statistics reports that artificial insemination was used by about 714,000 women (1.7% of women ages 25–44) between 2006 and 2010. What is certain, is that an increasing demographic for sperm bank customers are single women and lesbian couples who pay anywhere from \$450 to \$1,000 for each vial of sperm used for artificial insemination. The industry is booming, and debates on how it should be regulated have increased.



Ryan and Wendy Kramer

Adequate Screening?

Sperm banks are only required to adhere to FDA regulations for the screening and testing of reproductive tissue donors: Donors' medical records should be screened for evidence of communicable diseases, and donors should be tested for infectious diseases, such as HIV, hepatitis B and C, and other STDs.

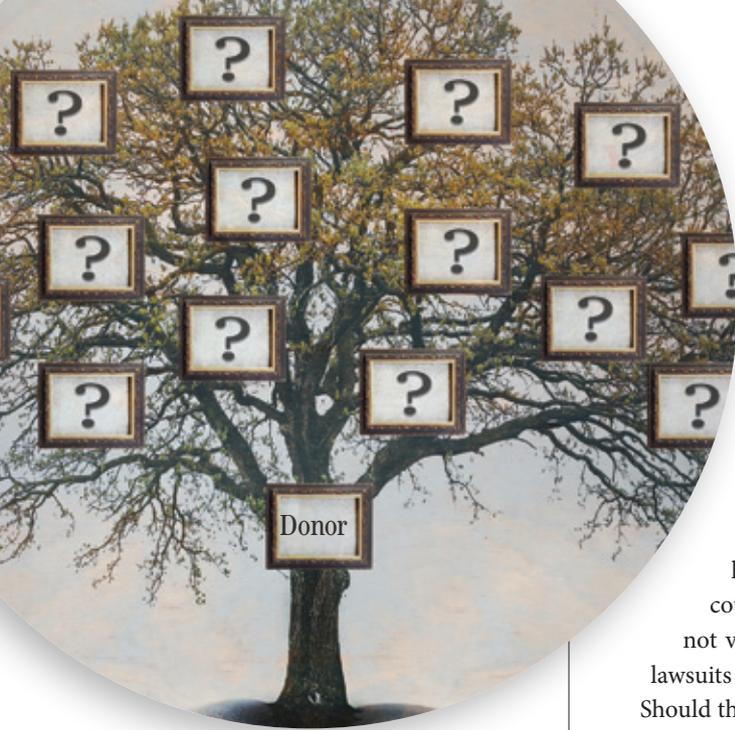
In their 2012 Committee Opinion "Recommendations for gamete and embryo donation," the American Society for Reproductive Medicine (ASRM) goes further and recommends a detailed medical history, complete physical examination, testing for STDs and some genetic diseases, and psychological counseling of the sperm recipients.

"Our member physicians follow our guidelines and if they are working with patients to acquire sperm from a bank, they want to see evidence in the facilities' records that they also adhere to our guidelines," says Eleanor Nicoll, public affairs manager at ASRM.

Most patients considering sperm donation ask reproductive endocrinologist Marguerite K. Shepard, MD, about picking a known donor, either a friend or a relative, and it's something Shepard discourages. She counsels them to use a bank instead.

"State law requires that even volunteer known donors are required to go through the same STD testing, freezing, six-month quarantine, and repeat STD testing as bank donors," says Shepard, professor Emerita in the Department of Obstetrics and Gynecology at Indiana University School of Medicine.

"The cost can get astronomical compared to the banked specimens because there is an economy of scale with the banks," she explains. "Banked specimens are carefully vetted with appropriate safeguards for disclosure."



“Proponents of the status quo in the U.S. have argued that eliminating anonymity would decrease the amount of donation. However, following the establishment of non-anonymity in the U.K. did not, in the end, decrease the number of donors.”



— ROBERT KLITZMAN, MD, FERTILITY DOCTOR AND BIOETHICIST, COLUMBIA UNIVERSITY, NEW YORK, N.Y.

Lawsuits and Headlines Spur Debate

A few attention-grabbing lawsuits and news stories have revealed the problems with limited regulations in the sperm donation industry.

Georgia-based Xytex Sperm Bank was sued in 2015 when a couple learned the donor of their daughter did not have multiple college degrees and an IQ of 160 as advertised by the bank. In fact, he was a college dropout with a diagnosis of schizophrenia, which the couple said gave their child a 10% chance of inheriting the disorder. The donor had reportedly at least 36 conceived offspring. Xytex argued that the couple knew the health information “was reported by the donor and were not verified by Xytex.” The case was later dismissed, but Xytex faces similar lawsuits in Canada from other families who have children from the same donor. Should the bank be held accountable?

And there was the 2011 *New York Times* article in which a mother revealed that her son’s donor had fathered 150 children. Both recipients and donors started asking why there was no cap on the number of children who can be fathered by one donor?

Although countries such as Britain, Sweden, and France have legal limits on how many children one donor can father, there is no such law in the U.S. The ASRM recommends restricting the number to 25. According to information on the Fairfax Cryobank website, it does cease a donor’s sales when 25 families have been reported in the U.S. The bank, however, depends on its customers to keep its records accurate and asks customers to “be diligent in reporting births” on its pregnancy reporting page.

“My donor donated three times a week for five years,” Kramer says. “It makes it very hard for banks to keep track of medical issues or of how many half-siblings are out there. And also for donors wondering how many kids they have.”

“So it’s very problematic because in our research we found that about a quarter of donors donate to more than one sperm bank,” Kramer says. “And, one sperm donation can be broken out into anywhere between six and 24 sellable vials of sperm.”

Do Donors Have a Right to Anonymity?

Sperm donations in the U.S. can be anonymous or directed (non-anonymous or known), but most are anonymous. Many clinics make the identity of the sperm donor available to a donor-conceived child at age 18 as part of “open identification,” but customers have to choose to use them so they can be effective.

Many donors’ offspring are claiming their right to know their biological donor.

“I think that offspring who are produced as a result of sperm donation have a right to know who the donor is, if they wish, and that this knowledge can be in their best interests,” says Robert Klitzman, MD, a fertility doctor and bioethicist at Columbia University in New York City.



Sperm banks are only required to adhere to FDA regulations for the screening and testing of reproductive tissue donors: Donors' medical records should be screened for evidence of communicable diseases, and donors should be tested for infectious diseases, such as HIV, hepatitis B and C, and other STDs.

“Proponents of the status quo in the U.S. have argued that eliminating anonymity would decrease the amount of donation,” Klitzman adds. “However, following the establishment of non-anonymity in the U.K. did not, in the end, decrease the number of donors.”

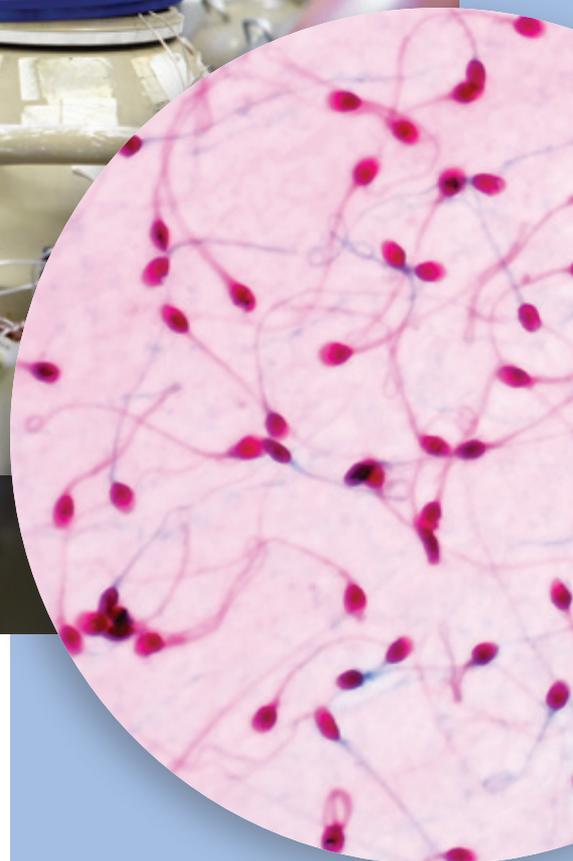
Rules on anonymity for sperm donors in the U.K. were changed in 2005 to allow any child born after that time to find their biological father at age 18. Over the past years, a growing number of countries have followed suit.

For its part, the ASRM believes that “disclosure to the child of the fact of donor conception and characteristics of the donor may serve the best interests of the offspring.”

“Anonymity is all an illusion anyway,” says Kramer. “With DNA testing, people are finding out that they are donor-conceived on a regular basis. My own son, just met two half-sisters two weeks ago. They didn’t know they were donor-conceived. One of them swabbed her cheek and put it into 23andMe (a DNA genetic testing site), and came back having a half-brother, and she’s like, ‘how can we have a half-brother?’”

Kramer’s son is now 26 years old and has matched with 10 half-siblings. He’s personally met six of them.

To date, Donor-Sibling Registry has helped connect more than 14,170 half-siblings and/or donors with each other. 



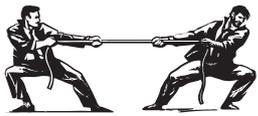
AT A GLANCE

- ▶ Sperm banks are only required to adhere to FDA regulations for the screening and testing of reproductive tissue donors.
- ▶ A few attention-grabbing lawsuits and news stories have revealed problems with limited regulations in the sperm donation industry.
- ▶ With DNA testing, people are finding out that they are donor-conceived on a regular basis.

FAUNTLEROY IS A CARMEL, IND-BASED FREELANCE WRITER AND A REGULAR CONTRIBUTOR TO *ENDOCRINE NEWS*. SHE WROTE ABOUT GENDER DISPARITIES IN THE LAB IN LAST MONTH’S LABORATORY NOTES COLUMN.



The Healthcare Reform TUG of WAR



BY MILA BECKER

When the U.S. House of Representatives passed health reform legislation in yet another attempt to repeal Obamacare, there were more questions than answers. *Endocrine News* examines the new bill to let you know what's in it, what's not, what's at stake, where the Endocrine Society stands, and what's next for you and your patients.

On May 4, the U.S. House of Representatives narrowly passed H.R. 1628, the American Health Care Act (AHCA) by a vote of 217-213. The legislation, designed to repeal and replace the Affordable Care Act (ACA), also known as “Obamacare,” was the top priority of the Trump administration and Republican congressional leadership.

During the two months prior to passage, the legislation went through numerous fits and starts, and in March it even appeared to be in jeopardy of never coming to a vote. However, a variety of changes were made to garner support of both conservative and moderate Republicans. The legislation now moves to the Senate where it faces a very uncertain future. Assuming united Democratic opposition, Republicans can afford to lose the support of no more than two of their senators to pass the bill. Already, many Republicans have expressed concerns with different aspects of the House legislation, and some

are calling for starting fresh, rather than work from the House proposal.

The Endocrine Society has been a long-standing advocate for affordable and adequate health insurance. In preparation for the congressional debate, the Society identified key, nonpartisan principles it believes should be incorporated into any proposal (see “Endocrine Society Core Principles for Health Reform Legislation” sidebar for details). Because the AHCA does not meet the Society’s health reform principles and would make coverage more expensive — if not out of reach — for poor and sick Americans, the Society opposed the legislation.

The health reform debate has been bitter, partisan, divisive, and confusing. It also has been fraught with misinformation. Consequently, *Endocrine News* wanted to take a look at what was actually included in the legislation, where the Endocrine Society stands, and what is next.



The American Health Care Act



“ The health reform debate has been bitter, partisan, divisive, and confusing. **It also has been fraught with misinformation.**”

Development of the AHCA

The original bill introduced on March 7 was passed through the House Energy and Commerce, Ways and Means, and Budget Committees. It then went to the Rules Committee prior to being considered by the House. On three different occasions, the House Rules Committee met and approved amendments to the bill that were incorporated into the text. For the most part, the major provisions of the AHCA as the bill stood on March 7 remain in the final bill, with some modifications reflected below:

- ✓ **Repeal of Mandates** — Repeal of the ACA’s employer and individual mandates (effective retroactively to December 31, 2015). As an alternative to the individual mandate, the AHCA imposes a one-year, 30% surcharge on the premium of an individual who has a break of more than 63 days in coverage.
- ✓ **Refundable Tax Credits** — Replacing the ACA tax credits and cost-sharing reductions with new refundable tax credits that vary by age for use by individuals who otherwise lack access to coverage (e.g., through an employer) and are phased out based on income. The credits do not vary by income (with lower-income individuals getting more in credits) and are not based on the cost of insurance in a given area.

✓ **Repeal of Taxes** — Repeal of the ACA's various taxes, including the medical device, pharmaceutical, and health insurance taxes, as well as delay of the tax on high-value, employer-sponsored health plans (known as the "Cadillac" tax). Subsequent amendments accelerated the repeal of some of the ACA taxes, such as the repeal of the net investment income tax, to 2017 (from 2018), while further delaying the repeal of certain other taxes, such as an additional repeal delay of a year for the Cadillac tax and an additional delay from 2017 to 2023 of the 0.9% additional Medicare tax.

✓ **Medicaid Expansion:**

- Eliminates the mandatory ACA requirement for states to expand Medicaid to 133% of the federal poverty level (FPL);
- Sunsets the ability of states to cover above 133% of FPL as of December 31, 2017;
- Preserves the ability of states to cover childless, non-disabled, non-elderly, non-pregnant adults at the state's regular matching percentage;
- Grandfathers expansion enrollees enrolled prior to December 31, 2019, at the 90% match rate for as long as they remain enrolled; and
- Limits enhanced federal match for grandfathered expansion enrollees to states that expanded as of March 1, 2017, thus prohibiting new states from expanding at the 90% match rate.

✓ **Medicaid Reform:**

- Implements in 2020 a per capita allotment funding approach across five beneficiary categories (children, blind and disabled, elderly, adults, and expansion adults);
- Allows a state the option to implement a block grant for specific populations (children and non-elderly, non-disabled, non-expansion adults);
- Repeals the ACA requirement that state Medicaid plans cover the entire essential health benefits (EHBs) packages, effective December 31, 2019;
- Retains the repeal of hospital disproportionate share cuts for non-expansion states effective Fiscal Year (FY) 2018 and for expansion states effective FY 2020;
- Added a state option for a work requirement for non-disabled, non-elderly, non-pregnant adults, subject to certain requirements, effective FY 2017; and
- Repeals the cuts in Medicaid Disproportionate Share Hospital (DSH) funding.

✓ **Safety-Net Funding for Non-Expansion States** — Beginning in 2018, provides \$10 billion in safety-net funding over five years to Medicaid non-expansion states. These states would receive an increased match rate of 100% for 2018–2021 and 95% in 2022 for services provided by safety-net providers. The allotment per



MAKE YOUR VOICE HEARD

The Endocrine Society will continue to advocate for its core principles and encourages its members to contact their Senators to make their voices heard. Please visit the Endocrine Society online advocacy center at www.endocrine.org/advocacy to learn how you can contact your senators.

state would be based on the number of individuals with incomes below 138% of FPL in the state in 2015, based on the American Community Survey.

- ✓ **Federal Insurance Regulations** — The bill does not repeal or alter many of the ACA's regulations on commercial insurance, including coverage of preventive services without cost sharing, allowing dependents to remain on their parents' policies up to age 26, no lifetime or annual policy limits, and medical loss ratio requirements. It did not alter the requirements for guaranteed issue and renewal, or the prohibition on pre-existing condition exclusions. The AHCA did change the ACA limitations on age-based variations in premiums from a maximum of 3:1 to 5:1, but it did not eliminate the EHB requirement except with regard to Medicaid expansion enrollees. *However, both the age-based premium and the EHB requirements could be impacted by the MacArthur Amendment (discussed below). That amendment could also impact the ACA's prohibition on pricing policies based on the insured's medical condition, which is otherwise not changed by the AHCA.*
- ✓ **"Pro Life" Provisions** — The bill cuts off Medicaid funding to Planned Parenthood for one year. It also does not allow the tax credit for purchasing insurance to be used on a plan that covers abortions.

Changes Made to the AHCA by Amendments & the Pre-existing Condition Debate

As noted above, a number of changes were made to the original bill after it was introduced. The key to ensuring passage was a compromise offered by Representative Tom MacArthur (R-NJ) that was further modified by an amendment by Representatives Fred Upton (R-MI) and Billy Long (R-MO).

Democrats and Republicans have made competing claims on whether the latest version of the healthcare bill maintains protections for people with pre-existing medical conditions. President Donald Trump has said, "Pre-existing conditions are in the bill. And I mandate it." While Senator Charles Schumer (D-NY) has said that "insurance companies could deny coverage to those with pre-existing conditions."

Neither of those comments quite gets it right. The latest version offers lesser protections than the ACA, but it does not allow insurers to deny coverage to someone with a health condition.

The MacArthur amendment would allow states to apply for waivers from certain ACA requirements for plans sold on the individual market, where those who buy their own insurance get coverage. Seven percent of the U.S. population, or 21.8 million people, are covered by health insurance purchased on the individual market.

The amendment calls for three waivers that would allow states to:

- ✓ **Increase how much insurers can charge based on age** — Under current law, insurers can charge older individuals up to three times as much as younger people. The AHCA, beginning in 2018, would allow insurers to charge older people up to five times as much, and the amendment would allow the ratio to go even higher.
- ✓ **Establish their own requirements for the essential health benefits** — Insurers currently must abide by a list of 10 benefits mandated by the ACA, known as EHB. The amendment would give the states the power to set their own EHBs, beginning in 2020.
- ✓ **Allow insurers to price policies based on health status in some cases** — The current law does not and the original bill would not allow insurers to set premiums based on health status. But the amendment would allow it for those who do not maintain continuous coverage, defined as a lapse of 63 days or more over the previous 12 months. Such policyholders could be charged higher premiums for pre-existing conditions for one year. After that, provided there wasn't another 63-day gap, the policyholder would get a new, less expensive premium that was not based on health status. This change would begin in 2019, or 2018 for those enrolling during special enrollment periods.

Under Obamacare, insurers could not deny anyone coverage based on their health status, and the amendment does not change that part. The House-passed bill would retain the "requirement to guarantee issue coverage" — which means coverage must be offered regardless of health status — and it would retain the "prohibition on pre-existing condition exclusions" — which forbids insurers from excluding coverage specifically for a policyholder's pre-existing conditions. But, a waiver would allow insurers to charge some with pre-existing conditions higher premiums.

“ Passage of the House bill is a significant step forward for Republicans to fulfill their promise to repeal and replace the ACA. **However, the prospects for enactment into law remains tenuous.**”



Waivers & Stability Programs

The original AHCA bill said that insurers, again on the individual market, were required to charge a 30% higher premium for one year to those entering the market who didn't have continuous coverage, defined as that 63-day lapse over the previous 12 months. The waiver, as proposed in the amendment, would enable states to instead allow insurers to price plans based on health status for those without continuous coverage. Consequently, consumers could be charged more than the 30% surcharge. States with such a waiver would also have to have either a "risk mitigation program," such as a high-risk pool, or participate in a new Federal Invisible Risk Sharing Program designed to help those with high medical costs.

To facilitate these programs, the bill creates a Patient and State Stability Fund, with \$100 billion in federal money over nine years and state matching requirements. States can apply to use the money for various purposes, including lowering out-of-pocket costs or setting up high-risk pools, which are state programs that cover high-risk individuals. Such pools existed in 35 states before the ACA, and they typically keep individual insurance market premiums down by keeping the high-risk (and high-cost) individuals in their own pool.

Instead of setting up their own programs, states could also use a default reinsurance program, administered by the Centers for Medicare and Medicaid Services (CMS), which would pay a percentage of high-cost claims. An additional \$15 billion would be used to set up the Federal Invisible Risk Sharing Program, another reinsurance program. (And \$15 billion is set aside specifically for maternity and mental health coverage.)

A state applying for the waiver to allow some insurance pricing based on health status would have to use Patient and State Stability Fund money for one of those options: their own program, CMS' default reinsurance, or the Federal Invisible Risk Sharing Program. What the waivers and stability programs would mean, however, for those with pre-existing conditions remains to be seen, as some analysts have predicted that health status underwriting could effectively make coverage completely unaffordable to people with pre-existing conditions.

To assist those with pre-existing conditions who find themselves facing higher premiums in waiver states, the Upton amendment provides an additional \$8 billion from 2018 to 2023. In addition, the higher premiums for those without continuous coverage would only last one year, provided the policyholder continued to have coverage. If there was not another 63-day gap, the policyholder would get a new premium that was not priced based on health status.

There is another way that the waivers could impact not just those with pre-existing conditions, but anyone buying an individual market plan. The ACA's EHB provision required insurance companies to cover 10 health services: ambulatory, emergency, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, rehabilitative services and devices, laboratory services, preventive care and chronic disease management, and pediatric services including dental and vision. The House-passed bill, however, allows states to propose their own EHBs, beginning in 2020. As a result, individual market policyholders could see a change in what benefits their insurance policies have to cover and the dollar amounts of coverage under the waiver program.



“ While the media typically focuses on the divisions between the parties, **disagreement and competitiveness between the House and Senate chambers can also be significant, even when both bodies are controlled by the same party.** This is especially true around a seminal piece of legislation such as the AHCA.”

Thus, President Trump’s claim that pre-existing condition protections were included in the House bill glosses over the fact that the bill weakens the ACA protections against higher premiums and less-generous benefit plans. Senator Schumer, meanwhile, was wrong to say that the bill goes “back to the day when insurance companies could deny coverage to those with pre-existing conditions.” Insurers would still be required to offer plans to anyone regardless of pre-existing conditions, although they could in some circumstances charge higher premiums based on health status.

Outlook for Legislation

Passage of the House bill is a significant step forward for Republicans to fulfill their promise to repeal and replace the ACA. However, the prospects for enactment into law remains tenuous. Now, it is the Senate’s turn to act. Its approach — both in process and substance — is expected to be dramatically different than that of the House for many reasons. Most senators serve broader constituencies than most House members. Further, the Senate process is different: The Senate uses an open-amendment process that gives the minority party the opportunity to be heard, and for this legislation, it must operate within budget reconciliation rules that allow the minority to strike provisions from the bill that do not meet the requirement to be directly budget-related. Finally, while the media typically

focuses on the divisions between the parties, disagreement and competitiveness between the House and Senate chambers can also be significant, even when both bodies are controlled by the same party. This is especially true around a seminal piece of legislation such as the AHCA.

It is to be expected that Senate Republicans will want to put their fingerprints on the contours of legislation to replace the ACA. If the margin of error in the House was narrow for AHCA passage, the margin in the Senate is razor thin. As in the House, it is unlikely that any Democrats will support legislation that aims to repeal the ACA. With only 52 Republican senators, and Vice President Mike Pence available to break a tie vote, it will be quite difficult to thread the needle of passage. There is a substantial and vocal constituency that is intensely opposed to the House-passed bill or any other bill to repeal the ACA. Following House passage, the chorus of voices — both pro and con — has grown even louder. As a consequence, many Republican and Democratic senators are likely to become more emboldened and entrenched in their respective philosophical and political viewpoints. 

BECKER IS THE CHIEF POLICY OFFICER AT THE ENDOCRINE SOCIETY. SHE OVERSEES THE GOVERNMENT AND PUBLIC AFFAIRS DEPARTMENT AND ALL ADVOCACY AND POLICY-RELATED ACTIVITIES.

INFORMATION FOR THIS ARTICLE WAS PREPARED BY THE HOLLAND & KNIGHT HEALTHCARE POLICY TEAM.



AFFORDABLE ACCESS TO HEALTH INSURANCE — Endocrinologists care for people who suffer from multiple chronic conditions that require access to coordinated care by many specialists. Many of these patients benefited from the ACA’s guarantee of health insurance with no annual or lifetime caps or pre-existing condition exclusions. The ACA has allowed many of these people to obtain affordable insurance coverage; the cost of care for endocrine conditions such as diabetes, which averages \$13,700 per year, is beyond the ability of most people to pay without insurance coverage. People with diabetes who do not have health insurance have 79% fewer physician office visits and are prescribed 68% fewer medications than people with insurance coverage — but they also have 55% more emergency department visits than people who have insurance.

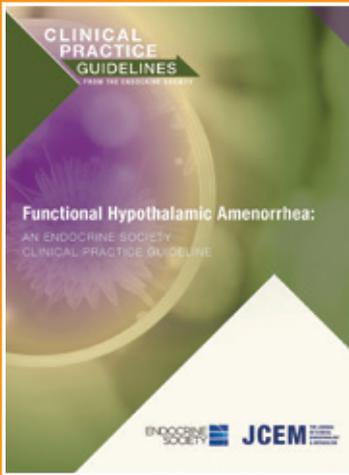
Alleviating some of the financial burden through insurance coverage allows those people with diabetes to follow the care plan developed with their physician and avoid costly complications. We believe strongly that no person who currently has health insurance should lose their coverage because of the repeal of the ACA. In summary, affordable access should include the following:

- A guarantee of health insurance coverage with no annual or lifetime caps or pre-existing conditions exclusions;
- An option for young adults to remain on their parents’ insurance plan until age 26; and
- Protections against unreasonable out-of-pocket costs that would cause a patient to delay or skip necessary healthcare.

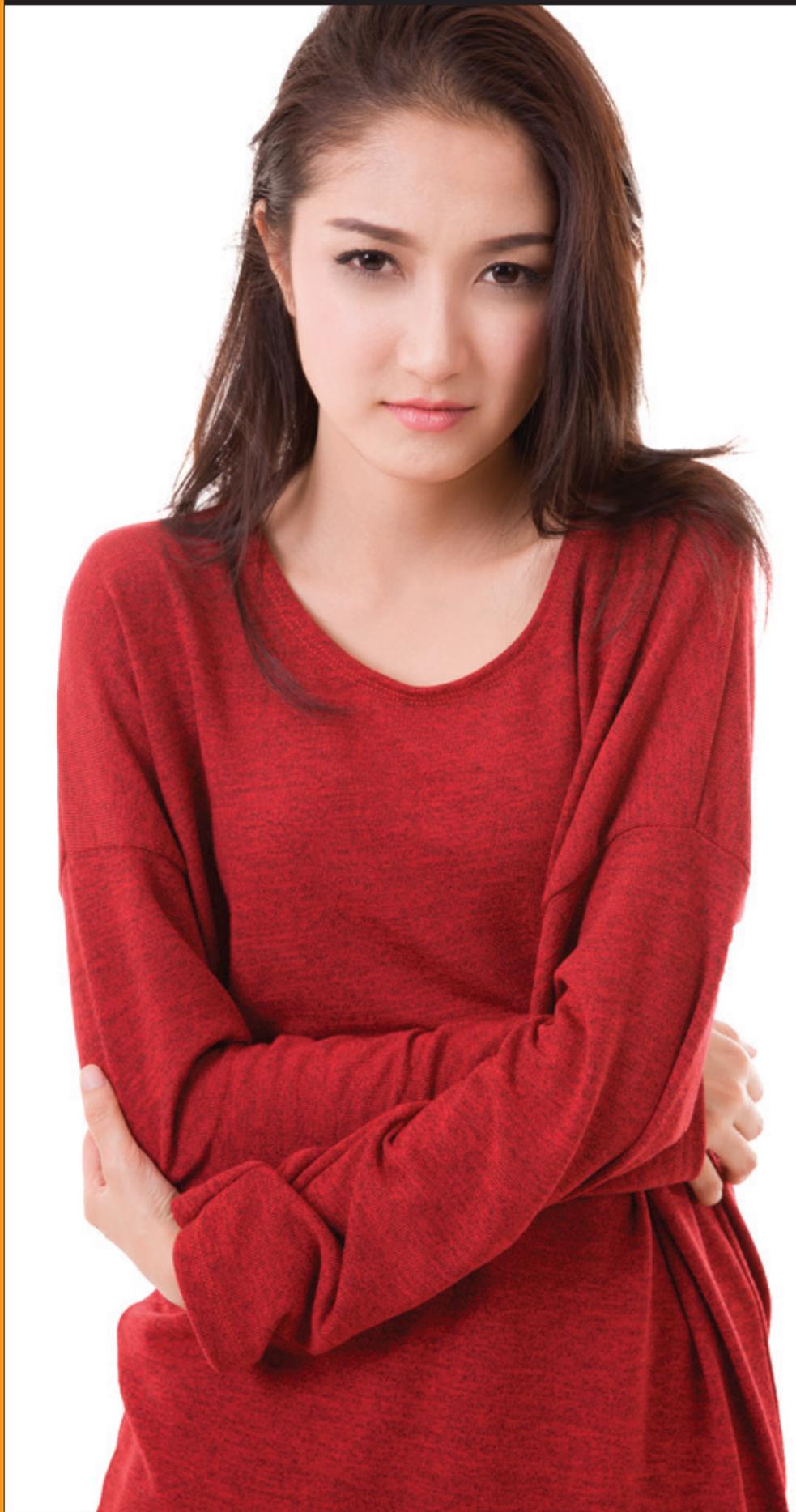
PREVENTIVE HEALTH BENEFITS — Patients with endocrine conditions have benefited from the elimination of beneficiary cost sharing for preventive screenings or care under the ACA. The ACA created the Prevention and Public Health Fund (PPHF), which has funded the expansion of effective prevention programs such as the evidence-based Diabetes Prevention Program (DPP). The DPP reduces the chances of a person with prediabetes from progressing to diabetes by 71%, resulting in savings of \$2,650 for each person enrolled. The number of Americans with prediabetes is estimated to be 86 million, with these people progressing to type 2 diabetes at a rate of 10% per year. Without PPHF funds, the Centers for Disease Control and Prevention (CDC) could not have expanded the DPP. Approximately 12% of the agency’s budget is funded through PPHF, and elimination of the Fund will have a significant impact on health programs beyond those funded by the CDC, as appropriators must reallocate funds within the Labor, Health and Human Services appropriation bill to allow the CDC programs to continue. Preventive healthcare improves the health of Americans while also reducing costs, and these programs must be continued under a new healthcare system. We believe it is critical that the Senate bill ensure access to preventive health services, including programs such as the DPP, at no cost to the beneficiary.

COORDINATED CARE — New care models developed through the ACA, such as accountable care organizations, or by the ACA-authorized Center for Medicare and Medicaid Innovation have increased the focus on providing coordinated care for people who are treated by multiple healthcare providers. Coordination (Innovation Center) of care has been shown to reduce costs and result in higher quality of care. A 2016 study found that people receiving the most fragmented care were more likely to receive care that departed from clinical best practices (32.8% vs. 25.9%), experience more preventable hospitalizations (9.1% vs. 7.1%), and pay more for care (\$10,396 average patient cost vs. \$5,854). As CMS implements the Medicare Access and CHIP Reauthorization Act (MACRA), the development of new payment models by the Innovation Center is critical to ensure that endocrinologists and other specialists can develop pathways to participate in alternative payment models (APMs). Any system that replaces the ACA must continue to support development of new models of care that Endocrine Society members can participate in and focus on coordinated care for people with multiple chronic conditions.

WOMEN’S HEALTH PROTECTIONS — Many conditions affecting women are the result of a disruption in the normal functioning of hormones in the body, such as menopause, infertility, breast cancer, and polycystic ovary syndrome. Treatment of these conditions is often provided by endocrinologists. The preventive health benefit has granted women access to contraception at no cost. While contraception allows a woman to plan when the right time is to start a family, hormonal contraception is also used to treat many endocrine conditions. We strongly urge that preventative health services, including contraception, continue to be covered free of charge under any ACA replacement plan. Ensuring that all women regardless of socioeconomic status have continued access to necessary healthcare services, contraception, and preventative screenings is a top priority for the Society. Furthermore, existing protections that ensure women are not charged higher premiums than men must be preserved.



The Endocrine Society's new clinical practice guideline on treating patients with functional hypothalamic amenorrhea highlights the need for a multidisciplinary approach to care. Patients generally must undertake lifestyle changes — and that poses a new set of challenges.



BY ERIC SEABORG

No Easy answers

When a very thin and active young woman presents complaining that she has stopped menstruating, the temptation may be to reach for an easy answer — but **the diagnosis and treatment may be somewhat complex, according to a new Endocrine Society guideline.**

Exercising too much, eating too little, and being under too much stress can lead to metabolic and hormonal problems — including the hypothalamus releasing too little GnRH in the condition known as functional hypothalamic amenorrhea (FHA).

But FHA is a “diagnosis of exclusion” that requires clinicians to rule out other conditions that could be interrupting the menstrual cycle — and requires treatment by a multidisciplinary team — says Catherine Gordon, MD, MSc, who chaired the committee that wrote the evidence-based report, “Functional Hypothalamic Amenorrhea: An Endocrine Society Clinical Practice Guideline.”

“It may be that this young person is not consuming enough calories, she may be overexercising, or she might be stressed, but we first have to make sure there is not an anatomic or organic abnormality that is causing the amenorrhea,” Gordon says. Clinicians need to rule out pregnancy and conditions that can halt menstruation, including benign tumors in the pituitary gland and adrenal gland disorders.

If the diagnosis is FHA, the key to overcoming it is alleviating the underlying causes. “It is easier said than done to get a young woman to change her ways,” Gordon says, and requires a multidisciplinary approach including medical, dietary, and mental health support.

Dispelling the Diagnostic Myths

“There are a lot of myths around the menstrual cycle and FHA, and we are hoping this guideline will dispel some of them,” Gordon says. The first myth is that menstrual irregularity is common in adolescent girls. “There may be some



“ There are a lot of myths around the menstrual cycle and FHA, and we are hoping this guideline will dispel some of them. There may be some irregularity during the first post-menarchal year, but thereafter, an adolescent should get into a regular cycle. If an adolescent’s or young woman’s periods have stopped or are only occurring every two or three months, that should be a red flag.”

— CATHERINE GORDON, MD, PROFESSOR OF PEDIATRICS,
UNIVERSITY OF CINCINNATI COLLEGE OF MEDICINE, AND
CHAIR OF THE GUIDELINE COMMITTEE

irregularity during the first post-menarchal year, but thereafter, an adolescent should get into a regular cycle. If an adolescent’s or young woman’s periods have stopped or are only occurring every two or three months, that should be a red flag that something could be going on,” says Gordon, who is a professor of pediatrics at the University of Cincinnati College of Medicine.

“There is another misconception that FHA is seen only in extremely underweight, over-exercising young women. But FHA could also occur in a normal weight young woman who is stressed. She may have just gone off to college and be anxious about a new environment and her academic work,” Gordon says. Some patients are of a normal weight and eating what they think is enough, but exercising so much that they have energy imbalance. “She may look completely healthy and not have an eating disorder, but she can still have FHA,” Gordon says.

Too Much of a Good Thing

“There is a spectrum of FHA,” Gordon says. At one end of the spectrum, some patients may have full-blown eating disorders that are hard to overcome, but at the other end are women whose attempts to follow a healthy lifestyle have gone awry. “Some patients set out to ‘eat healthy.’ ‘I’m going to eat a low-fat diet. I’m not going to overeat. I’m going to get more exercise.’ It is a good intent, but it can turn into too much of a good thing. It is a slippery slope. It starts out as a healthy intention, but a patient can become obsessed. An example is an elite young ballet dancer, gymnast, or figure skater who needs to perform at a certain level and feels that she performs her best at a low weight. It confers an advantage to have a very lean build,” Gordon says.

“I think clinicians don’t know how to care for these patients; there is a lot of confusion as to what they should be doing,” Gordon says. “Some are prescribing oral contraceptive pills, even though that is not the appropriate maneuver. The therapy for these patients is to eliminate that energy deficit. But it can be really hard to break habits and to convince patients that they need to eat a thousand more calories each day. If they are very used to eating in a ‘healthy’ fashion and exercising every day, they don’t want to change. They can become kind of addicted to that lifestyle, so they are often very resistant to change. They often are in denial of the problem and say to their health providers, ‘I feel fine.’”

Overcoming Denial

Because of this resistance to change, the guideline suggests a multidisciplinary approach to treatment, emphasizing the need for enlisting dietary and psychological support for the patient. Referring the patient to a nutritionist for dietary instructions can be an important part of their care. The guideline also recommends enlisting the help of a therapist. “We present some data showing that cognitive behavioral therapy can be helpful,” Gordon says.

“Eating disorders are a disease of denial. These patients don’t want to believe that anything is wrong with them,” Gordon says. Athletes and dancers can be on the milder end of the FHA spectrum, but overcoming denial can still be an important part of treatment. These patients are sometimes persuaded by the message that their amenorrhea is a sign that they should be concerned about, reflecting hormonal abnormalities that could affect them long term, including adverse effects on bone density. Gordon warns athletes about bone health and the danger of stress fractures: “Sometimes that is a hook or a wake-up call for dancers and runners. They are really committed to their sport, and they don’t want to get injured.”

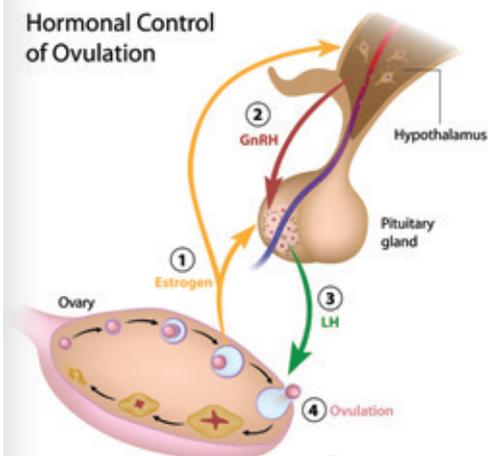
The Conundrum of Treating Bone

This bone density problem is important enough that it was the focus of a meta-analysis done in conjunction with the committee’s literature review. “We looked at skeletal agents that a clinician might prescribe to try to protect bone. There is a myth that giving young women oral contraceptive pills is beneficial for their bones,” which the literature review disproved, Gordon says.

“If you are unable to get patients to change their eating, stop over-exercising, or alleviate their stress, despite your multidisciplinary team, short-term transdermal estrogen therapy could be beneficial for the patient with longstanding amenorrhea,” Gordon explains. “Transdermal estrogen is metabolized differently than an oral contraceptive pill and other forms of oral estrogen. It is safer, less likely to be associated with an increase in clotting risk, and more bioavailable to bone. But I want to underscore that its use should be short term.”

“The other agents we looked at are bisphosphonates, which are prescribed commonly for postmenopausal osteoporosis. For adolescents and young women, there is not enough

Hormonal Control of Ovulation



AT A GLANCE

- ▶ **FHA is associated with stress, weight loss, or exercise — or a combination — but the diagnosis requires ruling out organic or anatomic causes of anovulation.**
- ▶ **A new Endocrine Society guideline recommends a multidisciplinary approach to treatment of FHA, including medical, dietary, and mental health support.**
- ▶ **The underlying cause of FHA can be a young woman’s overzealous approach to “healthy” behavior, and these habits can be difficult to change.**



Bones become brittle and fragile from loss of tissue, and hormonal abnormalities could affect them long term, including adverse effects on bone density. Athletes are warned about bone health and the danger of stress fractures in order to persuade them to make a lifestyle change.



evidence to support their use, and in fact, they may have some detrimental side effects,” Gordon says. “Bisphosphonates have a very long half-life and become intercalated into the skeleton. If the patient later becomes pregnant, pregnancy is a known high bone turnover state. The bisphosphonate could be released, and theoretically affect the fetal skeleton. So that is the major concern in women of reproductive age.”

Raising Awareness

The guideline “will be helpful” in raising awareness of FHA, says Robert W. Rebar, MD, chair of the department of obstetrics and gynecology at the Western Michigan University Homer Stryker M.D. School of Medicine: “The general obstetrician-gynecologist and the general internists don’t always think of FHA, so the guideline will be important in alerting clinicians to be cognizant of the condition.”

Rebar, who reviewed the guideline before it was released but was not on the committee that created it, said that the most valuable part could be the literature review. “They did a great job of surveying the literature, and a detailed job of summarizing it,” Rebar says. “This is a long and complex guideline that goes into lots of detail.”

Cosponsored by the American Society for Reproductive Medicine, European Society of Endocrinology, and Pediatric Endocrine Society, the guideline was published in the May issue of *The Journal of Clinical Endocrinology & Metabolism* and is available online at www.endocrine.org/CPGHypo. 

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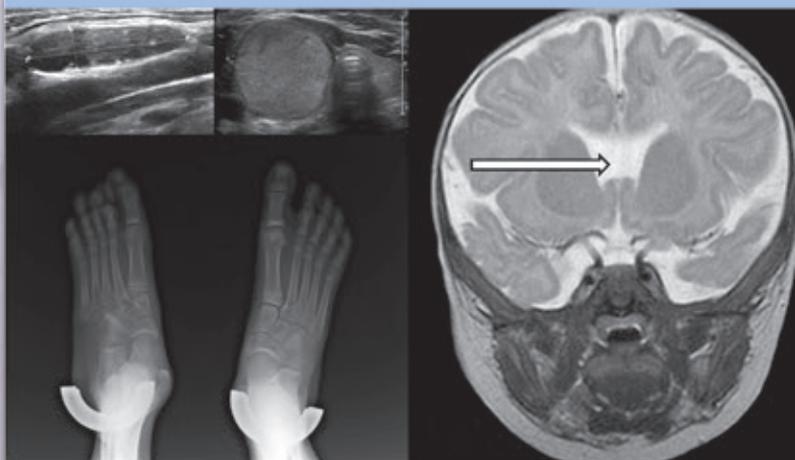
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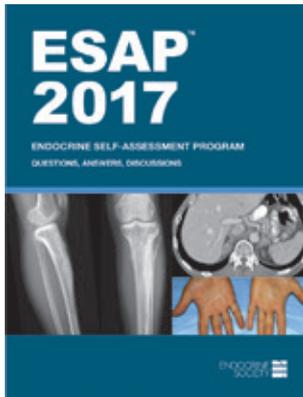
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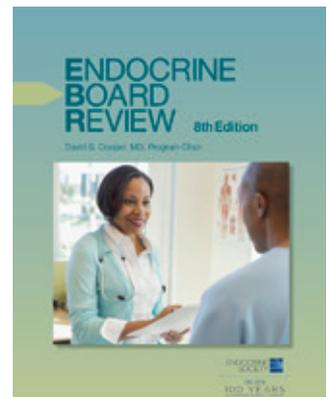


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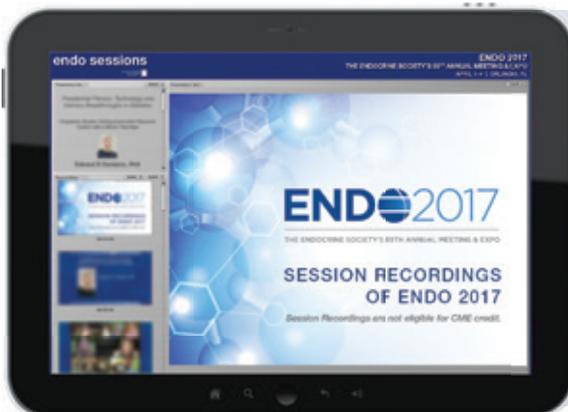
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Making *the* Grade:

Should You Get Certified in Obesity Medicine?



BY ERIC SEABORG

As trends go, obesity continues its climb to epidemic levels. Likewise, over the past five years the number of physicians certified in obesity medicine has increased tenfold. For clinicians who treat obese patients, getting certified in this specialty is a viable option.



As the obesity epidemic — and the need for evidence-based responses — continues to grow, many endocrinologists are reacting by gaining certification in obesity medicine. It is one of the newest and fastest-growing fields of medicine, increasing from 200 board-certified obesity doctors in 2012 to almost 2,000 today.

“I got certified in obesity medicine because I wanted to push the field in an academic direction,” says Rekha Kumar, MD, an endocrinologist who is an assistant professor of medicine at Weill Cornell Medical College, in New York, N.Y. “I felt like there should be strong guidelines, structure, and certain criteria that a physician who treats patients with obesity should meet. Just the way we do in any other field. My typical patients have fairly complex hormonal issues, with some kind of obesity problem as well. Obesity medicine overlaps several subspecialties, so being board-certified kind of forces you to understand some diabetes guidelines, lipid management, and hypertension, and basically to go back to the basics of a lot of metabolic disease.”

The certification movement is an attempt to ensure the practice of evidence-based medicine in this relatively new field, according to Scott Kahan, MD, MPH, a member of the board of directors of the American Board of Obesity Medicine (ABOM) and medical director of the Strategies to Overcome and Prevent (STOP) Obesity Alliance at George Washington University. “Part of what ABOM is doing is standardizing the expected reasonable practices for obesity treatment and trying to weed out practitioners who are not practicing appropriately [with] evidence-based practices,” Kahan says.

“I practice obesity medicine in New York, where there are a lot of doctors who claim to do weight management,” Kumar says. “But when there is no proper licensure or board certification, sometimes you see practice habits or behaviors that might cross more into the cosmetic world or unregulated supplement world. Because I practice in an academic environment, I want to have a legitimate educational background and certification for my patients to know that I am practicing according to academic guidelines.”

The Certification Process

The ABOM obesity medicine certification process differs from those of other subspecialties in that there is no requirement for a fellowship or internship, which is a recognition that there are very few such training programs.

Certification requires completion of 60 hours of continuing medical education hours in obesity-related topics in 36 months and passing an exam similar to those in other subspecialties.

“We went through a very in-depth, systematic process to identify the key competencies that obesity medicine physicians need to know” in developing the exam, Kahan says. “We worked with the National Board of Medical Examiners to create appropriate, didactic testing for board certification.”

The American Board of Medical Specialties (ABMS) does not yet recognize the certification, but ABOM is working toward that goal. “It is about a decade-long process, and we are over halfway there,” Kahan says. He believes that ABMS recognition will be a

step toward “better reimbursement for people who are certified in obesity. In the future, I anticipate that payers, whether Medicare or private payers, will select for board certification as a prerequisite for payment for specialists that are billing for obesity medicine services.”

Endocrinology is third among the specialties of those receiving certification, behind internal medicine and family medicine. Other specialties include obstetrics/gynecology, pediatrics, surgery, and gastroenterology.

Benefits of Certification

Kumar says that obesity is a complex disease, and “it is very difficult to treat if you haven’t been educated in it.” The certification process helped her learn the best practices for treating patients, for example, learning more about nutrition, a topic given little attention in most medical schools.

“Unless a physician understands the mechanism by which body weight is regulated, and what a complex disease obesity is, it is very difficult to treat,” she says. “You have to learn a fair amount of nutrition to take care of bariatric surgery patients, for example. It is easy to get lost in fad diets and things that are nonscientific. It is hard to differentiate the science from the non-science. What surprised me the most was learning the real science of basal metabolism and what determines how you burn calories. I think the biggest misconception for people who aren’t trained in this field is that there is one type of diet that is the proper diet to treat patients with obesity, when in reality, obesity is a very complex, heterogeneous condition, and a diet that is right for one person might not be right for another person.”

Choosing Among Options

Kahan says the advantage of board certification is that you have knowledge of the variety of obesity treatments and can match patients with the most appropriate treatments. “I have everything at my fingertips. I don’t do surgery, but I have a number of surgeons that I refer appropriate patients to. I can talk to patients about what surgery is and what the expectations are and help to identify good candidates. I don’t do endoscopic procedures to insert gastric balloons, but I have a range of referrals, and I can talk to patients about the benefits and drawbacks of the procedures. Although I prescribe medications, they are not for everyone, and I can talk about the benefits and risks. I counsel on nutrition and behavioral changes, and I also have dietitians and behavioral specialists that I can refer patients to in our clinic,” he says.

“Obesity treatment is still a ‘wild west’ sort of field. You have lots of practitioners and clinics and strip mall centers that are doing some pretty crazy and inappropriate stuff around obesity treatment.”

— SCOTT KAHAN, MD, MPH, A MEMBER OF THE BOARD OF DIRECTORS OF THE AMERICAN BOARD OF OBESITY MEDICINE (ABOM) AND MEDICAL DIRECTOR OF THE STRATEGIES TO OVERCOME AND PREVENT (STOP) OBESITY ALLIANCE AT GEORGE WASHINGTON UNIVERSITY

He says that obesity treatment is still “a ‘wild west’ sort of field. “You have lots of practitioners and clinics and strip mall centers that are doing some pretty crazy and inappropriate stuff around obesity treatment,” Kahan explains. “They are using supplements that have no data for efficacy for addressing obesity and that don’t have sufficient safety data. They are using concoctions of medications that are not approved for obesity and often selling them out of their offices. ABOM is standardizing the expected reasonable practices for obesity treatment and trying to weed out these practitioners who are not using appropriate evidence-based practices.”

Supporting the Field

“Board certification is the traditional accepted designation of professionalism in medicine, so if you are practicing obesity medicine, you should want to prove that by way of doing the requirements for certification and passing the exam to show that you have that expert level of knowledge and practice,” Kahan says.

“Another important reason to get certified is to support the movement of this field. We have worked hard over the past decade to take obesity medicine from an unrecognized field to one with a set of standards of knowledge and expertise. I think anyone involved in the field, even if they may not see immediate benefits in getting certified, has a responsibility to help move the field forward by supporting the ABOM and the process of board certification,” Kahan concludes.

Information on certification can be found at www.abom.org.

SEABORG IS A FREELANCE WRITER BASED IN CHARLOTTESVILLE, VA. HE WROTE ABOUT A VARIETY OF NEW OPTIONS TO TREAT OBESITY IN THE MARCH ISSUE.

Labs *Made* Easier

BY GLENDA FAUNTLEROY

Keeping the modern research lab up-to-date as the technology evolves can often be a full-time job. Since most scientists would rather be focused on their research, *Endocrine News* has compiled a few of the coolest gadgets to make your lab life a little easier.



Bead Baths

Experts agree that using metallic bath beads instead of water can eliminate the majority of sample contamination that happens in water baths. Usually, contamination occurs from the water in a bath or when something contaminated — such as the bench, a glove, or vessel — touches the sample before it's placed in the bath. While bead baths are not new to the market, many lab managers are making the switch to enjoy the many advantages. Bead baths can keep a lab greener and can heat samples while using less energy. They also save time from reworking ruined experiments and cut out cleaning and filling work. Take a look at Lab Armor's dry bead bath products. www.labarmor.com



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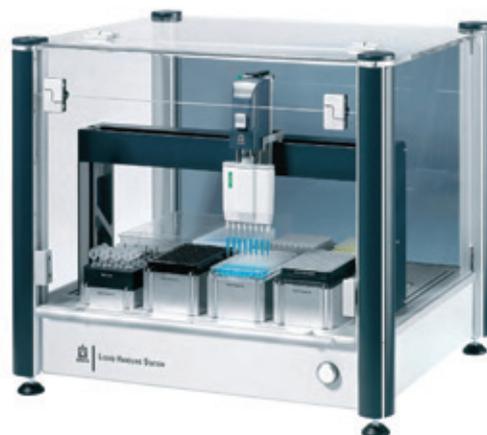
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If your budget allows, considering an automated liquid pipette handling system (pipetting robots) may be worth the investment. The system can run your lab's samples independently for hours on end, saving time and eliminating human error and fatigue. Systems range in price and options, but the most popular are stand-alone or individual benchtop workstations. Vendors include Aurora Biomed's VERSA series (www.aurorbiomed.com) and BrandTech Scientific (www.brandtech.com).



SPACE SAVERS



Space-saving CO2 incubator

If limited space in your lab is an issue, Caron's new Wally CO2 incubator is a perfect solution. Unlike traditional cube incubators where most of the space in the rear of the unit goes unused, the Wally unit has a slim, rectangular, wall-hugging design to conserve space in crowded areas. The incubator has a no-touch door opening, smart glass culture space viewing, and easier culture access. www.caronproducts.com



NuWind Centrifuge

NuAire boasts that its new general purpose NuWind Centrifuge is "smaller in size, big in capacity" to spare you valuable counter space. It also offers timesavers such as a tool-free rotor exchange and the ability to use the same rotor to spin plates and tubes on a single run. www.nuaire.com



Combination Refrigerator and Freezer

The Jewett Dual-Temperature Refrigerator/Freezer by Thermo Scientific™ allows you to cool your specimens while saving space. Two separate compartments give cold storage at temperatures of 1° to 8°C (refrigerator) and -20°C (freezer). Includes a door key lock for added security and an optional alarm/monitoring system. www.thermofisher.com

Congress Passes FY 2017 Funding with \$2 Billion Increase for the NIH



By April 27, both the U.S. House of Representatives and the Senate passed legislation to keep the government funded through September 30, 2017, and it included a \$2 billion increase for the National Institutes of Health (NIH).

This was one of the Endocrine Society's top advocacy priorities as grant funding for our member researchers was at stake. The bill also included an increase for the National Diabetes Prevention Program, for which we advocated. We visited congressional offices, we had our members call their representatives and senators, and we employed a lot of social media. We want to thank the hundreds of Society members who took action on our online advocacy campaign — our most successful one to date.

This is a big victory for us! The Society's Government and Public Affairs Department has prepared a summary of the bill below:

Fiscal Year 2017 Omnibus Appropriations Summary

The FY 2017 omnibus appropriations bill includes a full year appropriation (through September 30, 2017) for all government agencies except the Department of Veterans Affairs (which was previously funded) at an overall level of \$1.070 trillion. Although our priority program areas were initially threatened with significant cuts, the final bill included \$34.08 billion for the NIH, 6.2% increase, and \$22 million, a 12.5% increase, for the National Diabetes Prevention Program (NDPP). In addition to the specific funding levels for programs, the omnibus appropriations bill was accompanied by language with instructions to federal agencies about certain policies. The

following is a list of significant funding and language relevant to Endocrine Society priorities.

National Institutes of Health

The omnibus bill provides the NIH with a \$2 billion increase over FY 2016 funding, however, some of the funds are dedicated to specific research areas, for instance: \$352 million in funds are specifically for those projects related to the 21st Century Cures Act; the BRAIN initiative, the Precision Medicine Initiative, antibiotic resistance, and the Cancer Moonshot. Another \$152 million was allocated to the National Institute of Allergy and Infectious Diseases (NIAID) to fund research on the Zika virus, and the National Institute of Aging (NIA) received an additional \$400 million for research efforts related to Alzheimer's disease. Funds for the Clinical and Translational Science Awards were increased to slightly over \$516 million, and Congress directed National Center for Advancing Translational Sciences (NCATS) to maintain the same number of Clinical and Translational Science Awards (CTSAs) in FY 2017. Funding for the Institutional Development Awards were increased to a little more than \$333 million.

The NIH is expected to: support an increase in the number of new and competing Research Project Grants, support a consistent NIH-wide inflationary policy across all institutes, continue its focus on emerging investigators and first-time renewals of young investigators with actions to significantly reduce the average age of an NIH-supported new investigator, and provide an update in the FY 2018 budget request on how the NIH is implementing

changes to ensure that new policies to balance gender and sex in clinical and pre-clinical research are in place.

Diabetes

The NDPP received an increase of \$2.5 million to bring total funding for the program to \$22.5 million. The Senate report further requested an update in FY 2018 on the feasibility of establishing a certification process for NDPP providers within the Centers for Medicare and Medicaid Services (CMS). The Centers for Disease Control and Prevention (CDC) also received a total of \$72 million for the diabetes division, and the agreement supports CMS' expansion of the Medicare Diabetes Prevention Program beginning in January 2018 to improve health outcomes and reduce diabetes-related healthcare costs. The total increase in diabetes prevention and control efforts amounts to \$185 million, with the expectation that the increase

will go to communities with the highest burden of disease to support scientifically validated risk factor reduction measures. Of note, the bill did not include funding for the Special Diabetes Program (SDP), which we expect to be attached to legislation later this year.

Medicare Physician Payment

In addition to the Senate request for an update on the feasibility of establishing a certification process for NDPP providers in FY 2018, the House and Senate reports requested an update on planned or on-going research related to Evaluation and Management (E&M) Codes. The Senate specifically encouraged CMS to use these findings to develop new outpatient service codes and the associated documentation requirements, and then revise the other evaluation and management code families, with an update on progress in 2018.



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NIH Proposes Limits of Total Grant Support to Individual Investigators



NIH principle deputy director
Lawrence A. Tabak, DDS, PhD

In May, the National Institutes of Health (NIH) proposed a new policy aimed at addressing the hypercompetitive atmosphere in biomedical research and supporting a more stable research workforce. Specifically, the NIH is planning to place a cap on total research support that may be received by an individual investigator from the NIH based on a new index called the Grant Support Index (GSI). Although at the time this article was written many details about the GSI calculation and impact on the research workforce have yet to be finalized, the NIH has stated that the GSI cap for researchers will be 21, equivalent to 3 R01 grants.

“NIH’s plan to implement a new policy to balance funding support across all career stages is aimed at ensuring the long-term strength and stability of the U.S. biomedical research enterprise,” says NIH principal deputy director Lawrence A. Tabak, DDS, PhD.

Our understanding is that the GSI will be similar in principle to the Research Commitment Index. Using this index, large grants (e.g., P50, U54) will have a score of 11, R01s and similar grants have a score of 7, and grants requiring less substantial commitments (e.g., R21, R03) have comparatively lower scores. Grants with multiple Principal Investigators will have slightly decreased point assignments for each investigator. The NIH will calculate GSI for all applicants, and applicants would be required to submit a plan to reduce their GSI to remain within the cap, should a new grant award cause their GSI to extend above the cap. The NIH will not cancel any existing grants under the new policy; enforcement of the cap only applies to new applications. The NIH estimates that roughly 6% of supported investigators will be affected by the new cap, while around 1,600 new awards would become available in the ensuing years to broaden the pool of NIH-funded researchers.

In describing the rationale for implementing this policy, the NIH has focused on several points:

- A dramatic increase in applications for NIH funding since 2003 has created a hypercompetitive environment for a relatively stable number of awards, limiting the ability of researchers to explore transformational or innovative areas.
- Data suggests that a relatively small proportion of scientists and institutions are receiving a large proportion of available funds.
- The scientific workforce is aging at a much greater rate, relative to the general workforce; early-stage and increasingly mid-career investigators are dropping out of the pipeline.
- Data suggests that on average, additional grants to individual investigators eventually offer diminishing returns in terms of scientific output.

The NIH has proposed an aggressive schedule for implementing the new policy with grant applications starting in September. An analogous policy may also be implemented for the intramural campus. Over the summer, the NIH will collect feedback from advisory councils and other stakeholders. A website will also be delivered to solicit public comments. For more information, members can examine the Open Mike blog or announcements from the NIH Director’s page. The Endocrine Society will closely monitor this rapidly evolving policy, and we encourage members to contact the Government and Public Affairs team at jlaakso@endocrine.org with your thoughts or questions on the policy and how it might affect you.



Society Works with Manufacturers to Address Insulin Pricing Issues

“The Society is pleased at the steps these companies have taken to address this critical barrier for patients who rely on insulin to manage their diabetes.”

Over the past year, the Society has been working with manufacturers to address rising insulin costs to ensure that patients at greatest risk are able to receive subsidies to cover this lifesaving medication.

Recently, two new programs were announced to for individuals facing high out-of-pocket costs. Novo Nordisk recently announced a partnership with CVS Caremark on a new program called Reduced Rx, a patient assistance program that enables patients to purchase human insulin, Novolin®, for \$25 per 10 mL vial. Reduced Rx can be used by those who are uninsured or underinsured and has no limit on the number of times the program can be accessed. Additional information on eligibility requirements and participating pharmacies can be found at reducedrx.com.

Eli Lilly & Company also announced a similar program through a partnership with Express Scripts, designed to lower out-of-pocket costs for more than 40 brand-name drugs, including a range of insulins. Inside RX is designed for individuals who have no insurance or who are underinsured (e.g., in a deductible phase of a high-deductible plan). Patients who are younger than 65 can sign up for the program at insiderx.com.

The Society is pleased at the steps these companies have taken to address this critical barrier for patients who rely on insulin to manage their diabetes. While these programs are encouraging, we believe that increasing transparency across the insulin supply chain is needed to make pricing more predictable, reduce out-of-pocket costs, and help patients and clinicians maintain access to affordable, patient-centered therapies. ^{EN}

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HORMONES AND ERECTILE DYSFUNCTION

WHAT YOU NEED TO KNOW

The endocrine system is a network of glands and organs that produce, store, and secrete hormones, which are really important in maintaining a healthy sex drive. Hormones play a big role in men's health, affecting energy, weight, mood, sex, fertility, and much more. Low blood testosterone (male sex hormone) concentrations can result in a lower sex drive and even erectile dysfunction. This is a condition in which a man may have trouble getting or keeping an erection.

WHAT IS ERECTILE DYSFUNCTION

Erectile dysfunction (ED), or impotence, is the inability to consistently get or keep an erection (hard penis) long enough to have satisfactory sex.

While it's perfectly natural to notice a gradual decrease in **libido** (sex drive) as you age, the degree of decline varies. Men generally maintain some interest in sex well into their 60s, 70s, and beyond. If you're concerned about loss of sex drive, especially if it happens suddenly, you should consult your doctor. He or she can do a physical exam and request lab tests to determine the cause.

COMMON CAUSES

The most common causes of ED are underlying health problems that affect blood vessels and blood flow in the penis. These include hardening of the arteries (atherosclerosis), diabetes, obesity, smoking, high blood pressure, and high cholesterol.

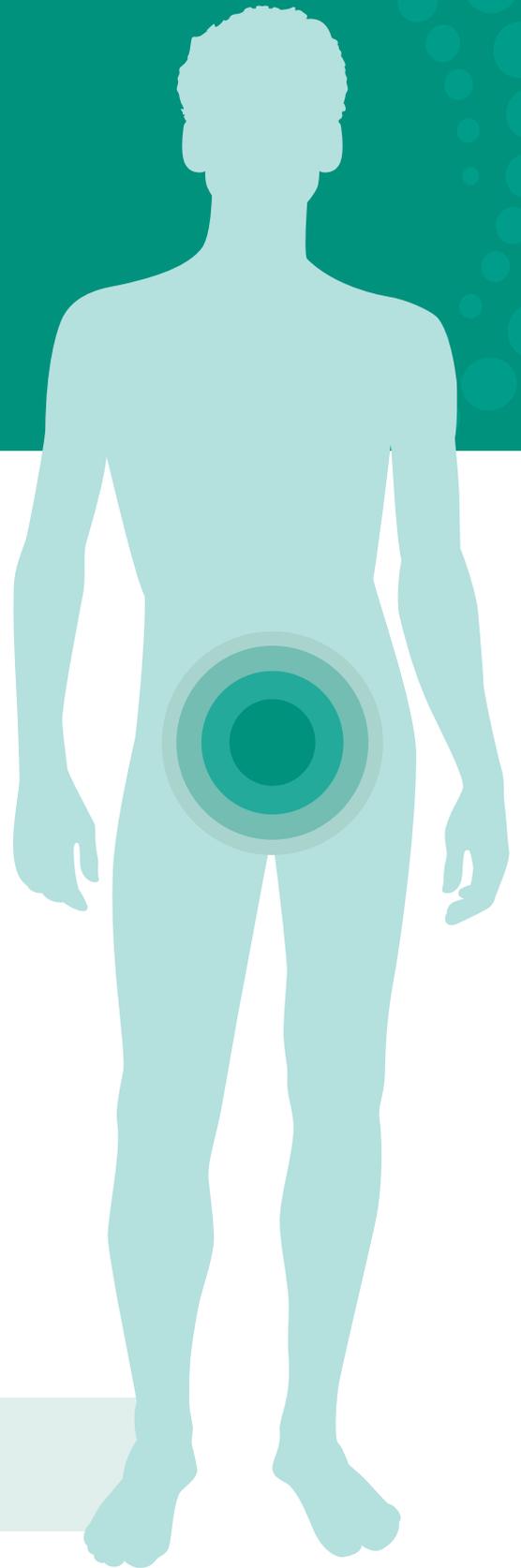
Other common causes of ED may include:

-  Depression or stress
-  Anxiety or fear of sexual failure
-  Decrease in blood testosterone due to an endocrine disorder
-  Medications (antidepressants, sleeping pills, and drugs to treat high blood pressure, pain, or cancer)
-  Alcohol and illegal drugs

Even if ED has a physical cause, emotional factors may make the condition worse.



Don't be embarrassed. It's worth it to have an open and honest discussion with your doctor about your loss of sex drive or erectile dysfunction. A healthy sex life is part of a healthy life in general.



Visit hormone.org for more information.

Additional Editing by Bradley D. Anawalt, MD,
University of Washington



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DID YOU KNOW?

While it is true that older men may not get “turned on” as quickly, they should still be able to get and keep an erection and enjoy sex.

- Researchers estimate that ED affects as many as 30 million men in the United States.
- About 12 percent are younger than age 60.
- About 30 percent are age 70 or older.

Source: National Institutes of Health

Complications of ED may include:

- Unfulfilled sex life
- Emotional problems, including depression, anxiety, and low self-esteem
- Loss of intimacy with partner, causing a strained relationship
- Inability to get partner pregnant

DIAGNOSIS

Your doctor will carefully evaluate your medical history, including a history of sexual function, medications, illnesses, emotional changes or injuries that could be causing your ED. He or she may also give you a physical exam, schedule lab work like a urinalysis and blood tests, or ask you mental health questions.



TREATMENT

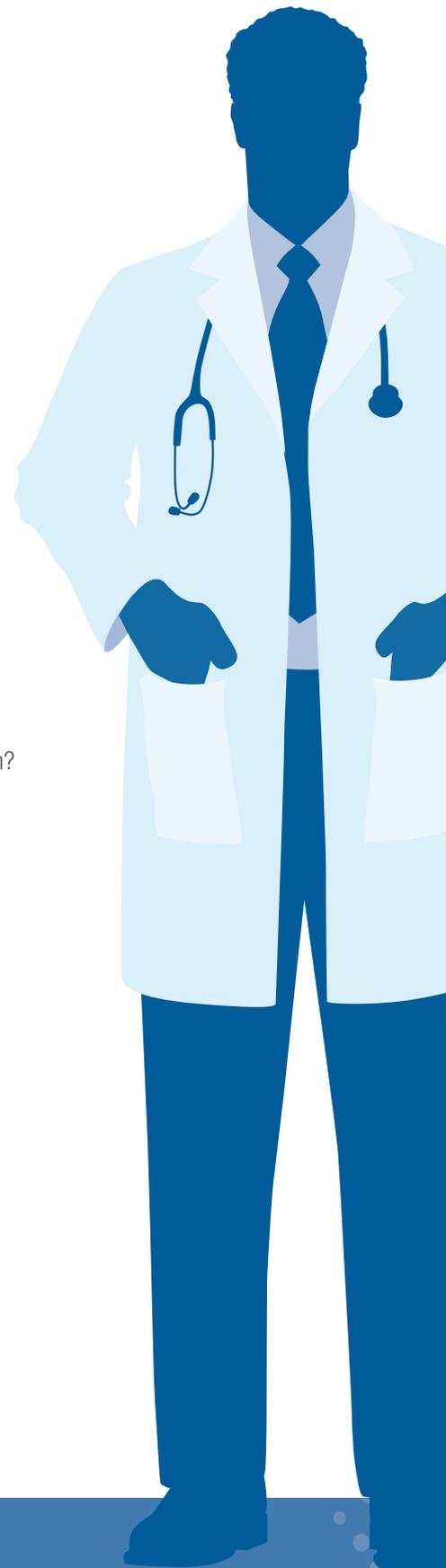
If you only have ED “every once in a while,” you may not need treatment. If your doctor diagnoses you with ED, then the options to treat it will depend on the cause and may include medicine, lifestyle changes, therapy, devices, and other options.

4 QUESTIONS TO ASK YOUR DOCTOR

- Could my ED be caused by another condition?
- Are any of the medications I’m taking making it worse?
- What are the pros and cons of your recommended treatment?
- Are there lifestyle changes I might make to improve my condition?

LIFESTYLE CHANGES THAT MIGHT HELP

- Quit Smoking
- Limit or stop drinking alcohol
- Increase physical activity
- Stop illegal drug use



Patients have questions. We have answers.

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Chief Division of Endocrinology, Metabolism, and
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