

JUNE 2016

THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

Endocrine news

Men's Health

THE BENEFITS OF ENDOCRINE SCIENCE FOR GUYS OF ALL AGES:

- **Testosterone Gel:** Older men are reaping the benefits of this treatment that has more ups than downs.
- **The Male Pill:** How soon will the birth control pill for men arrive... and what impact will it have?
- **Boys to Men:** How does race, weight, and age impact puberty's arrival?

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ICE-CSE goes to China

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TESTOSTERONE GEL AND OLDER MEN

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BY MARK A. NEWMAN




FROM THE **EDITOR**

The Continuing Evolution of *Endocrine News*

THIS MONTH'S ISSUE HAS SOMETHING IN COMMON WITH LAST month's issue: It is also one of the biggest issues of *Endocrine News* since the magazine was first started in 2000. You've probably already noticed how much heavier the magazine feels as well as a "sturdiness" in the cover. We've been gratified in recent months to learn of the magazine's recent ranking among 14 publications in the endocrine/diabetes marketplace: We are currently No. 2 in ad pages and readers, even ahead of such medical stalwarts as *JAMA* and the *New England Journal of Medicine*.

It has been my goal from the time I began here over three years ago to make the information presented in each issue useful to our readers. In that vein, I have adjusted the content you receive each month to more of a "service journalism" model. This means that essentially anyone who picks up *Endocrine News* can take something away from any of the articles they read and apply it immediately to their practice, clinic, lab, research, classroom, report, or whatever they happen to be engaged in as part of their work in endocrine science or practice.

Moreover, another goal has been to make *Endocrine News* an accurate representation of all of the members of the Endocrine Society. Our stories focus on the research studies you've had published in our journals and elsewhere. Our interviews are with members in laboratories and doctors' offices and classrooms from around the world. In fact, we want to have members be a part of the magazine in even bigger ways. You may remember our "First Person" articles from last fall, which were personal stories written by members. We want more of these types of articles, and that's where you can help shape *Endocrine News*.

Share your stories with your colleagues the way that Katy J. Brown gave an in-depth account of her participation in the Ambassador Exchange Program, when she journeyed to Addis Ababa, Ethiopia, in the December issue ("Out of Africa," p. 30). It was an experience made possible by the Endocrine Society, and one that profoundly changed her outlook on life and on how to practice medicine. Help your fellow endocrinologists by telling them how you accomplished something the way Matthew Bouchonville detailed his experience with telemedicine in rural New Mexico in the September issue ("Long Distance Relationship," p. 34). These are your stories, and they belong in your magazine, *Endocrine News*. So if any of you have a story to tell, I encourage you to contact me at mnewman@endocrine.org. Share your story with the most receptive audience you could have: thousands of people with the same passion as you striving to make the world a better place through endocrine science and practice. 

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

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Society Publications: Creating a Greater Understanding of Endocrine Science

I WANT TO TELL YOU ABOUT EXCITING NEW PLANS for the Endocrine Society's prestigious suite of publications. These are the culmination of a thoughtful examination of the Society's options.

As with all scholarly journals these days, the Endocrine Society's journals face multiple challenges in response to changing technology, increasing competition, and shifting business models. Early in 2015, the Council approved a Strategic Planning Initiative to assess and improve the impact, sustainability, and service to readers of our journals program. The Publications Core Committee, chaired by Peter Fuller and supported by our new chief publications officer, Richard O'Grady, was assisted in this endeavor by publishing experts from Kaufman Wills Fusting & Company.

They examined how our journals program could:

- Ensure the ongoing excellence of all Endocrine Society (ES) scientific and clinical programming and content;
- Increase the influence of ES publications on the science and practice of endocrinology by leveraging our access to leading scientists and clinicians and our growing technological capabilities;
- Analyze key advances and trends in endocrine research and clinical care;
- Enhance ES's ability to customize our programs and services to meet the individual needs of our diverse membership;
- Explore new ways to enable ES members with common interests to connect and form intellectual communities;
- Diversify ES programs and services to attract and serve our communities of scientists and clinicians; and
- Maintain a sustainable business model for ES while making strategic investments in the future.

Year 1 (2015) of the project was devoted to research and discovery, including:

- Situation Analysis & Environmental Scan, including over 35 other organizations' journal programs;
- Stakeholder Interviews, including Society leaders, the Publications Core Committee, editors-in-chief, and focus groups of basic scientists, clinical scientists, and clinical practitioners; and
- Author & Reader Survey of more than 3,500 ES members and contributors to our journals.

With the Council's approval of additional Strategic Planning Initiative funds for 2016, the project moved into its implementation phase, which is planned to run through 2018. Plans for each of our journals include the following:

For *The Journal of Clinical Endocrinology & Metabolism (JCEM)*, with editor-in-chief, R. Paul Robertson, the goal continues to be to establish *JCEM* as the premier clinical journal in its field. *JCEM* will continue to publish in print and will introduce continuous online publication of articles as they clear peer review and editing. The Clinical Practice Guidelines and other appropriate Society-generated content will continue to appear in *JCEM*.

For *Endocrine Reviews*, with editor-in-chief, Leonard Wartofsky, the goal is to further enhance this highly valued resource by providing executive summaries of its articles, more invited reviews, and plans to integrate and curate its online content with that of other ES journals' reviews, mini-reviews, and other enduring Society material to create a "living textbook."

The two major, and most exciting, changes to ES's publishing program for 2016/2017 are the merger of *Endocrinology* with *Molecular Endocrinology*, and the launch of an Open Access journal, the *Journal of the Endocrine Society (JES)*.

In January 2017, *Endocrinology* and *Molecular Endocrinology*, under the joint leadership of Andrea Gore and Steve Hammes, will combine their content, scopes, and editorial teams to create a single, comprehensive, basic science journal. Publishing in print and with continuous online publication of articles as they clear peer review and editing, under the retained title of *Endocrinology*, with the tagline, “Molecular and Physiological Basis of Endocrine Health and Disease,” the combined journal will encompass and expand on the scopes of its two antecedent journals to provide important insights into endocrine systems and diseases at molecular, biochemical, cellular, genomic, comparative, and organismal levels. Article types will include full-length research articles, mini-reviews, commentaries, rapid communications, technical papers, and resource articles. Article-level metrics will provide feedback to authors on the impact that their articles are having.

JES will be our first new journal in 30 years, and our first Open Access journal. Launching in the fall of 2016, it will publish across the Society's mission in all areas of basic science, clinical science, and clinical practice. As an Open Access journal, its content will be freely available online to physicians, scientists, and the public worldwide. *JES* will publish research articles, mini-reviews, editorials, and perspectives. Images, case reports, articles about databases and methods, and interactive media will also be featured. Key to the success of the journal is the agreement of J. Larry Jameson to be its founding editor-in-chief. An international group of associate editors will be working with Larry to attract a broad range of submissions, maintaining the Endocrine Society's traditional high standards for peer review while ensuring timely publication decisions. Articles will be published continually and within a week of acceptance, with article-level metrics provided.

The topics previously covered in the journal, *Hormones and Cancer* — which ES did not own and which, as of the end of 2016, is reverting back to its owner, Springer Nature, with no further ES involvement — will now be included in *JES* under the continuing leadership of Nancy Weigel, as one of the associate editors of *JES*.

Indeed, *JES* will launch with the following topic categories, overseen by its editor-in-chief and associate editors:

- Adrenal Research
- Diabetes and Gastrointestinal Hormones

- Growth, Growth Hormone, and Growth Factors
- Hormone-Responsive Cancers
- Lipids and Cardiovascular Research
- Nuclear Receptors and their Ligands
- Obesity and Adipocyte Biology
- Parathyroid, Bone, and Mineral Metabolism
- Pituitary Research and Neuroendocrinology
- Reproductive Biology and Sex-Based Medicine
- Signaling Pathways
- Thyroid Research

And with the following cross-cutting terms:

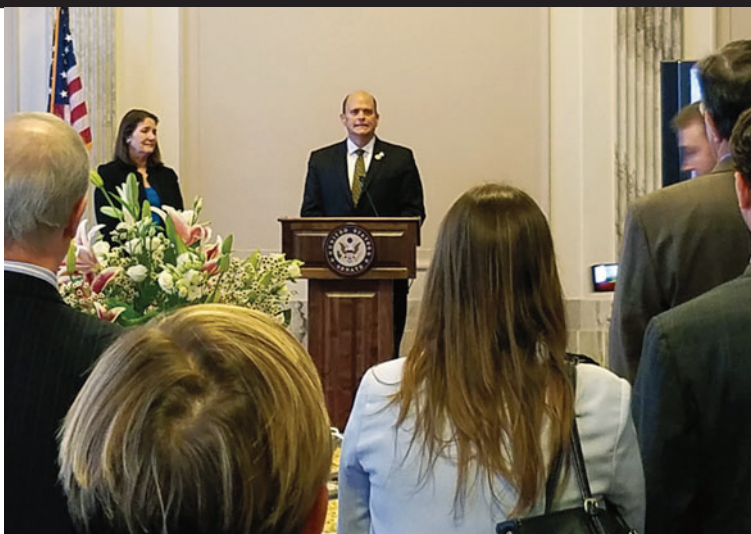
- Aging
- Autoimmunity and Inflammation
- Bioinformatics
- Development
- Endocrine Disruptors
- Genetics and Genomics
- Health Disparities
- Neoplasia
- Pediatrics
- Protein Translation and Proteomics
- Surgery
- Therapeutics
- Transcription and Gene Regulation

In sum, it is our aspiration that *JES*, in concert with the rest of our impressive family of journals, will contribute to greater understanding in science and medicine by facilitating the broad communication of high-quality, authoritative information in endocrine research and clinical care. I want to thank those mentioned above and the large number of ES members and staff who have brought this enormous project to this exciting stage. But the success of these journals will depend on all the members of the Endocrine Society who contribute articles and read these journals.

Feel free to contact me at president@endocrine.org if you have any questions or comments. 

— **Henry M. Kronenberg, MD**, President, Endocrine Society

Congressional Members Share Personal Diabetes Stories on Hill Day



At a congressional reception on Capitol Hill to celebrate the Society's centennial, congressman Tom Reed (R-NY) tells attendees about caring for his son with diabetes.

After a day educating members of Congress about the importance of the field of endocrinology and emphasizing the need for federal funding for the National Institutes of Health (NIH) to support the development of new treatments for endocrine conditions, the Endocrine Society hosted a Congressional Reception on Capitol Hill to celebrate its 100th birthday.

Society president Henry Kronenberg, MD, of Massachusetts General Hospital, underscored the shortage of endocrinologists as he spoke at the reception, saying that more and more people are diagnosed with hormone disorders every year, and that we need to grow the endocrinology workforce by a rate of 14% just to approach what those workforce estimates are over the next several years. He laid some of the blame for the shortage as a result of the lack of NIH funding.

Kronenberg was joined by the co-chairs of the Congressional Diabetes Caucus, representatives Diana DeGette (D-CO) and Tom Reed (R-NY), who spoke not only of their respective families' experiences with diabetes but also the challenges and opportunities of diabetes legislation.

"The Diabetes Caucus is the largest caucus in the House," DeGette says, "and we make sure to keep it that way. It's not a hard caucus to recruit members for, because every family

— whether it's Democrat or Republican — has issues in their families." She told the story of her daughter Francesca, who was diagnosed with type 1 diabetes (T1D) at age four, now graduating from college, whose endocrinologist is retiring this year. "I thanked her for waiting to retire," DeGette says.

Reed reiterated his personal stake in joining the Diabetes Caucus, relating the story of his son Will, telling of having to hold the boy down in the emergency room as doctors were administering insulin, praising his team of endocrinologists, and expressing his hope for a cure for diabetes. "We're going to work together," he says, "Diana and I, Republican and Democrat, on this issue in Washington to ensure that you do what you do best, and that is to find a cure for these diseases that impact so many of our fellow Americans."

DeGette and Reed also touched on bills they're cosponsoring concerning NIH funding and extending Medicare coverage of continuous glucose monitors, pointing out that this legislation will impact Americans in a positive way. "Democrats and Republicans can come together," Reed says, "we do come together, more often than what is reported in the news."

— DEREK BAGLEY



David Mangelsdorf Receives Honorary Degree

David J. Mangelsdorf, PhD, received an honorary degree from his alma mater, Northern Arizona University (NAU), during commencement on May 13.

Mangelsdorf, professor and chair of the Department of Pharmacology, University of Texas Southwestern Medical Center in Dallas, has led research that uncovered the fundamental role of nuclear receptors in the pathways that control carbohydrate and lipid metabolism. His discoveries have prompted the development of new therapeutic strategies for treating diverse diseases such as atherosclerosis, fatty liver disease, cholestasis, obesity, and even nematode parasitism.

He is actively involved in teaching and supervises one of the longest running NIH-funded graduate training programs in the pharmacological sciences. He also is an investigator of the Howard Hughes Medical Institute.

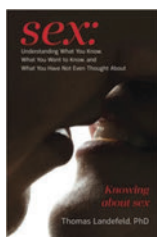
Mangelsdorf received his bachelor of science degree in biology and chemistry from NAU in 1981, and his PhD in biochemistry from the University of Arizona in 1987. He received his postdoctoral training at the Salk Institute for Biological Studies in La Jolla, Calif. In 1993, he started his independent career at the medical center.

Aside from receiving the Society's Gerald D. Auerbach Award, Mangelsdorf holds the Alfred G. Gilman Distinguished Chair in Pharmacology and the Raymond and Ellen Willie Distinguished Chair in Molecular Neuropharmacology in Honor of Harold B. Crasilneck. He has received several honors including the John J. Abel Award in Pharmacology; the Adolf Windaus Prize for Bile Acid Research; the Heinrich-Wieland-Preis in Lipid Research; and many more.



Thomas Landefeld Publishes Book on Sex

According to Amazon.com's rankings, the no. 1 new release in "health teaching materials" is a book by Endocrine Society member Thomas Landefeld, PhD. And it's all about sex.



Sex: Understanding What You Know, What You Want to Know, and What You Have Not Even Thought About: Knowing About Sex was written by Landefeld to provide readers some additional knowledge about sex.

Originally, Landefeld wrote the book to provide supplemental information for students in his biology courses since the background topic for all the courses he teaches is reproduction. "Then, in the course of writing the book, coupled with general discussions about reproduction, it seemed obvious that the general public could benefit from the same type of information," Landefeld says.

Landefeld, professor of biology and pre-health advisor at California State University Dominguez Hills in Carson, Calif., is trained in the area of reproductive endocrinology, previously conducting research on the regulation of the female sexual cycle as well as actively teaching aspects of sex and sexuality in the college classroom, with an emphasis not just on learning for the class but most importantly for practical applications in life.

When asked what would surprise readers the most, Landefeld says that some of the "interesting facts" cited throughout the book as well as in a special section are nuggets of information that are not typically common knowledge. "These facts were both unique as well as basic and things that most folks probably did not know," he says.

Landefeld says that he was prompted to write the book after being consistently surprised and, unfortunately, disappointed that his students had so little knowledge about some of the most basic information about sex and the processes associated with it, especially since he was teaching biology classes. "With that, and as a result of some of those discussions, it also became obvious that there was a broader need to be met, e.g., outside of the classes as well," he explains. "This is especially the case when 'sex' is all around us in the media via commercials, TV, movies, and so on, without much attention devoted to its proper teaching."

Experts Address Need to Improve Hormone Tests and Lack of Standardization



Members of the Partnership for Accurate Testing of Hormones met at the Endocrine Society offices to discuss a strategy to standardize hormone tests and communicate the importance of standardized tests to physicians, policy makers, and the public.

Members of the Partnership for the Accurate Testing of Hormones (PATH) met in April at the Endocrine Society headquarters to develop strategies to standardize hormone tests and raise awareness among physicians of the poor quality and incommutability of the tests they order.

PATH seeks to improve patient care and public health through universal use of accurate and reliable hormone tests in healthcare and research. Its ultimate goal is to advance the development of standardized hormone assays and advocate for the universal adoption of these assays in medical practice and research.

“Inaccurate tests can lead to misdiagnoses, and this is happening every day on a global scale,” says Alvin M. Matsumoto, MD, FACP, associate director of the Geriatric Research, Education and Clinical Center at the VA Puget Sound Health Care System and professor of medicine at the University of Washington, and co-chair of PATH. “Whether it’s testosterone, estradiol, or vitamin D, unreliable hormone tests are a threat to patients whose medical care depends upon accurate measurement.”

The meeting brought together the partnership’s many members, including the Endocrine Society and the Centers for Disease Control and Prevention (CDC), to crystallize

goals and tactics to not only standardize hormone tests and harmonize reference ranges in clinical care and diagnosis, but to communicate the importance of standardized tests to public health to physicians, policy makers, and the public.

“We know there are cases where individuals might be deemed deficient or sufficient in a certain hormone like vitamin D depending on the laboratory where the blood is tested,” Matsumoto says. “These problems are caused mainly by inaccurate and unreliable tests. Standardized hormone tests are essential, and we are working to educate physicians about this issue and encourage policymakers to ensure universal use of standardized tests.”

Aside from the Society and the CDC, other PATH members include the American Association for Clinical Chemistry, American Society for Bone and Mineral Research, American Urological Association, Androgen Excess/PCOS Society, Association of Public Health Laboratories, College of American Pathologists, International Society of Andrology, LabCorp, National Association of Chronic Disease Directors, National Institute of Child Health and Human Development (Reproductive Sciences Branch), North American Menopause Society, Pediatric Endocrine Society, and Quest Diagnostics.

For more information, go to www.hormoneassays.org.

Endocrine Society Opposes Increase in SBIR/STTR Set-Aside

On May 10, the Endocrine Society joined a coalition of research and professional societies and educational institutions to oppose a provision in the Commercializing on Small Business Innovation Act of 2016 (H.R. 4783) that would increase the set-aside funding for small business grants at federal agencies such as the National Institutes of Health (NIH).

The NIH is required by law to spend a percentage of its budget each year on Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. H.R. 4783 would increase this set-aside from 3.46% in fiscal year 2018 to 4.5% in fiscal year 2022. While the sign-on letter expresses support for the SBIR/STTR programs in general, there is concern that increasing the set-asides will adversely impact funding for research by reducing the funds spent on other worthwhile programs at the NIH and other research funding agencies.

The SBIR/STTR programs are not underfunded relative to other types of research, and the SBIR/STTR programs increased by 29.0% between fiscal years 2011 and 2016, while the NIH budget as a whole grew by only 4.5%. The Society also urged the House Science Committee to hold hearings to review the outcomes of the previous SBIR/STTR reauthorization and evaluate any change in the set-aside for these programs based on the merits and justification for doing so.



Pictured left to right are Nelly Mauras, John Nestler, Gary Hammer, A. Shaikh, Susan Mandel, and Daniel Bessesen.

Endocrine Society Presents 7th Annual Endocrine Summit in Mumbai

The Endocrine Society hosted the Endocrine Summit in Mumbai, India, to conduct clinical courses that covered a breadth of endocrinology topics from April 30 to May 1.

This year's Summit took place over a day and a half and was made possible with support from Sun Pharmaceuticals and a partnership with MediQuest. The Society brought a team of physicians to Mumbai for presentations on obesity and nutrition, adrenal cancer, thyroid, pediatrics, and reproduction. The faculty members who journeyed east were Daniel Bessesen, MD, University of Colorado; Gary Hammer, MD, PhD, University of Michigan; Susan Mandel, MD, MPH, University of Pennsylvania Perelman School of Medicine; Nelly Mauras, MD, Nemours Children's Health System; and John Nestler, MD, Virginia Commonwealth University.

According to Hammer, this Summit provided up-to-date, state-of-the-art, and state-of-the-science presentations to the broad and diverse audience of endocrinologists throughout India who have a diverse range of practice styles and patient care. "I learned and was reminded of the important cultural issues and differences in disease management related to drug availability and practice styles (multidisciplinary care versus private practice clinic versus academic setting)," he says, adding that he "developed collaborations and professional friendships that will continue to build bridges between endocrinologists and between the Endocrine Society and sister societies such as the Indian Endocrine Society."

The program was attended by over 250 Indian endocrinologists from around the country. The next Endocrine Summit will be held in spring 2017. There will be an Endocrine Society-sponsored Dimensions in Diabetes held in Mumbai July 16 and 17, 2016.

New Clinical Practice Guideline Calls for Expanded Screening for Primary Aldosteronism

In April, the Society issued a Clinical Practice Guideline calling on physicians to ramp up screening for primary aldosteronism, a common cause of high blood pressure.

The guideline is available online at www.endocrine.org/aldosteronism.




The guideline, entitled “The Management of Primary Aldosteronism: Case Detection, Diagnosis, and Treatment: An Endocrine Society Clinical Practice Guideline,” was published online and appeared in the May 2016 print issue of *The Journal of Clinical Endocrinology & Metabolism (JCEM)*. The guideline updates recommendations from the Society’s 2008 guideline.

Primary aldosteronism occurs when the adrenal glands — the small glands located on the top of each kidney — produce too much of the hormone aldosterone. This causes aldosterone, which helps balance levels of sodium and potassium, to build up in the body. The resulting excess sodium can lead to a rise in blood pressure.

“In the past eight years, we have come to recognize that primary aldosteronism, despite being quite common, frequently goes undiagnosed and untreated,” says John W. Funder, MD, PhD, of the Hudson Institute of Medical Research in Clayton, Australia, and chair of the task force that authored the guideline. “This is a major public health issue. Many people with primary aldosteronism are never screened due to the associated costs. Better screening processes are needed to ensure no person suffering from primary aldosteronism and the resulting risks of uncontrolled high blood pressure goes untreated.”

Other members of the Endocrine Society task force that developed this guideline include: Robert M. Carey, MD, MACP, University of Virginia Health System, Charlottesville, Va.; Franco Mantero, MD, PhD, University of Padova, Padua, Italy; M. Hassan Murad, MD, Mayo Clinic, Rochester, Minn.; Martin Reincke, MD, Klinikum of the Ludwig-Maximilians-University of Munich, München, Bavaria, Germany; Hirotaka Shibata, MD, PhD, Oita University, Oita, Japan; Michael Stowasser, MBBS, FRAC, PhD, University of Queensland, Brisbane, Australia; and William F. Young, Jr., MD, MSc, Mayo Clinic, Rochester, Minn.

The Clinical Practice Guideline was co-sponsored by the American Heart Association, the American Association of Endocrine Surgeons, the European Society of Endocrinology, the European Society of Hypertension, the International Association of Endocrine Surgeons, the International Society of Hypertension, the Japan Endocrine Society, and the Japanese Society of Hypertension. 

ADA 76th Scientific Sessions

New Orleans, June 10 – 14

This event offers researchers and healthcare professionals from around the world the unique opportunity to share ideas and learn about the significant advances in diabetes research, treatment, and care. Over the course of five days, participants will receive exclusive access to more than 2,500 original research presentations, take part in provocative and engaging exchanges with leading diabetes experts, expand their professional networks, and so much more.

www.diabetes.org

Dimensions in Diabetes

Mumbai, India, July 16 – 17

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

The Santa Fe Bone Symposium is an annual forum devoted to advances in the science and economics of osteoporosis, metabolic bone disease, and assessment of skeletal health. Close interaction and collaboration between faculty and participants is an integral part of this event.

www.nof.org

AADE16

San Diego, August 12 – 15

Each year, thousands of diabetes educators from around the country attend the American Association of Diabetes Educators (AADE) Annual Meeting and Exhibition to learn about the newest and greatest in the world of diabetes through presentations and hands-on experience with products in the exhibit hall.

www.aademeeting.org

Clinical Endocrinology Update 2016

Seattle, September 8 – 10

This three-day meeting provides the latest information available in clinical endocrinology. Taught by expert faculty in a dynamic meeting format, you will return from CEU confident that your endocrine practice benefits from the most current and advanced information possible.

www.endocrine.org/ceu

Endocrine Board Review 2016

Seattle, September 11 – 12

Identify areas for improvement at the most in-depth board preparation available. Fellows preparing to sit for the boards and certified practitioners needing to maintain certification will benefit from EBR, the premier preparatory mock exam.

www.endocrine.org/ebr

86th Annual Meeting of the American Thyroid Association

Denver, September 21 – 25

The ATA meeting is designed for the community of endocrinologists, internists, surgeons, basic scientists, nuclear medicine scientists, pathologists, trainees, nurses, physician assistants, and other healthcare professionals who wish to broaden and update their knowledge of the thyroid gland and its disorders.

www.thyroid.org

EndoBridge 2016

Antalya, Turkey, October 20 – 23

EndoBridge provides a comprehensive update in the field of endocrinology and is specifically designed for the clinical endocrinologist. The official language of the meeting is English, but simultaneous translation will be available in Russian, Arabic, and Turkish.

www.endobridge.org



Beijing, China

ObesityWeek 2016

New Orleans, October 31 – November 4

The preeminent annual scientific and educational conference covers the full scope of the obesity issue, from cutting-edge basic science and clinical research to intervention and public policy discussions that can impact the quality of life for millions affected by obesity.

www.obesity.org

PPTOX V

Fukuoka, Japan, November 13 – 16

The international summit of Prenatal Programming and Toxicity (PPTOX) is dedicated to cutting-edge discussion of environmental hazards during early life and long-term consequences. PPTOX is one of the premier international venues for scientists to evaluate current knowledge and guide forward momentum for this burgeoning field.

www.pptoxv.com

ENDO 2017

Orlando, April 1 – 4, 2017

The Endocrine Society holds its annual meeting within arm's reach of the "happiest place on Earth" in Orlando. With over 9,000 attendees, nearly 3,000 abstracts and over 200 other sessions, it is the leading global meeting on endocrinology research and clinical care. The meeting also hosts other satellite and pre-conference events, such as our Early Career Forum and Hands-On Thyroid Workshops.

www.endocrine.org/endo-2017

17th International Congress of Endocrinology/15th Annual Meeting of Chinese Society of Endocrinology

Beijing, China, August 31 – September 4

This event furthers the collaboration between ICE and CSE and promotes the long-term commitment to supporting endocrinology around the world, especially in developing

nations. Local and international experts are working together to develop an unmissable program of the highest scientific standards appealing to the full spectrum of endocrinologists around the globe — basic scientists, clinician scientists, practicing endocrinologists, and of course, trainees.

Held jointly with the CSE annual meeting, ICE-CSE 2016 promises to be a rich and fulfilling educational event with the opportunity to learn from experts, colleagues, and peers based around the world in a diverse and colorful environment, unique only to ICE! *For a more in-depth look at ICE-CSE 2016, see p. 35, for "Journey to the East."*

www.ise-cse2016.org



WHY ENDOCRINOLOGY?

The Perfect Combination of Science and Medicine

BY RICARDO CORREA, MD, ES.D, FACP, National Institutes of Health, Bethesda, Md.

My passion for medicine, specifically endocrinology, started very early in my life. My mother recently reminded me that when I was seven years old, I told her that I wanted to become a doctor, not just a simple doctor, but one who contributes in some fashion to the world. At the age of 13, I had the need to see an endocrinologist. That visit changed my entire life. The hormonal world started to become something more important in my daily life, and my love for medicine developed and intensified. By the age of 15, I started reading about cellular biology, and I figured out that hormones, in any of their forms, are how our body communicates.

Finally, during my adolescence, I realized that endocrinology was the area of medicine that really controls our bodies and that the pituitary system was the center of this entire engine. Before entering medical school, my desire to become an endocrinologist and more specifically, a neuroendocrinologist, was so high that I spent the majority of my nights reading about the pineal and hypophysis glands. I was impressed how most ancient cultures considered these two glands the center of our body. For the Indians, the pineal gland is the third-eye or the “Ajna Chakra.” After all of this reading,

I realized that what we consider modern endocrinology is deeply based in ancient cultures and medicines.

Upon entering University of Panama School of Medicine in 2006, I was randomly assigned to a mentor who was both an endocrinologist and my biochemistry professor. What a beautiful combination! Dr. Enrique J. Mendoza inspired me to work harder to achieve my dreams in endocrinology. I remember that when I had any free time, I accompanied him to see patients in his clinic, correlating all the pathologies with biochemical pathways. When I finished medical school, I was sure that what I wanted to dedicate my entire life was to the study of hormones and to focus on the neuroendocrine system. With that, I decided to pursue an internal medicine residency at the University of Miami - Jackson Memorial Hospital. During my residency, I immediately found two great mentors (Drs. Hermes Flores and Alejandro R. Ayala) who guided me through the science of endocrinology and research, and reinforced my passion for this area.

“
Understanding how one cell controls another through hormonal pathways is what I consider the future of medicine.
”

Later, I had the opportunity to pursue an endocrine fellowship with a focus on neuroendocrine research at the National Institutes of Health under the guidance of


To celebrate 100 years of the Endocrine Society, throughout 2016 *Endocrine News* is running a “Why Endocrinology?” column in each issue. If you’d like to share your story with our readers, contact Mark A. Newman at mnewman@endocrine.org.

WHY ENDOCRINOLOGY?

Dr. Constantine Stratakis and other wonderful mentors (Drs. Monica C. Skarulis, Ranganath Muniyappa, Smita Abraham, Angela Delaney, Maya Lodish, and Susmeeta Sharma).

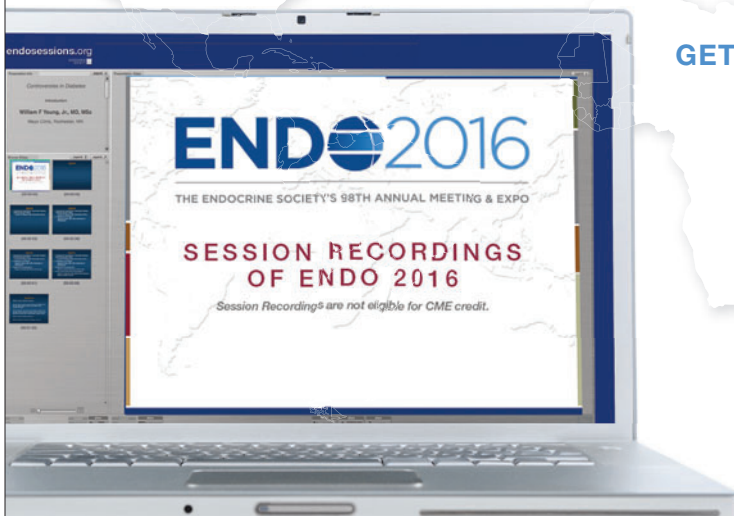
During that time, I realized that endocrinology was the perfect combination between science and medicine. I understand the complexity of the endocrine system and how to discover new pathways that will guide treatment and diagnosis in the future, which is why I believe that endocrinology is the most perfect area of all clinical specialties. Understanding how one cell controls another through hormonal pathways is what I consider the future

of medicine. Endocrinologists have the keys and the knowledge to do this.

I chose endocrinology because I wanted to be an excellent researcher, clinician, and educator, and there is no other area of medicine that can combine these three skills in such a perfect way. I have been fortunate to have great mentors along my career path, and I hope to provide such guidance to future researchers and doctors going forward to repay in some small measure the good fortune I have received, and to further influence the future of medicine overall. 

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OF HORMONE SCIENCE TO HEALTH

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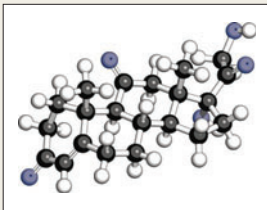
“ **The biggest benefit [of testosterone treatment] is usually in how men feel.** For hypogonadal men, testosterone often makes them feel better. Many men will report improved sexual function and pleasure, and some will report improved energy and vitality.”

— BRADLEY ANAWALT, MD, chief of medicine, University of Washington Medical Center, Seattle, in “Feeling Good” on page 18.

FROM THE CENTURY OF ENDOCRINOLOGY TIMELINE

1935:

Discovery of Cortisone



The adrenocortical hormones, cortisone and cortisol, were discovered between 1935 and 1938. E.C. Kendall first isolated compound E (later renamed cortisone) in 1935 from bovine adrenal glands along with a series of structurally related steroids (including cortisol, then named compound F) capable of improving muscular strength when administered to adrenalectomised rats or dogs (Mason et al. 1936, Reichstein 1936).

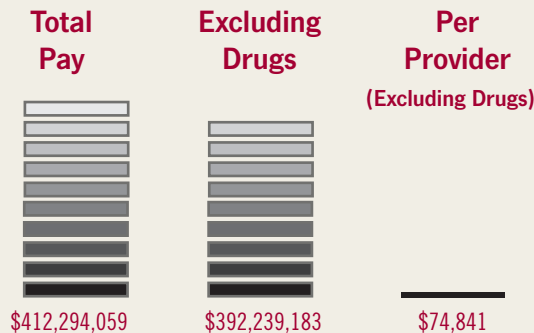
For more about the Century of Endocrinology, go to: www.ESCentennial.org/timeline.

\$206,000

Average annual compensation for an endocrinologist for patient care. For employed physicians, patient-care compensation includes salary, bonus, and profit-sharing contributions.

— SOURCE: MEDSCAPE'S PHYSICIAN DEBT AND NET WORTH REPORT 2016

2014 MEDICARE ENDOCRINOLOGY PART B PAYMENTS



— SOURCE: CENTERS FOR MEDICARE & MEDICAID SERVICES

730

Number of deaths over a decade that could be averted in Philadelphia if a 3 cents/oz. tax on sugar-sweetened beverages is enacted.

— SOURCE: HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH

“Either we score some higher reimbursements rates...or we’re going to have to punt.”



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Testosterone Therapy Linked to Lower Hospital Readmission

BY DEREK BAGLEY

Older men taking testosterone therapy were less likely to have complications requiring hospital readmission within 30 days than men not using this therapy, according to a study recently published in *Mayo Clinic Proceedings*.

Researchers led by Jacques Baillargeon, PhD, of the University of Texas Medical Branch in Galveston, point out that testosterone deficiency occurs in a high percentage of older men with chronic diseases like heart failure, diabetes, and chronic kidney disease. They also note that no large-scale studies have looked at the effectiveness of androgen therapy — which has been reported to improve strength and functional health — in hospital settings. Therefore, the scientists conducted a retrospective cohort study of 6,372 men who were hospitalized for nonsurgical procedures from January 1, 2007 to December 31, 2012 — representing a 5% national sample of Medicare beneficiaries.

The researchers found that of 929 men on androgen therapy, 91 were back in the hospital within a month of hospital discharge. Of the 5,443 non-androgen users, 708 were rehospitalized. Since it's a 9.8% to 13.0% comparison, the authors write that in “older men with testosterone deficiency, receipt of androgen therapy was associated with a reduced risk of rehospitalization.”

Findings: The authors conclude: “Androgen therapy may reduce the risk of rehospitalization in older men with testosterone deficiency. This finding persisted across a range of propensity score and sensitivity analyses. Given the importance of reducing avoidable hospital readmissions among older adults, further exploration of this intervention holds broad clinical and public health relevance.” They also say that this study could have major implications for androgen therapy, as there is now strong evidence suggesting it leads to quicker recovery from hospital stays and lower readmission rates.

Tendency to Obesity and Diabetes Can Be Inherited



German researchers from Technical University of Munich (TUM) in collaboration with researchers at Helmholtz Zentrum München and the German Center for Diabetes Research (DZD) have shown that diet-induced obesity and diabetes can be epigenetically inherited by the offspring via both oocytes and sperm, according to a study recently published in *Nature Genetics*.

Professor Johannes Beckers and his team at the Institute of Experimental Genetics (IEG) used mice that had become obese and had developed type 2 diabetes due to a high-fat diet. Their offspring were obtained solely through in vitro fertilization (IVF) from isolated oocytes and sperm, so that changes in the offspring could only be passed on via these cells. The offspring were carried and born by healthy surrogate mothers. This enabled the researchers to rule out additional factors such as the behavior of the parents and influences of the mother during pregnancy and lactation.

“The results showed that both oocytes and sperm passed on epigenetic information, which particularly in the female offspring led to severe obesity,” says Beckers, who directed the study. In the male offspring, by contrast, the blood glucose level was more affected than in the female siblings. The data also show that — like in humans — the maternal contribution to the change in metabolism in the offspring is greater than the paternal contribution.

“This kind of epigenetic inheritance of a metabolic disorder due to an unhealthy diet could be another major cause for the dramatic global increase in the prevalence of diabetes since the 1960s,” says Professor Martin Hrabě de Angelis, chair for Experimental Genetics at TUM. The increase in diabetic patients observed throughout the world can hardly be explained by mutations in the genes themselves (DNA) because the increase has been too fast. Since epigenetic inheritance — as opposed to genetic inheritance — is in principle reversible, new possibilities to influence the development of obesity and diabetes arise from these observations, according to the scientists.



Findings: “From the perspective of basic research, this study is so important because it proves for the first time that an acquired metabolic disorder can be passed on epigenetically to the offspring via oocytes and sperm — similar to the ideas of Lamarck and Darwin,” Beckers says.



Type 2 Diabetes Linked to Development of Osteoarthritis

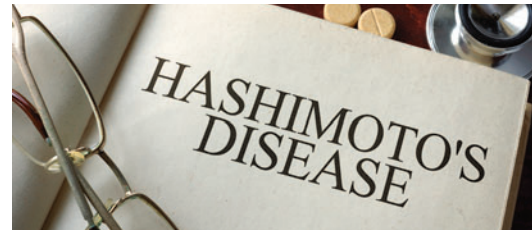
Researchers at the Cleveland Clinic have found an association between type 2 diabetes (T2D) and the development and progression of osteoarthritis (OA), based on a review and meta-analysis of literature, according to a paper recently published in the *Journal of Diabetes and Its Complications*.

A team led by Sangeeta R. Kashyap, MD, point out that while observational studies have reported an association between T2D and OA, no systematic review of the literature exists to solidify the correlation. Kashyap and her team searched a number of databases, including MEDLINE, SCOPUS, and EMBASE, “for prospective cohort, cross-sectional, and case-control studies with confidence intervals (CI) that reported an association between type 2 diabetes and impaired glucose tolerance (IGT) and the development or presence of OA of any joint.”

The researchers included 10 studies and 14 ratios in their analysis, and the pooled population size in their meta-regression was 16,742 patients. Seven of the studies controlled for weight or BMI and included a pool of 7,156 patients. They found that T2D was significantly associated with the development and presence of OA, and in the studies that controlled for weight, the association was even more significant.

Findings: The authors conclude: “Type 2 diabetes is associated with the development and presence of radiographic and symptomatic OA even when controlling for body mass index and weight.”

Thyroid Stimulating Antibodies Highly Prevalent in Hashimoto’s Thyroiditis and Associated Orbitopathy



Antibodies that stimulate the TSH receptor may play a role in the development of thyroid-associated orbitopathy (TAO) in patients with Hashimoto’s thyroiditis (HT), according to a study recently published in *The Journal of Clinical Endocrinology & Metabolism*.

Researchers led by George J. Kahaly, MD, PhD, of Johannes Gutenberg University Medical Center in Mainz, Germany, point out that TAO rarely occurs in patients with HT, so they wanted to examine what causes the pathogenesis of TAO in these patients. They write that there is evidence that TSH receptor stimulating antibodies (TSAb) play a role in the pathogenesis of TAO, so they studied a total of 1,055 patients in a longitudinal observational study that took place in an academic joint thyroid-eye clinic. The team analyzed the medical records of 700 consecutive and unselected patients with HT, as well as 53 patients with Graves’ disease (GD), and 302 healthy persons as controls.

The authors write: “Of 700 consecutive and unselected patients with HT, 44 (6%) had overt TAO. Patients with HT+TAO were older ($P < .001$), heavier smokers ($P = .032$), and clustered less with autoimmune diseases ($P = .005$). All healthy controls were TSAb negative. In contrast, serum was TSAb positive in 30/44 (68.2%) and 36/656 (5.5%, $P < .001$) patients with HT+TAO and HT, respectively.”

Findings: The researchers found the highest TSAb values in the patients with active and severe TAO. Based on these findings, Kahaly and his team conclude that TSAb is strongly associated with TAO in HT. They write that even though no causality has been proven, “that more than two-thirds of the HT patients with associated orbitopathy are TSAb positive points to the possibility that circulating TSAb binding to TSHR-bearing target cells in orbital connective tissue contribute to the clinical phenotype of thyroid eye disease.” ^{EN}

Despite some of the controversies surrounding testosterone gels, a new study of older men found that this treatment had positive effects, from increased sexual activity and more vitality to just feeling better.



Feeling GOOD:

TESTOSTERONE GEL AND OLDER MEN

BY GLENDA FAUNTLEROY

Staving off what happens to our bodies as we age is an enormous industry in the U.S. Both women and men depend on products sold over-the-counter and by prescription to relieve problems that arise as levels of women's estrogen and men's testosterone decrease — and bring a whole host of body changes and symptoms.

For millions of men in the U.S., boosting decreasing testosterone with gel supplements is a daily regimen — turning it into a reported \$2 billion industry. But do all men experience the benefits they hope for?

In its February 16 issue, the *New England Journal of Medicine* published results from the Testosterone Trials in which a team of investigators aimed to determine whether there were benefits of boosting testosterone levels in men older than age 65.

The 12-month Testosterone Trials were funded in part by the National Institutes of Health as well as AbbVie, the maker of the popular testosterone product AndroGel®. AbbVie donated the testosterone and placebo gel.

Researchers screened 51,085 men but were able to enroll only 790 who met all the criteria. The authors noted that, “relatively few men had a sufficiently low testosterone level to qualify.” Participants were 65 years or older and had serum testosterone levels that averaged less than 275 ng per deciliter. Three separate trials were conducted: the Sexual Function Trial, the Physical Function Trial, and the Vitality Trial. Each man participated in one or more of the three trials. One group received placebo only.



TESTOSTERONE

AT A GLANCE

- ▶ **Boosting decreasing testosterone with gel supplements is a current daily regimen of millions of men in the U.S. — turning it into a reported \$2 billion industry.**
- ▶ **Men in the Testosterone Trials who received testosterone reported better sexual function than those in the placebo group. This included more sexual activity, improved sexual desire, and increased erectile function.**
- ▶ **In a 2015 Safety Announcement, the FDA said the popular treatments have not been established as safe or effective for men with common age-related issues like low libido and fatigue.**

Men in the Testosterone Trials were given an initial dose of 5 g daily of AndroGel 1% in a pump bottle. Their testosterone serum levels were tested regularly, and gel doses were adjusted as necessary to keep testosterone levels within the normal range for men 19 to 40 years of age.

“When men get older, their testosterone levels decline and they experience a number of symptoms,” says study co-author Shalender Bhasin, MD, from Brigham and Women’s Hospital, Harvard Medical School. “Some of these symptoms are similar to those experienced by men who have testosterone deficiency. The most common complaints are sexual symptoms, but they often complain of lack of energy or lack of vitality. Older men may also experience decrease in their physical function, their mobility.”

Testosterone gel is often prescribed to offer aging men a boost from these symptoms. AndroGel shares the gel market with brands such as Axiron®, Testim®, and Aveed®. Net sales of AndroGel in 2015 equaled \$692 million, according to Libby Holman, AbbVie’s senior manager of public affairs.

“Testosterone gel is the most commonly prescribed method in the U.S.,” says Bradley Anawalt, MD, chief of medicine at the University of Washington Medical Center, who specializes in male reproductive endocrinology. “In the rest of the world, a long-acting testosterone injection that is administered every ten to 12 weeks is the most common testosterone prescription. This injectable testosterone (testosterone undecanoate) has recently been approved for use in the U.S., but it is very expensive, nearly \$4,000 per year.”

Testosterone Therapy “Often Makes Them Feel Better”

There appears to be little argument to the fact that men with below normal testosterone levels experience a benefit from testosterone gel — and at times multiple benefits.

“The biggest benefit is usually in how men feel,” Anawalt says. “For hypogonadal men, testosterone therapy often makes them feel better. Many men will report improved sexual function and pleasure and some will report improved energy and vitality.”

The Testosterone Trials proved these outcomes. “The most striking and consistent improvements were in sexual function,” Bhasin says. Men who received testosterone reported better sexual function than those in the placebo group. This included more sexual activity, improved sexual desire, and increased erectile function.



In the Physical Function Trial, the men's six-minute walking distance was measured. There was some improvement in the walking speed in all men who were included in the trial. The percent of men whose six-minute walking distance increased by at least 50 m did not differ significantly between the two groups. However, when men were asked whether their walking ability was better, they perceived that it had improved, according to Bhasin.

Results of the Vitality Trails were mixed. Men who took testosterone showed no benefit over placebo on the fatigue scale. Men on testosterone did, however, report slightly lower depression symptoms. And at the end of the trial, men in the testosterone group were more likely to report that their energy was better compared with those given placebo.

Over-Prescribed Despite the Risks?

The boosts to sexual performance and mood do not come without risks. Several research studies have investigated the possible link between testosterone therapy and an increased risk of prostate cancer and heart problems. There have been mixed results with some studies reporting a benefit to testosterone — with decreased cardiovascular events and decreased mortality — and some showing an increase.

“ The biggest benefit is usually in how men feel. For hypogonadal men, testosterone often makes them feel better. Many men will report improved sexual function and pleasure and some will report improved energy and vitality.”

— BRADLEY ANAWALT, MD, CHIEF OF MEDICINE,
UNIVERSITY OF WASHINGTON MEDICAL CENTER,
SEATTLE



“There’s a lot of hype and misperception about what testosterone does and does not do, but...in men who have low testosterone levels and have low libido there is benefit in terms of improved sexual desire and sexual activity but the magnitude of the benefit is modest.”

— SHALENDER BHASIN, MD, BRIGHAM AND WOMEN’S HOSPITAL, HARVARD MEDICAL SCHOOL, BOSTON

In a large 2014 UCLA study published in *PLOS One*, researchers analyzed health insurance claims of more than 55,000 men prescribed testosterone and reported that among men 65 and older, there was a two-fold increase in the risk of heart attack in the 90 days after filling an initial testosterone therapy prescription. In men younger than 65 with a history of heart disease, the risk was two- to three-fold in the first 90 days.

While the Testosterone Trials revealed no differences in major cardiovascular events between the testosterone and placebo groups during the 12-month study, Bhasin points out the set of trials were not powered to determine the long-term risks, particularly cardiovascular and prostate risks. “So the risk-to-benefit ratio still remains unclear and much larger and longer randomized trials are needed,” he says.

Taking note of the enormous jump in sales and proven health risks, the Food and Drug Administration (FDA) issued a Safety Announcement in March 2015 against over-prescribing testosterone-boosting drugs. The FDA said the popular treatments have not been established as safe or effective for men with common age-related issues like low libido and fatigue.

The agency required drug makers to add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone.

The FDA announcement further called for healthcare professionals to prescribe testosterone therapy only for men with low testosterone levels caused by certain medical conditions and confirmed by laboratory tests.

“Many men who are being prescribed T therapy are not being properly evaluated,” Anawalt says. “Some are being started on therapy without having their testosterone blood concentrations measured. Others are being diagnosed with hypogonadism based on a single blood test or tests performed on blood obtained in the afternoon.”

To be diagnosed with hypogonadism, a man must have reproducibly low blood testosterone concentrations on at least two occasions, Anawalt explains. The testosterone measurement should be performed on blood drawn between 7 and 10 a.m. when testosterone concentrations peak. The normal range is based on peak, early morning blood testosterone concentrations, he says.

Bhasin reiterates that while many men may be using the testosterone to enhance sexual performance, the important lesson from the trial is that only men who had consistently low testosterone levels actually improved their sexual desire and function.

“So there’s a lot of hype and misperception about what testosterone does and does not do,” Bhasin says. “But...in men who have low testosterone levels and have low libido there is benefit in terms of improved sexual desire and sexual activity but the magnitude of the benefit is modest.”

FAUNTLEROY IS A FREELANCE WRITER BASED IN CARMEL, IND., AND A REGULAR CONTRIBUTOR TO *ENDOCRINE NEWS*. SHE WROTE ABOUT INCREASED RESEARCH OF NATURAL PRODUCTS IN THE MARCH ISSUE.

NEW RESEARCH SHOWS PROMISE FOR ORAL TESTOSTERONE


BY MARK A. NEWMAN

Two different posters presented at **ENDO 2016** demonstrated positive efficacy in the use of a novel, long-term oral testosterone treatments that are not prone to accidental transference. While one study showed that a twice-daily administration of oral testosterone was effective in improving the psychosexual symptoms in hypogonadal men regardless of the presence of cardiovascular disease, another study revealed that the treatment was safe in the long-term (52 weeks) management of hypogonadal subjects.

Both of the studies — “Hypogonadal Men with and without Cardiovascular Disorders Benefit from LPCN 1021 (Oral Testosterone)” and “Long-Term Safety and Tolerability of Oral Testosterone (LPCN 1021) in Hypogonadal Men” — reported their results from the 52-week, phase 3 Study of Androgen Replacement (SOAR), a randomized, active-controlled, two-arm, 12-month, open-label, multicenter, dose-titration trial that included 314 hypogonadal men between the ages of 18 and 80 years. LPCN 1021 is also branded as TLANDO.

“Long-Term Safety and Tolerability of Oral Testosterone (LPCN 1021) in Hypogonadal Men” demonstrated that LPCN 1021, an investigational oral testosterone replacement therapy that is currently under the Food and Drug Administration (FDA) review, restored testosterone levels in men with hypogonadism who received treatment for up to 52 weeks, according to the study’s lead author, Adrian Sandra Dobs, MD, MHS, professor of Medicine and Oncology, the Johns Hopkins University School of Medicine, Baltimore, Md. “This study also assessed the safety profile of LPCN 1021 over the duration of the study versus the leading topical gel. Notably, no liver function issues were identified in patients who received LPCN 1021. The long-term safety profile suggests that, if approved, LPCN 1021 could fill a significant unmet need for an oral testosterone replacement therapy option that does not carry the risk of inadvertent transference associated with gels.”

“Hypogonadal Men with and without Cardiovascular Disorders Benefit from LPCN 1021 (Oral Testosterone)” suggests




LPCN 1021, also branded as TLANDO, could fill a significant unmet need for an oral testosterone replacement therapy option that does not carry the risk of inadvertent transference associated with gels.

that oral LPCN 1021 offers a safe and effective treatment, without some of the concerns associated with other available testosterone replacement therapy (TRT) formulations, such as the risk of inadvertent transference with topical gels or the pain of injections, for hypogonadal men with or without cardiovascular disease, according to Mohit Khera, MD, MPH, director of the Laboratory for Andrology Research at Baylor College of Medicine’s McNair Medical Institute and medical director for the Houston Hospital for Specialized Surgery and Baylor College of Medicine’s Executive Health Program.

“This study assessed the efficacy and safety of LPCN 1021 in men with and without cardiovascular disease,” Khera continues. “It demonstrated that twice-daily oral LPCN 1021 improves psychosexual symptoms in hypogonadal men with or without cardiovascular disease.”

Dobs adds that her study suggests that the safety and efficacy profile of oral LPCN 1021 supports its use as a treatment option for men with hypogonadism. “LPCN 1021 combines testosterone undecanoate and a proprietary delivery system which enables it to be primarily absorbed through the lymphatic system and not the liver to allow absorption and mitigate the risk of hepatic toxicity,” she says.

Although the results of both of these studies seems to show that oral testosterone treatment is an effective alternative to topical treatments without the side effects, both researchers feel that further studies are needed. “Additional research on LPCN 1021 could further explore dosing frequency,” Dobs says, “as well as head-to-head comparisons to provide more information about the benefits and risks compared with non-oral testosterone replacement therapy options.”

Khera, on the other hand, feels that a larger trial using controls would be helpful: “A larger randomized, placebo-controlled study assessing the effects of LPCN 1021 and cardiovascular risk would be beneficial.” 



Hard *to* SWALLOW

BY MARK A. NEWMAN

Both men and women have been wondering what the holdup is with the male birth control pill. While research has shown promising first steps in understanding the science, that elusive pill is still a few years away.

Gender bias and inequality have been in the headlines a lot in recent months, especially as political talking points boil over from simmer seemingly every night. While most of these sound bites center around how women are typically not earning as much as men — a topic even *Endocrine News* has broached (“Gender Bias,” December 2015) — there is one area where women come out ahead: birth control.

Specifically, the pill. Why is the birth control pill — arguably the safest and most effective form of

contraception — only for women? According to the Centers for Disease Control and Prevention/National Center for Health Statistics, of the 62% of U.S. women using contraception, 17% are using the pill (10% rely on condoms, interestingly enough). Aside from the pill, women have a variety of other options (diaphragms, rings, IUDs, implants, patches).

Meanwhile the only reasonable choice for men is a condom or a vasectomy. So where is that male pill?

FUNNY YOU SHOULD ASK...



“ The development of a male pill or another form of male hormone contraception would be the most revolutionary contraceptive development in decades — all new contraceptives that have been developed over the past century have focused on preventing ovulation or fertilization in the woman.”

— BRADLEY D. ANAWALT, MD, CHIEF OF MEDICINE, UNIVERSITY OF WASHINGTON MEDICAL CENTER AND PROFESSOR AND VICE CHAIR, UNIVERSITY OF WASHINGTON DEPARTMENT OF MEDICINE, SEATTLE

SO NEAR, YET SO FAR

The male pill has been as elusive as the white rhino. It's been hotly anticipated for years and always seems to be “just around the corner.” How close are we to seeing the first prescription written for the male contraceptive pill?

Hormonal contraception for men is based on suppressing endogenous production of testosterone and sperm, according to Bradley D. Anawalt, MD, chief of medicine, University of Washington Medical Center and professor and vice chair, University of Washington Department of Medicine, Seattle. “Most of the research has focused on the combination of testosterone plus a progestin, another sex steroid hormone that is found in men and women,” he explains. “Previous studies of male hormonal contraceptives have shown that injectable formulations provide effective contraception that is far superior to the condom and compares favorably to most female contraceptive options.”

Before there's a men's birth control pill, there will more likely be other contraceptives administered via implant, injection, or transdermally, according to Stephanie Page, MD, PhD, Robert B. McMillen Professor in Lipid Research, section chief, Endocrinology and Diabetes, Harborview Medical Center; professor, Division of Metabolism and Endocrinology, University of Washington, Seattle. “This is due to some of the challenges with oral testosterone delivery, which include issues of serum half-life — how long it remains in the blood and therefore how often a pill would need to be dosed — and some potential side effects.”

Anawalt concurs and says that despite the great public interest in a male pill, he predicts that the first reversible male hormonal contraceptive will be one of those methods mentioned above. “Such formulations have already been developed and tested,” he says. “There is currently no safe oral form of testosterone that is effective with a single daily dose.”

Anawalt adds that taking a pill two to three times a day is simply not practical. “However, because of the increasing number of prescription of testosterone products for the treatment of male hypogonadism (or ‘low T’),” he says, “there has been more work done to develop oral forms of testosterone and oral forms of androgens (compounds that act like testosterone in the body). So, the development of a male pill is much more promising.”

LIFE AS WE KNOW IT

There is little doubt that the market — and the populace — would welcome a male birth control pill. For one thing, it would take the onus of contraception off of the woman. According to Anawalt, men would welcome a reliable, reversible contraceptive method other than the condom. “Having a male pill available would allow men to participate meaningfully in family planning,” he says. “In addition, the development of a male pill or another form of male hormone contraception would be the most revolutionary contraceptive development in decades — all new contraceptives that have been developed over the past century have focused on preventing ovulation or fertilization in the woman.”

A male pill will need to be nearly side-effect-free in order to make it through the regulatory process, according to Page, since they don’t provide a direct health benefit to their users, whereas female methods protect a woman from pregnancy, which can be a life-threatening condition in some cases.

Of course, the impact of the male pill — or any reversible method for that matter — would depend on cost, availability, and acceptability. While there probably won’t be a cultural revolution such as the one that occurred with the original pill, a male contraceptive pill will definitely influence cultures, as well population growth. “The market for such a product will likely vary amongst different countries and cultures,” Page says. “For example, there is likely a market within monogamous couples, especially those where the female partner cannot use hormones, and, conversely, among single men who want to control their own fertility.”

Page adds that population growth is a hugely important issue for the next century, both from an environmental and health perspective and that many men want to be partners in contraception, and there is overwhelming data that increased contraceptive availability increases use and reduces unplanned pregnancy. “In this regard, male hormonal contraception could have a big impact if it is readily available, and affordable, to men,” she adds. “Non-hormonal methods are being very actively pursued in the laboratory, but there has been almost nothing that has made it to human trials, and nothing yet tested in the U.S. in this space, so that is likely why the research hasn’t garnered as much attention.”



AT A GLANCE

- ▶ **With either a vasectomy or condoms, men have had far fewer options than women when it comes to birth control.**
- ▶ **Male hormonal contraception is based on suppressing testosterone and sperm production, and experts agree that a gel, implant, or injection would arrive long before a pill.**
- ▶ **Research into a male birth control pill has been ongoing for many years, but a male pill is still at least a decade away.**



“ The market for [the male pill] will likely vary amongst different countries and cultures. For example, there is likely a market within monogamous couples, especially those where the female partner cannot use hormones, and, conversely, among single men who want to control their own fertility.”

— STEPHANIE PAGE, MD, PHD, ROBERT B. MCMILLEN
PROFESSOR IN LIPID RESEARCH, SECTION CHIEF,
ENDOCRINOLOGY AND DIABETES, HARBORVIEW
MEDICAL CENTER; PROFESSOR, DIVISION OF
METABOLISM AND ENDOCRINOLOGY, UNIVERSITY OF
WASHINGTON, SEATTLE

FROM BENCH TO MEDICINE CABINET

A study published in the October 2015 issue of *Science* showed that male mice treated with cyclosporine A and FK506, which act as calcineurum inhibitors, resulted in male infertility within two weeks. Fertility returned one week after stopping the treatment. The researchers, led by Haruhiko Miyata of Osaka University in Japan, discovered a protein called calcineurin, which is responsible for propelling the sperm through the membrane of a female egg and thus fertilizing it.

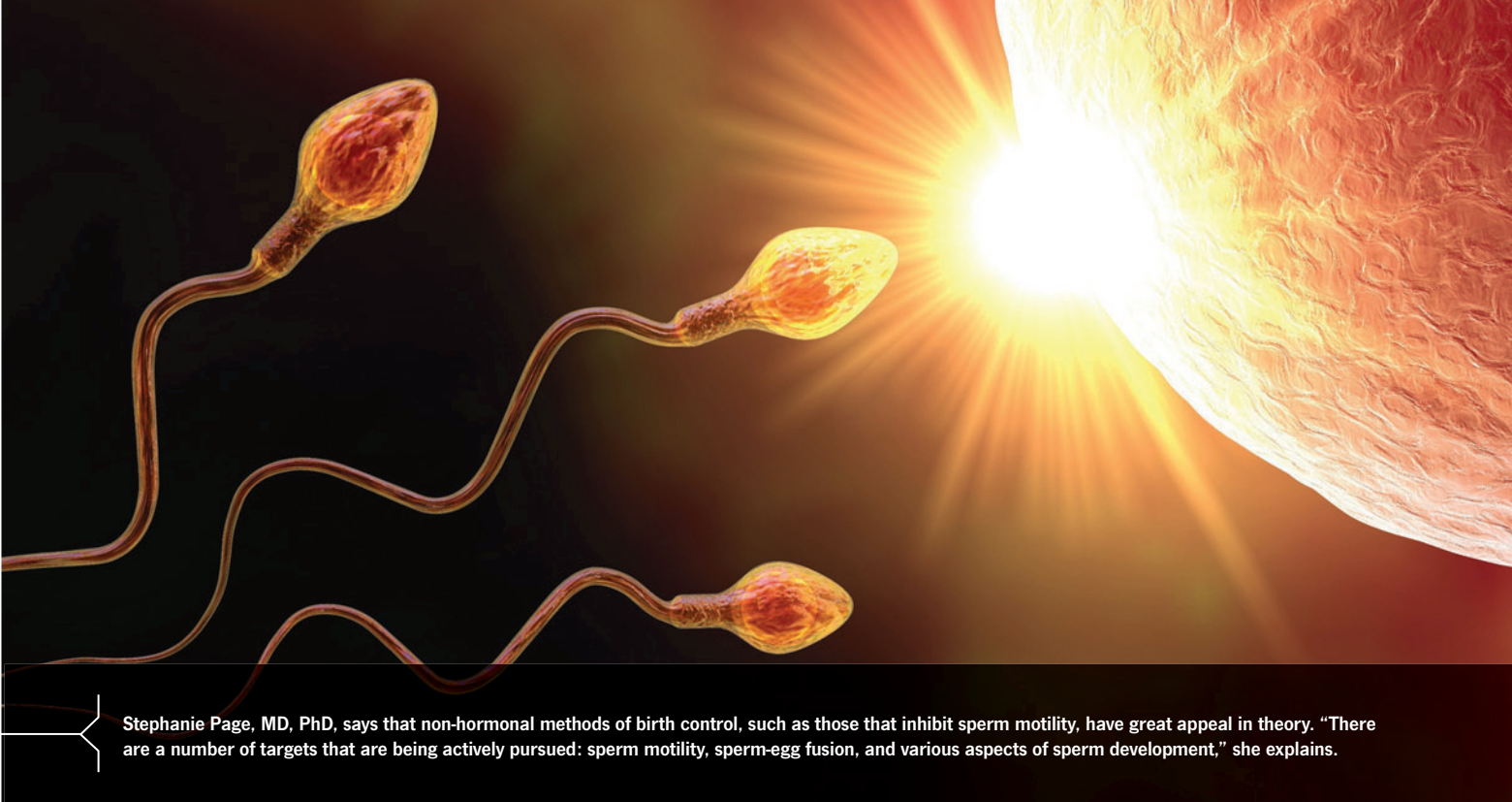
“We found that the sperm-specific calcineurin is essential for sperm fertility, and its inhibitor could work as a male contraceptive in mice,” says one of the study’s authors, Masahito Ikawa, PhD, professor, Animal Resource Center for Infectious Diseases, Research Institute for Microbial Diseases, Osaka University, Osaka, Japan, who adds that since humans also have sperm calcineurin, the same effect would be expected.

“However, there is a problem that the somatic cells also have a different type of calcineurin,” Ikawa continues. “The inhibitor we tried [cyclosporine A and tacrolimus] also inhibit somatic ones and lead to immuno-suppression. Therefore, we cannot use these drugs. We hope to find the lead molecules within two to three years and examine their effects in animals in five to six years.”

Another study from 2015 examined the protein architecture of sperm and revealed that there may actually be components that serve as a “battering ram” to get the sperm into the egg to fertilize it. The study was led by John Herr, PhD, a professor of cell biology at the University of Virginia, Charlottesville, and was such big news that it was the cover story for the August 2015 issue of *Andrology*.

“An important component in the quest for a non-hormonal approach to male contraception is the identification of tissue-specific drug targets,” Herr says. “Because the bar is very high for a male contraceptive drug, which treats otherwise healthy subjects, drug targets that are restricted to the testis provide a key strategy to achieve a selective mechanism of drug action. In the SLLP family, SLLP1, 2 and 6, are testis-specific proteins that are restricted to post-meiotic spermatids and sperm in their expression patterns. These proteins provide a means to target the very last step of spermatogenesis: the differentiation of spermatids into sperm.”

Page adds that non-hormonal methods of birth control, such as those that inhibit sperm motility, have great appeal in theory. “There are a number of



Stephanie Page, MD, PhD, says that non-hormonal methods of birth control, such as those that inhibit sperm motility, have great appeal in theory. “There are a number of targets that are being actively pursued: sperm motility, sperm-egg fusion, and various aspects of sperm development,” she explains.

targets that are being actively pursued: sperm motility, sperm-egg fusion, and various aspects of sperm development,” she explains. “The problems in this area have been a real lack of specificity in the proteins involved in these processes in humans. For example, enzymes that propel sperm are very closely related to enzymes that propel other vital cell types in the body, so designing a drug that only affects that process in sperm is very tricky. Calcineurin is not a sperm-specific protein, but rather quite a ubiquitous one.”


Ikawa and the Osaka University team have partnered with researchers at the Baylor College of Medicine in Houston to perform further studies to find specific drugs that inhibit calcineurin, but not somatic cells. He adds that even with these further studies he does not see an actual male pill for at least another decade, if not longer.

THE WAITING GAME

Anawalt is very encouraged by two areas of research that could lead to making the male pill a reality. “The NIH has funded research on novel hormonal compounds that have androgenic and progestinic properties. Some of these novel compounds appear to be highly potent, safe, and effective as an oral pill or capsule,” he explains. “Besides

the development of new compounds, the NIH has funded an international study of a testosterone-nesterone gel. This study will shed insight into the effectiveness, safety, and acceptability of a male hormonal contraceptive gel that is applied daily.” This is the type of research that is crucial for the future development of safe, reversible male hormonal contraceptive such as gel, implant, or a male pill.

Likewise, Page feels that progress is being made on other fronts as well; the FDA is planning to review two oral testosterone products within the next couple of years. “Moreover, despite a current lack of support from the pharmaceutical industry, the NIH has continued to fund a small program testing novel androgens [derivatives of testosterone] and these look promising for once-a-day oral delivery,” she says. “Thus, the 10-year benchmark that we have talked about for a few years now looks more promising than in the past.”

“We need more creative and talented scientific energy directed at these projects as well as investors who are willing to make this a priority,” Page adds. “These issues will far outlast my time as an investigator, but investing in discovery and delivery is critical to making both short- and long-term impacts on health and choice for families.” 

NEWMAN IS THE EDITOR OF *ENDOCRINE NEWS*. HE WROTE ABOUT THE ENDOCRINE SOCIETY'S NEW OPEN ACCESS JOURNAL IN THE MAY ISSUE.



BOYS *to* MEN

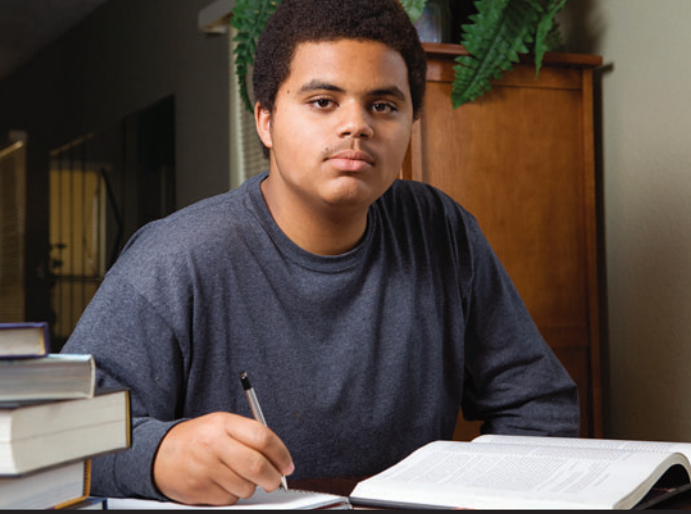
BY KELLY HORVATH

A new study shows that weight and race could play a role in what ages that certain boys hit puberty.

Spurred by mixed and even conflicting results from studies evaluating whether an association exists between weight and timing of puberty in boys, as it is known to exist in girls, a recent article published in *Pediatrics* reported findings that body weight not only does affect timing of puberty in U.S. boys, but does so in a strikingly nonlinear fashion.

In “Timing of Puberty in Overweight Versus Obese Boys,” study authors led by Joyce Lee, MD, at the University of Michigan in Ann Arbor, found that in certain ethnic groups, obesity contributed to delayed puberty in boys compared to normal-weight boys, whereas overweight contributed to earlier pubertal timing. Using data collected by pediatricians during routine well-child visits from approximately 3,900 boys, in addition to height and weight for age, researchers analyzed the age at which Tanner genital development stages 2 through 5 were reached. Of the participants, 49.9% were white, 25.8% were African American, and 24.3% were Hispanic, with 60% being normal weight, 17% overweight, and 23% obese (body weight categories defined by the Centers for Disease Control and Prevention).

The data showed that overweight white boys entered Tanner stage 2 genital development (Tanner GD2), an early stage of puberty comprising testicular enlargement, at average age 9.3 years, which is about .7 years earlier than their normal-weight peers who entered puberty at an average age of 10 years. This cohort also entered Tanner GD5, the final pubertal stage, earlier, at about age 14.5 years compared with age 15.2 years. Obese white boys, by contrast, entered Tanner GD5 later than average, at around 15.4 years old.



“If there is a relationship between pubertal delay and obesity, it is most clearly seen in African-American boys, although there may be a smaller trend in the same direction in Hispanic boys.”

— PAUL KAPLOWITZ, MD, CHILDREN'S NATIONAL HEALTH SYSTEM IN WASHINGTON, D.C.

In African-American boys, obese boys entered Tanner GD3 (characterized primarily by penile elongation) about 11 months later than overweight boys and Tanner GD4 12 months later, whereas normal-weight boys entered Tanner GD4 (characterized by overall penile enlargement and other changes) four months later than overweight boys.

In Hispanic boys, significant differences in puberty onset were not found across weight categories.

It's Complicated

Such findings come from taking the data at face value, explains Paul Kaplowitz, MD, from the Children's National Health System in Washington, D.C., who is acknowledged as contributing his expert opinion on development of the study manual and who is also an Endocrine Society expert. The actual take-away is considerably more nuanced.

The idea of body weight affecting pubertal timing in boys is still controversial, despite the many attempts to verify a relationship, in part because there are problems with reliably assessing the onset of puberty in males. “The bottom line is that defining the onset of puberty in boys is somewhat more challenging than defining the onset of puberty in girls, in whom breast development is a fairly reliable indicator,” Kaplowitz says. “In boys, the earliest sign of puberty is not genital enlargement but testicular enlargement, which can be very subtle and takes careful measurement. The question is, then, what point of testicular size determines onset of puberty? I believe that the 3 ml and 4 ml markers used in this study might not be reliable indicators of puberty. In my practice, I have seen many boys with 3–4 ml testes who are not going into puberty, but 5 or 6 ml is a different story.”

A related issue is the confounding delay between Tanner GD2 and Tanner GD3 that researchers reported. “If puberty were really starting at stage 2, then stage 3 should have been reached within six to 12 months later, instead of two to three years later,” Kaplowitz says. For example, normal-weight African-American boys were reported to have reached GD2 at an average age of 8.8 years and GD3 at age 11.1 years, or 2.3 years later. Further evidence that 3 ml testicular volume (TV) is not reliable for defining onset of puberty is that progressing from TV 3 ml or greater to TV 4 ml or greater was reported to take 1.6 to 2.0 years, a very long time for such a small increase. Therefore, staging male puberty at GD3, which is characterized by both penile and testicular enlargement, is more reliable. Focusing on when Tanner GD3 was reached rather than on Tanner GD2 reveals little overall difference among the groups, except in African-American boys — obese African-American boys reached Tanner GD3 about 0.6 years later than normal-weight African-American boys, and this delay continued through Tanner GD4 and GD5. “If there is a relationship between pubertal delay and obesity, it is most clearly seen in African-American boys, although there may be a smaller trend in the same direction in Hispanic boys,” Kaplowitz says.

Another puzzling problem with the data analysis is that it leads to the conclusion that overweight boys start puberty *earlier* than normal-weight boys, which seems counterintuitive. If obese boys start puberty later, logically, overweight boys would enter puberty either at slightly less of a delay than their obese counterparts or show no difference in timing from their normal-weight counterparts. “Due to the problem with the definition of GD2 used in the study, I think there is reason to be

suspicious of claims that overweight induces earlier timing of puberty,” Kaplowitz says. “A fundamental problem with this article is that it looks at the data and says there must be two opposite things going on: There is an overweight puberty effect and there is a separate obesity puberty effect, and that does not make biological sense.”

It Gets Even More Complicated!

If no clear relationship exists between obesity and the timing of puberty in males that covers all ethnic groups, why is this association so much more robust in girls, in whom earlier puberty, as indicated by breast development and the appearance of pubic hair, is consistently seen with obesity? “There is quite a sexual dimorphism regarding the impact of obesity on puberty,” Kaplowitz says. His theory as to why the dimorphism arises centers on the reproductive axis, specifically, the leptin produced in adipocytes, which not only regulates appetite and is an essential factor in entering and progressing through puberty, but is also found in higher levels in females and even more so just before puberty.

“It makes a lot of sense to have a mechanism that shuts down reproduction in females when fat stores are low and increases the likelihood of being reproductively mature and capable of supporting a pregnancy when fat stores are good,” Kaplowitz explains. “With males, once they make their contribution, the sperm, there really is no evolutionary reason why body weight would influence reproduction or ability to go through puberty.”

Weight Limits

Supposing obesity does cause delayed puberty in males, are there implications for individual patients? “Prevention of obesity would prevent a slight delay in timing of puberty,” Kaplowitz says. “But nobody has a handle on prevention of obesity because it is such a complex, multifactorial issue. Moreover, there are far more serious consequences of being obese than what you can say about altering the timing of puberty.”

Nevertheless, according to the study authors, the inconsistent findings themselves in this study warrant further investigation into the possible role of weight and puberty in boys. ^{EN}

HORVATH IS A FREELANCE WRITER BASED IN BALTIMORE, MD. SHE WROTE ABOUT GROWTH HORMONE AND ITS EFFECTS ON OSTEOPOROSIS OUTCOMES IN THE MAY ISSUE.



AT A GLANCE

- ▶ Given a marker of 3 or 4 ml testicular volume to signal Tanner genital development stage 2 (Tanner GD2), overweight white boys entered puberty earlier than normal; obese boys entered Tanner GD later than normal. However, differences in timing of Tanner GD3 were not found in white boys, suggesting that the marker used for Tanner GD2 is unreliable.
- ▶ Obese African-American boys entered Tanner GD3 and Tanner GD4 later than normal.
- ▶ Hispanic boys did not exhibit statistically meaningful differences across body weight categories.

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100 YEARS
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The Journey East:

ICE-CSE GOES TO CHINA

BY MARK A. NEWMAN



When the 17th International Congress of Endocrinology/15th Annual Meeting of Chinese Society of Endocrinology debuts in Beijing in August, it will have a scientific program created by an international team of endocrine experts. Serving as the international chairman is Endocrine Society past president, William F. Young, Jr., who shares his enthusiasm for this once-in-a-lifetime conference and tells you why you should attend.

The China National Convention Center (CNCC) is located in the Olympic Green in Beijing, and was originally used for the 2008 Summer Olympics. It covers an area of 270,000 square meters and its stunning architectural design combines traditional Chinese quins with a contemporary design.

For the first time in history, Beijing, China, will play host to the brightest minds in endocrinology who will travel from around the world to be a part of the 17th International Congress of Endocrinology/15th Annual Meeting of Chinese Society of Endocrinology (ICE-CSE) from August 31 to September 4. When the International Congress of Endocrinology was held in conjunction with ENDO 2014 in Chicago, attendance records were shattered.

HEAD

Leading up the scientific program of ICE/CSE 2016 is Endocrine Society past president William F. Young, Jr., MD, MSc, chair, Division of Endocrinology, Diabetes, Metabolism, and Nutrition, Tyson Family Endocrinology Clinical Professor, professor of medicine, Mayo Clinic College of Medicine, Rochester, Minn., who is putting his wealth of knowledge to use as the international chairman, Program Organizing Committee.

ICE/CSE will provide attendees with an experience of unparalleled diversity in terms of the setting, topics, faculty, and participants, according to Young. “It is an international celebration of endocrinology that spans basic science, clinical science, and clinical practice and will be the first International Congress of Endocrinology in mainland China,” he explains, adding that he anticipates more than 8,000 endocrinologists from around the world will attend the event August 31 to September 4 at the stunning China National Convention Center, which was built for the 2008 Olympic Games.

“The convention center is located in the heart of the Beijing Olympic Green precinct and is adjacent to the ‘Bird’s Nest’ Olympic Stadium, the Water Cube, and the National Indoor Stadium,” Young says. “There is a robust social program to visit historic Beijing sites such as Tian’anmen Square, the Forbidden City, the Summer Palace, Ming Tombs, and the Great Wall of China. Attendees will have the opportunity to enjoy Chinese culture — its history, religion, and cuisine.”

Young took time out of his extremely busy schedule to answer more questions about ICE-CSE 2016, what you can expect from the scientific program, and what he’s really looking forward to when he arrives in Beijing.

Q&A WITH WILLIAM F. YOUNG, JR., MD, MSC

Endocrine News: *If a trainee was on the fence about going to ICE-CSE 2016, what would you say to him or her to convince them to go to Beijing?*

William F. Young, Jr.: The program is fantastic. An international Program Organizing Committee has developed a remarkable program that includes 11 plenary presentations, 60 symposia, and 38 meet-the-expert sessions. The program faculty come from 28 countries. What an outstanding opportunity to meet and learn from the world experts! Personally, I find international meetings unique in that the atmosphere is more relaxed, and it is easier to network with the experts. (The details of the program can be found at <http://www.ice-cse2016.org/en/page.asp?pageid=13.html>.)

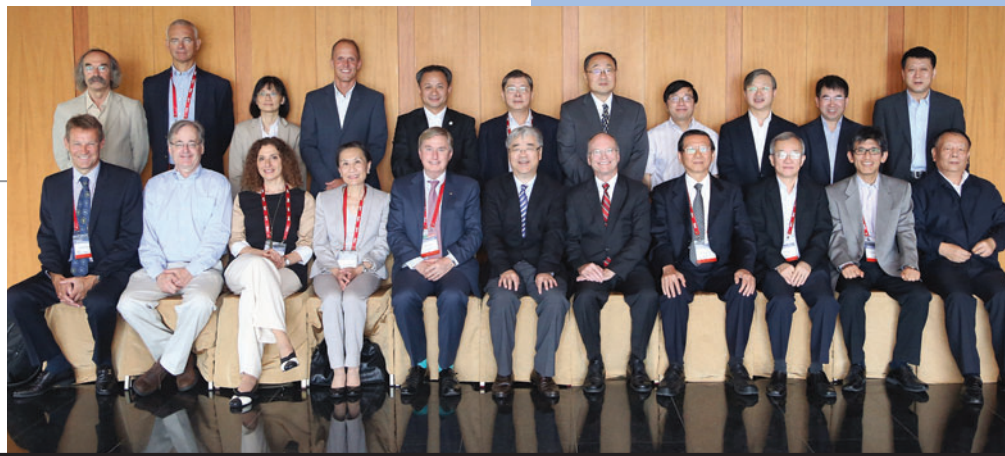
EN: *Endocrine Society members who have attended many ENDOs in their careers may think that they don’t need to go to ICE-CSE 2016. Why should they add this meeting to their schedule?*

WY: Endocrine Society members should consider attending ICE-CSE 2016 because of its truly international program in a fantastic setting. Advances and discoveries in endocrinology are being

“Advances and discoveries in endocrinology are being made worldwide, and they will be on display in Beijing.”



Local and International Program Organizing Committee members at the ICE-CSE 2016 program planning meeting. Members of the POC come from 28 countries, thus creating a truly international perspective for the scientific program.



ICE-CSE 2016 FAST FACTS

made worldwide, and they will be on display in Beijing. Although the program design of ICE-CSE 2016 will be similar to a typical ENDO meeting, the content will be truly international and all taking place in a once-in-a-lifetime setting.


EN: As a past president of the Endocrine Society, what sort of unique perspective do you bring to your role as international chairman of the Program Organizing Committee?

WY: In my role as the international chair of the Program Organizing Committee for ICE-CSE 2016, I relied heavily on past similar roles with the Endocrine Society – I was theme chair for ENDO 2003 and overall chair of the Annual Meeting Steering Committee for ENDO 2007. In addition, having served as president of the Endocrine Society (2012 – 2013), I was able to build on many international connections, friends, and resources. We have an outstanding Program Organizing Committee that worked very hard to develop an innovative and exciting program.

EN: Can you give some of our basic scientists and clinical researchers a sneak peek at some of the new science that will be presented in Beijing?

WY: The ICE-CSE 2016 program is simply fantastic. Plenary topics span new insights in hormones and cancer to iodine and thyroid disorders in China to origins of sex differences in the brain to endocrine-disrupting chemicals to mechanisms of cell signaling in insulin secretion to nuclear receptors in development. We have an all-star cast of plenary speakers, including professors Wayne Tilly, Guan Ning, John Funder, Weiping Teng, Susumu Seino, Graham Williams, Sedaf Farooqi, Margaret McCarthy, Vincent Laudet, Andrea Dunaif, and Jean-Pierre Bourguignon. The 60 symposia topics span the breadth of endocrinology – the typical symposia has three experts and all from different countries.

EN: Finally, what are you looking forward to the most when you step off the plane in China?

WY: As any program organizing committee chair can tell you, what we most look forward to is a successful execution and completion of the meeting! This will be my fourth trip to China, and each time it has been a great adventure – the culture, the sites, and of course the food. In the evenings, I am looking forward to sampling Peking duck, Jiaozi dumplings, and Zha Jiang noodles! 

MEETING DATES:

August 31 – September 4, 2016

MEETING VENUE:

China National Convention Center,
No. 7 Tianchen East Road, Chaoyang
District, Beijing 100105, China,
www.cncchina.com

LANGUAGE:

English is the official language of
the meeting

CLOTHING:

Informal for all occasions

WEATHER:

Autumn weather arrives in September
as the summer heat begins to wane,
and the weather in the north becomes
cooler. There may still be prolonged
rain, but it is usually not as heavy.

WIFI:

The CNCC provides free WI-FI:
CNCC-FREE

For more information, go to
www.ice-cse2016.org.

Bridging THE Gap BY KURT ULLMAN



Care coordination software connects a patient's many providers to one another... and it may actually increase reimbursement.

As value-based reimbursement and reporting requirements of the Affordable Care Act roll out, it is becoming important that practitioners not only treat their patients according to guidelines but also be able to prove they did. This can be difficult when patients with chronic conditions, such as diabetes, are seen by multiple providers. One application to address this is care coordination software (CCS).

“In the U.S., we have a fragmented healthcare system where many people see their primary care physician (PCP) who has one electronic medical records (EMR) program and one or more specialists who are often on one or more different EMRs,” says Joseph Mayer, MD, CEO of Cureatr in New York City. “The many people taking care of a patient may not know the others exist or know for sure what happened with the patient when they are released from one organization to another.”

Health Team Communication

CCS is designed to allow all healthcare professionals involved with a patient to communicate with each other seamlessly independent of the specific EMR they use. They also have solutions to track, manage, and analyze patients.

These programs sit atop the EMR and pull out information needed to document that the patient is getting care according to guidelines. They make it harder for things to drop through multiple cracks when care is handed off across many providers.

“One of the main complaints about having all of this new information from EMRs is that there is too much data,” says Derek Kosiorek, principal consultant for MGMA Healthcare Consultants in Denver. “EMRs are often set-up to transmit the entire encounter when all that is needed is just a small bit, so all of the providers have to wade through pages and pages of information. CCS works to allow customization of the reply so the individual practitioner gets only the information that is important to them.”

Financial Concerns

There are financial concerns, as about the last thing a practice needs is to spend more money. However, if you have signed on to a value-based reimbursement program or an accountable care organization (ACO), your ability to document what is being done for the patient, and the outcomes, directly impacts reimbursement.

“For endocrinologists, these programs can be very important because diabetes is one of the biggest high-risk chronic conditions that needs the care coordination functionality,” says Nancy Fabozzi, principal analyst for connected health at Frost & Sullivan in Mountain View, Calif. “These patients are likely to see a number of specialists because of the many comorbidities associated with the disease, and all of the documentation from the neurologist, podiatrist, cardiologist, and even ancillary services such a dieticians, needs to be accessible.”

CORE FUNCTIONS OF CARE COORDINATION SOFTWARE

Nancy Fabozzi, principal analyst for connected health at Frost & Sullivan, says there are five core functions needed to support care coordination:

- 1. DATA INTEGRATION.** “You have to have a tool that is going to bind together data from many different areas.”
- 2. RISK INTEGRATION FUNCTION.** “This is an analytic tool that flags and stratifies those who are at highest risk for bad outcomes.”
- 3. CARE PLANNING.** “You should have evidence-based care management protocols included to provide clinical decision support outlining what needs to be done once the patient is identified as being at high risk.”
- 4. PATIENT ENGAGEMENT.** “This closes the loop between patients and the care team. A robust CCS solution brings in messaging, patient education content, apps, and all of the other things that help people engage in managing their own health.”
- 5. REPORTING.** “As we transition to value-based reimbursement, you have to be able to prove you are managing these patients and that there are positive outcomes. Your reimbursement is going to depend on that.”

“ For endocrinologists, these programs can be very important because diabetes is one of the biggest high-risk chronic conditions that needs the care coordination functionality. These patients are likely to see a number of specialists because of the many comorbidities associated with the disease.”

— NANCY FABOZZI, PRINCIPAL ANALYST FOR CONNECTED HEALTH AT FROST & SULLIVAN IN MOUNTAIN VIEW, CALIF.



Rolling Out the System

When rolling out a system, there are some considerations for the practice to consider early in the process. Probably the first call should be to their EMR vendor to see if they have a solution that fits with the practice's current program. These add-ons are becoming more widely available because interoperability is part of the next round of Meaningful Use (MU) rules.

For others a third-party solution may be the best fit. Either way, the practice should ask the vendor about how it will support changes required as standards for data transmission are promulgated.

Developing Area

This is still a developing area, so the practice will have to decide how soon, or even if, it wants to start working toward its own solution. On the one hand, if the practice doesn't have a good system, it may be at a competitive disadvantage to those who can communicate effectively with referral sources. On the other, there isn't an accepted

definition of what CCS means so what is included in the package may vary greatly from one vendor to another.

“I'd probably sit it out a bit,” says Kosiorek. “I think eventually every EMR will have to have a standardized interface method built in. My current suggestion is making sure your records programs are certified to MU standards. This means it is up-to-date so the interfaces, when they are agreed upon, can be easily used.”

For the most part, the experts say that interoperability standards would negate the need to work with others on the patient care team to get the same program. They do suggest that practices contact any ACOs or hospitals they are involved with as some may provide subsidies for adopting specific programs.

“The main goal of care coordination software is to solve the problems related to treating a patient across many providers,” says Mayer. “In my mind, it isn't just one thing, but many different things all leading to better care of the patient as they move around the healthcare system.” ^{EN}

ULLMAN, RN, MHA, IS AN INDIANA-BASED FREELANCE WRITER WITH NEARLY 30 YEARS OF EXPERIENCE. HE WROTE ABOUT REFERRALS IN THE DECEMBER ISSUE.

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From the **BOARDROOM** *to the* **LAB** BY MELISSA MAPES



Nowhere is mentoring more important than in the world of medicine. Here are six mentoring tips from the business world that could handily apply to your lab.

Every physician and researcher fills the role of an apprentice in the early years of his or her career. The guidance of seasoned experts is vital to mastering any profession, but this is especially emphasized in two domains: business and medicine. Mentorships have an enormous impact on the direction and success of one's career in both of these sectors, yet there has been far more writing and research about mentoring in business.

In the world of medicine, limited resources exist to guide scientists and physicians through the transition from mentee to mentor. One might think that life is easier as the expert, but mentoring is an art in and of itself requiring a whole different set of knowledge and skills from the field in which one actually practices.

Pulling on advice from the business sphere, here are six tips for becoming a great mentor that are equally applicable to medicine.

Set expectations together

1

Defining the relationship between mentor and mentee is the first step to establishing a positive and productive dynamic. What will one-on-one time look like? How will feedback be communicated, and what are the areas that the mentee hopes to develop? How can you two best work together? All of these questions should be considered at the very beginning of a mentorship relationship.

When one or both individuals fail to communicate expectations, it can lead to disappointment and confusion on either end. Mentorships sometimes dissolve when trainees and fellows do not know the terms of the relationship and feel uncomfortable asking for feedback or help from their mentor. Often, the impetus falls on the mentor to make sure that a conversation outlining these terms occurs early on, finding out what the mentee needs, and letting them know the ways in which you can help.

Take a genuine interest

2

Both professionally and personally, it is important to really get to know your mentee. Sure, good advice can be given to aspiring endocrinologists without the time investment of developing an individual rapport. But great advice comes when you truly understand the person you are mentoring.

There is a singular refrain that emerges across articles on mentorship: listen. It may feel like there is pressure to immediately provide helpful feedback, but it is often better to let the mentee lead a conversation, asking questions and waiting to offer guidance until after you have had a chance to give serious thought to their situation. Through close listening, mentors also demonstrate that they have a genuine interest in their mentee, which fosters a supportive bond.

5 QUESTIONS TO ASK YOUR MENTEE

Inspired by Deepak Chopra, business mogul Mats Lederhausen told the *Harvard Business Review* the five questions that every mentor should ask their mentee, no matter if they work in finance, politics, media, or, of course, medicine.

1. What is it that you really want to be and do?
2. What are you doing really well that is helping you get there?
3. What are you not doing well that is preventing you from getting there?
4. What will you do differently tomorrow to meet those challenges?
5. How can I help and where do you need the most help?

3 Provide honest, but diplomatic, feedback

A successful mentorship requires honest, critical feedback. Mentors need to be upfront and direct with their thoughts on a mentee's work but should couch criticism with encouragement. The challenge is finding the right balance between candidness and reassurance.

Mentors should think about what their mentee needs to hear from them, not what they want to hear from them. With that as a barometer, the most constructive feedback for a trainee or fellow should come to mind, both positive and negative.

4 Share what you know

Passing on knowledge is the most basic underpinning of mentorship. However, the imparting of skills comprises only part of the wisdom that great mentors share with their mentees. In addition to the steps that led to accomplishments, mentors should also explain the mistakes they made along the way. Your biggest bloopers may provide more valuable learnings than your biggest successes.

5 Think long term

Eventually, every mentorship reaches a natural conclusion. The relationship between the two individuals may continue, but the need for frequent oversight and direction will diminish as the mentee grows in his or her career. This means a mentor has done his or her job well — it is the ultimate goal of any mentorship.

To attain this end, the mentor and mentee need a long-term plan. When a fellow or trainee is ready to start thinking about independent projects, it is time to outline next steps for his or her career and the changing circumstances of the mentorship. There is no exact formula for a mentor “exit strategy,” so the best way to move forward is through open communication about evolving expectations.

6 Celebrate achievements

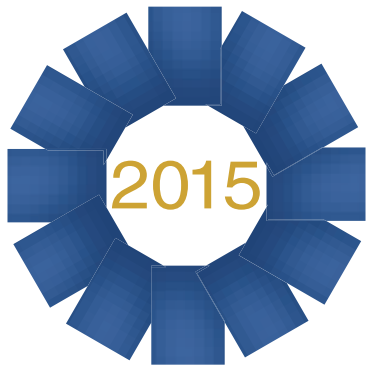
Conversations between mentors and mentees have a tendency to focus around problems that need to be solved rather than success that has been achieved. This is generally because the mentee is asking for guidance with obstacles he or she is working to overcome. But making a point of highlighting a mentee's accomplishments will not only lift the mood of meetings, it will help build confidence.

When a mentee makes a smart move, recognition from a mentor reinforces such behavior in the future. This will keep him or her motivated despite the inevitable setbacks that come at the beginning of any career, and it is meaningful to hear positive words from someone he or she wishes to impress. Such commendation can take multiple forms, ranging from a private compliment to public acknowledgment in front of peers and other experts.



Every mentoring relationship is different, and there is no template for how to lead your mentees to success. The approach mentors take simply has to work for them and for the individuals they mentor. By keeping the channels of communication open and remembering these six tips from the business world, mentors can enhance the productivity and positive dynamic of the relationship helping ensure that the next generation of endocrinologists is positioned for great progress. ^{EN}

MAPES IS A WASHINGTON, D.C.-BASED FREELANCE WRITER AND A REGULAR CONTRIBUTOR TO *ENDOCRINE NEWS*. SHE WROTE ABOUT THE ARTIFICIAL PANCREAS AT THE PRESIDENTIAL PLENARY AT ENDO 2016 IN THE FEBRUARY ISSUE.



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100 YEARS
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Centennial Hill Day Participants Urge Congress to Support NIH, Medicare Coverage of Continuous Glucose Monitors

The Endocrine Society members representing the Society's leadership, Advocacy & Public Outreach Core Committee, Clinical Affairs Core Committee, Research Affairs Core Committee, Centennial Task Force, and Future Leaders to Advance Research in Endocrinology (FLARE) headed to Capitol Hill April 28 to educate members of Congress about the importance of the endocrinology field. The Society held the Hill Day and a congressional reception as part of its centennial celebration.

With Congress in the midst of the federal appropriations process, Hill Day participants emphasized the importance of federal funding for the National Institutes of Health (NIH) to support the development of new treatments for endocrine conditions. Society members also called on Congress to extend Medicare coverage to continuous glucose monitors so that people who are insulin dependent don't lose access to this lifesaving technology when they age into Medicare.



Endocrine Society president Henry Kronenberg, MD, introduces Congressional Diabetes Caucus co-chairs Diana DeGette (D-CO) and Tom Reed (R-NY) at the Endocrine Society Centennial Reception on Capitol Hill.



Society members Ann Nardulli, PhD, Rhonda Souvenir, PhD, and past president Richard J. Santen, MD, meet with Senator Charles Grassley (R-IA).

Participants visited with almost 60 congressional offices. As a result of these visits, we gained several additional House and Senate co-sponsors of legislation to extend Medicare coverage for continuous glucose monitors, and we educated many offices about the value of endocrine research.

At the end of the day, the Society hosted a congressional reception on Capitol Hill to celebrate our 100th birthday. We were honored to have the co-chairs of the Congressional Diabetes Caucus, representatives Diana DeGette (D-CO) and Tom Reed (R-NY), join us and speak about their families' experiences with diabetes and their appreciation to the Society for the work we do, including our robust advocacy on the Hill for diabetes legislation and research funding.

TAKE ACTION: Make Your Voice Heard in Congress by Joining Endocrine Society Advocacy Campaigns

All Endocrine Society members are encouraged to share key endocrine messages with their congressional delegations by joining Society online advocacy campaigns. Current campaigns include support for: NIH funding, the Treat & Reduce Obesity Act, the Personal Care Products Safety Act, and Medicare coverage of Continuous Glucose Monitors. The Society's online advocacy center provides information on legislative issues, sample emails, and connects you directly to your congressional delegation's offices after you enter your ZIP code.

Please take a moment to take action today by visiting www.endocrine.org/advocacy.

Society Discusses Priorities and Opportunities for Collaboration with NICHD Leadership



Carole Mendelson, PhD, and Richard Legro, MD, meet with NICHD acting director Cathy Spong, MD. The NICHD is the second largest source of NIH institute funding for Endocrine Society members.

Legro and Mendelson shared Society concerns about set-asides for special projects and how these might impact support for the pool of R01-supported investigators.

On May 6, Endocrine Society members Richard Legro, MD, and Carole Mendelson, PhD, represented the Society at a meeting with leadership from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), including the acting director of the NICHD, Catherine Spong, MD.

During the meeting, Legro and Mendelson discussed how to maintain support for the next generation of researchers given the challenging fiscal climate. Spong discussed the results of a review by the institute of its training programs for graduate students and early career investigators. Moving forward the NICHD will have a greater focus on individual awards to trainees and will make a concerted effort to increase support for the successful K99/R00 program.

The group also discussed challenges facing the biomedical research enterprise generally, including difficulties in maintaining support for investigator-initiated research projects. The NICHD described how it is reviewing its grant portfolio and comparing it to other institutes to determine what variances exist and how they should be managed. Legro and Mendelson shared Society concerns about set-asides for special projects and how these might impact support for the pool of R01-supported investigators.

Spong highlighted the many synergies that exist between the priority areas supported by the NICHD and the disease and research interests of Endocrine Society members. She encouraged us to continue to raise the profile of research on women and children's health and work with the institute to raise awareness among trainees of the programs at the National Institutes of Health (NIH) to support their research.

We will continue to work with the NICHD to advance endocrine research and explore further opportunities to collaborate. For more information on NICHD priorities and news from the institute, please see the NICHD website at <https://www.nichd.nih.gov/Pages/index.aspx>.

White House Launches National Microbiome Initiative; Half a Billion Dollars Pledged to Study the Microbes in Humans, Crops, Soils, Oceans, and More



On May 13, the White House Office of Science and Technology Policy (OSTP), in collaboration with federal agencies and private-sector stakeholders, announced a new National Microbiome Initiative (NMI) to foster the integrated study of microbiomes across different ecosystems.

The NMI aims to advance understanding of microbiome behavior and enable protection and restoration of healthy microbiome function. In a year-long fact-finding process, scientists from federal agencies, academia, and the private sector converged on three recommended areas of focus for microbiome science, which are now the goals of the NMI:


1. **Supporting interdisciplinary research** to answer fundamental questions about microbiomes in diverse ecosystems.
2. **Developing platform technologies** that will generate insights and help share knowledge of microbiomes in diverse ecosystems and enhance access to microbiome data.
3. **Expanding the microbiome workforce** through citizen science, public engagement, and educational opportunities.

The NMI builds on strong and ongoing federal investments in microbiome research and will launch with a combined federal agency investment of more than **\$121 million** in fiscal years (FY) 2016 and 2017 funding for cross-ecosystem microbiome studies. This includes:

- The **Department of Energy** proposes \$10 million in new funding in FY 2017 to support collaborative, interdisciplinary research on the microbiome.
- The **National Aeronautics and Space Administration (NASA)** proposes \$12.5 million in new funding over multiple years to expand microbiome research across Earth's ecosystems and in space.
- The **National Institutes of Health** will invest an extra \$20 million into microbiome research in grants in FY 2016 and FY 2017 with a particular emphasis on multi-ecosystem comparison studies and investigation into design of new tools to explore and understand microbiomes.
- The **National Science Foundation** proposes \$16 million in FY 2017 for microbiome research that spans the spectrum of ecosystems, species, and biological scales.
- The **U.S. Department of Agriculture** proposes more than \$15.9 million for FY 2017 to expand

computational capacities for microbiome research and human microbiome research through the Agricultural Research Service, and approximately \$8 million for FY 2017 to support investigations through the National Institute of Food and Agriculture of the microbiomes of plants, livestock animals, fish, soil, air, and water as they influence food-production systems.

In addition, more than 100 external institutions announced new efforts to support microbiome science. These include:

- The **Bill and Melinda Gates Foundation** will invest \$100 million over four years to investigate and develop tools to study human and agricultural microbiomes.
- **JDRF** will invest \$10 million over five years to address microbiome research related to type 1 diabetes.
- The **University of California, San Diego**, is investing \$12 million in the Center for Microbiome Innovation to enable technology developers to connect with end users.
- **One Codex** is launching a public portal for microbiome data, allowing greater access to this data for researchers, clinicians, and other health professionals.
- **The BioCollective, LLC**, along with the **Health Ministries Network**, are investing \$250,000 toward building a microbiome data and sample bank, and the engagement of underrepresented groups in microbiome research.
- The **University of Michigan**, with support from the Howard Hughes Medical Institute and Procter and Gamble, will invest \$3.5 million in the Michigan Microbiome Project to provide new research experiences for undergraduate students. 

DISCOVER THE THEORIES AND CONCEPTS BEHIND THIS EMERGING FIELD IN NUTRITIONAL SCIENCE.

EDITORS: JEFFREY I. MECHANICK, MD; MICHAEL A. VIA, MD; AND SHAN ZHAO, PHD

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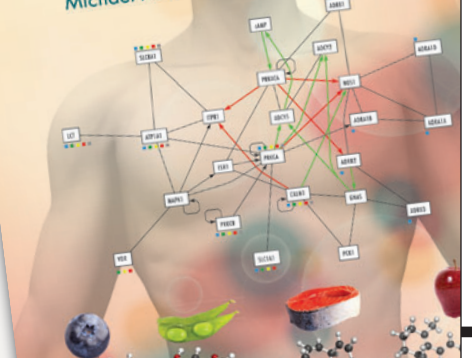
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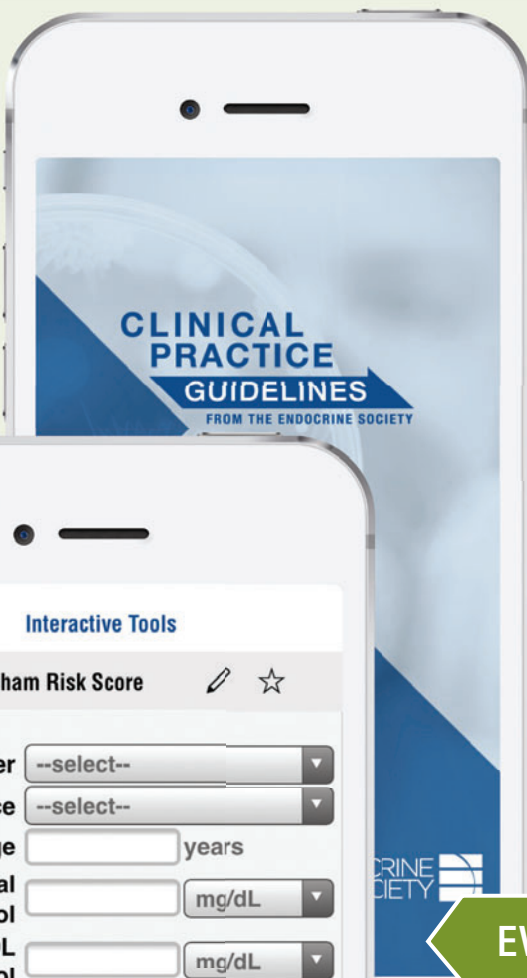
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THE TRUTH ABOUT TESTOSTERONE TREATMENTS

You've seen the ads. You've heard the hype. But testosterone supplements aren't the anti-aging cure-alls that they're marketed as. The use of doctor-prescribed testosterone replacement therapy, however, is safe and can be effective for men who are diagnosed with consistently abnormal low testosterone production and symptoms that are associated with this type of androgen deficiency.

Visit hormone.org for more information.

TESTOSTERONE FACTS FOR MEN

-  Low testosterone comes with age — T levels naturally decrease by 1% each year after age 30, though don't severely deplete, even in advanced age
-  T production may be disrupted by disorders of the testicles, pituitary gland, or brain
-  T levels change from hour to hour — highest in the am; lowest at night
-  T levels can temporarily lower due to too much exercise, poor nutrition, severe illness, and with certain medications
-  Normal T levels should be between 300-1,000 ng/dL (nanograms per deciliter), depending on age and lab used
-  Testosterone must be measured more than once for accurate assessment

TESTOSTERONE THERAPY IS ONLY RECOMMENDED FOR HYPOGONADISM PATIENTS

?

Boosting testosterone is NOT approved by the US Food and Drug Administration (FDA) to help improve your strength, athletic performance, physical appearance, or to treat or prevent problems associated with aging. Using testosterone for these purposes may be harmful to your health.

Men with **HYPOGONADISM** are prescribed testosterone treatment to raise levels to the middle of the normal range, in turn addressing related symptoms of androgen deficiency.

MALE HYPOGONADISM = a combination of low testosterone levels and the presence of any of these symptoms:

- Drop in sex drive (libido)
- Erectile dysfunction (ED — inability to get or keep an erection) and loss of spontaneous erections
- Lowered sperm count and infertility (inability to have children)
- Breast enlargement or tenderness
- Reduced energy
- Increased irritability, inability to concentrate, and depressed mood
- Hot flashes (when testosterone levels are very low)

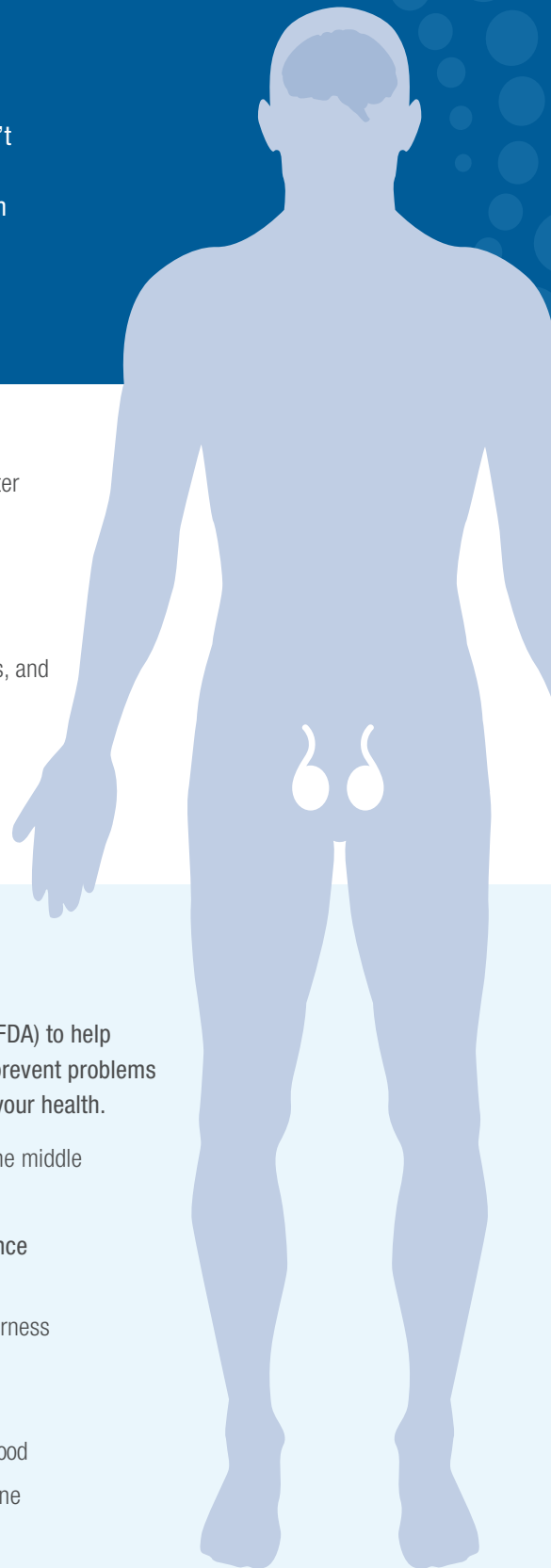
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You should not receive testosterone therapy if you have:

- Prostate or breast cancer (or suspected)
- Uncontrolled heart failure
- Enlarged prostate causing difficulty with urination
- Untreated sleep apnea (obstructed breathing during sleep)
- High number of red blood cells



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THERE ARE VARIOUS METHODS OF TESTOSTERONE THERAPY

Method of treatment depends on the cause of low testosterone, the patient's preferences, cost, tolerance, and concern about fertility.



Injections: self or doctor administered in a muscle every 1-2 weeks; administered at a clinic every 10 weeks for longer-acting. Side effects: uncomfortable, fluctuating symptoms.



Gels/Solutions: apply to upper arm, shoulder, inner thigh, armpit. Side effects: may transfer to others via skin contact — must wait to absorb completely into skin.



Patches: adhere on skin every day to back, abdomen, upper arm, thigh; rotate locations to lessen skin reaction. Side effects: skin redness and rashes.



Buccal Tablets: sticky pill applied to gums 2x a day, absorbs quickly into bloodstream through gums. Side effects: gum irritation.



Pellets: implanted under skin surgically every 3-6 months for consistent and long-term dosages. Side effects: pellet coming out through skin, site infection/bleeding (rare), dose decreasing over time and hypogonadism symptoms possibly returning towards the end of dose period.



Nasal Gel: applied by pump into each nostril 3x a day. Side effects: nasal irritation or congestion.

THERE ARE RISKS TO TESTOSTERONE THERAPY

- Elevated red blood cell count
- Acne
- Sleep apnea
- Possible prostate and/or breast enlargement

There is no firm scientific evidence that long-term testosterone replacement is associated with either prostate cancer or cardiovascular events.

The FDA requires that patients are made aware that the possibility of cardiovascular events may exist during treatment.

Prostate cells are stimulated by testosterone, so be extra vigilant about cancer screenings.

African American men over age 45 — especially those with family history of cancer — are already at risk for prostate cancer.



YOUR DOCTOR SHOULD BE YOUR PARTNER IN CARE

If you are concerned about your testosterone levels and interested in learning more about ways to manage hypogonadism, an endocrinologist can help.

Visit “Find an Endocrinologist” at hormone.org.

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

Additional editing by Alvin M. Matsumoto, MD, University of Washington School of Medicine



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SEEKING TWO ENDOCRINOLOGISTS

Lehigh Valley Health Network (LVHN) in eastern Pennsylvania seeks two BC/BE endocrinologists to join a large network practice. Our new associate will join 9 other endocrinologists who enjoy a favorable call schedule and the benefits of working for the area's largest employer. The position offers the opportunity to teach residents/medical students as well as eligibility for faculty appointment at the University of South Florida, LVHN's academic affiliate.

The physicians, together with 5 NPs, do consults at the 800-bed main campus and the 188-bed Muhlenberg campus, just 20 minutes apart. They also see patients in outpatient offices on these hospital campuses. The LVHN network has a dedicated endocrine testing unit and active diabetes teaching unit with a pump program supported by CDEs, NPs and RDs. The endocrinologists work closely with the physicians within the network's growing bariatric program.

LVHN is a community health network just 60 miles north of Philadelphia and 90 miles west of NYC. For 21 consecutive years LVHN has been listed in U.S. News & World Report as one of the nation's best hospitals. Last year we were recognized for being in the top 3% of leading hospitals in diabetes and endocrinology.

The Lehigh Valley area is anchored by the city of Allentown, the fastest growing city in the state. Urban redevelopment that includes new businesses, sophisticated metropolitan-style housing, four-star restaurants and entertainment venues are credited with the city's growth. Within 10 minutes of the downtown are beautiful suburban neighborhoods, city parks, bike trails, ski areas and more. The academic opportunities in the area include excellent public schools, highly regarded private schools plus 10 colleges and universities. More than 700,000 people live, work, learn and play in the greater Lehigh Valley.

If interested in this opportunity, please email your CV to:
 Pamela.Adams@LVHN.org
 or call 484-862-3202.

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Manager of Physician Recruitment
 (937) 558-3477 office • (937) 657-2447 cell
 sandy.jones@ketteringhealth.org



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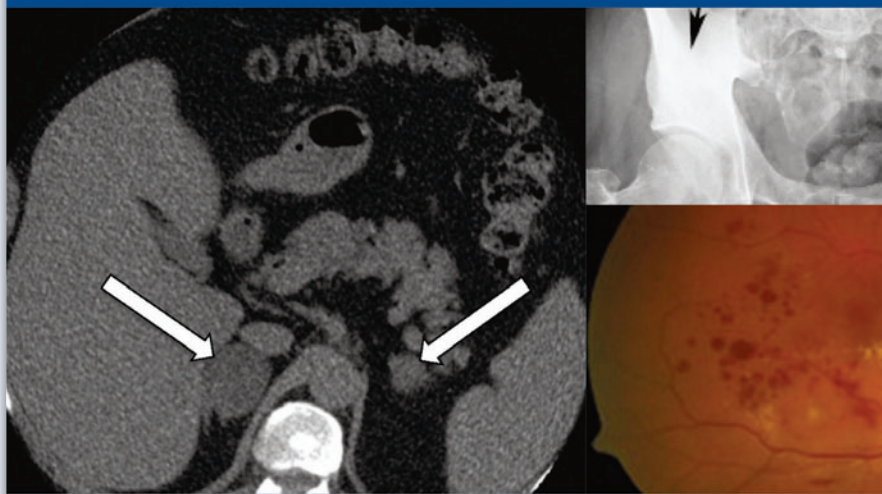
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