# THE LEADING MAGAZINE FOR \_\_\_\_ ENDOCRINOLOGISTS **NOVEMBER 2018** Endocrine INTERNATIONAL

To commemorate National Diabetes Awareness Month, Endocrine News looks at some of the everyday challenges endocrine clinicians face when treating patients with diabetes.

- As insulin prices increase, should older insuling formulations be given a second look?
- How the continuing evolution of diabetes technology is proving to be a challenge for some patient populations.
- Finding new and creative methods to treat diabetes with a human-first, design-centric approach.
- **An Endocrine Society Position Statement identifies** barriers to accessing affordable insulin as well as viable solutions to address this growing crisis.

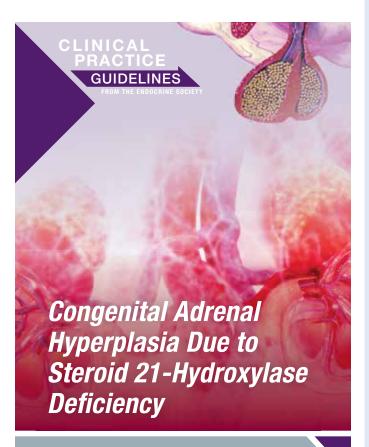
# HAT TRICK:

The many hats you must wear to launch a lab.

# **TEACHABLE MOMENTS:**

A journey through diabetes for pediatric patients.





# A NEW STANDARD FOR CARE

Get the latest recommendations on how to promptly diagnose, treat, and provide ongoing care for patients with Congenital Adrenal Hyperplasia (CAH) due to steroid 21-hydroxylase deficiency, an inherited endocrine disorder.

Recommendation Highlights:

- All newborn screening programs should incorporate screening for CAH.
- Healthcare professionals should inform all parents of pediatric patients with CAH about surgical options.
- Shared decision making among CAH patients, their families, and healthcare professionals should be applied when it comes to the medical, surgical, and psychological treatment of minors.

READ THE GUIDELINE AT ENDOCRINE.ORG/CPG





THE LEADING MAGAZINE FOR ENDOCRINOLOGISTS

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# Improving the Lives of **People with Diabetes**

ovember is Diabetes Awareness Month, an opportunity to highlight the diabetes epidemic and focus our efforts on improving the lives of people with diabetes. Given there are 30 million people in America with diabetes and 84 million at risk for developing the disease, it is critical that we improve screening, prevention, and treatment. Over the past year, we made significant headway in championing this work. Below are just a few examples of ways the Society is helping: Addressing Insulin Affordability

Over the past 15 years, the price of insulin has nearly tripled. As a result, patients who rely on the drug to survive are being forced to make tough decisions when they cannot afford their insulin. We spent much of the last year talking with our members, convening focus groups, and looking at policy options to increase insulin affordability and we are proud to release our new position statement on insulin affordability in this issue of Endocrine News (page 30). We are also pleased that Congress has taken a first step and passed legislation we supported to eliminate gag rules that prevented pharmacists from helping patients find less expensive alternatives outside their formularies.

# Promoting Research & Prevention

Funding research to find cures and promote prevention is a critical step in addressing the diabetes epidemic. Over the past year, our advocacy has contributed to a number of important wins, including: \$600 million for the Special Diabetes Program that supports type 1 research and prevention programs for at-risk populations, \$2 billion in funding for the National Institutes for Health, and \$25 million for the National Diabetes Prevention Program. We will continue to advocate for adequate research funding at the NIH and for these critical programs.

# Reducing Hypoglycemia

The Society has also launched a multi-year effort to reduce the incidence of hypoglycemia in at-risk patients. Our Hypoglycemia Prevention Initiative will focus on ways to integrate educational resources into clinical workflow so that primary care physicians and their patients can set appropriate goals and mitigate the risk for hypoglycemic events. Additional information on the initiative is available at endocrine.org/hpi.

66 **Given there** are 30 million people in **America** with diabetes and 84 million at risk for developing the disease, it is critical that we improve screening, prevention, and treatment.

# Increasing Access to Diabetes Technology

Through our policy efforts, we increased access to diabetes technologies like the continuous glucose monitors (CGMs) and continue our work to advance the pathway to the artificial pancreas. For example, patients were prevented from using a smart phone application with their CGMs because of regulatory language that was included in the coverage determination. The app serves as a safety net for many patients who are at risk for severe hypoglycemia. Working with other diabetes organizations and manufacturers, we successfully advocated for the removal of this language and, as a result, patients can now utilize this important device feature.

# **Disaster Relief Efforts**

The Society is also working with diabetes stakeholders to get lifesaving medications and supplies to those in need following a natural disaster. In response to a spate of Atlantic hurricanes that devastated parts of Texas, Florida, and Puerto Rico last fall, the Diabetes Disaster Response Coalition delivered nearly 4,000 pounds of diabetes supplies to individuals left without access to water and electricity. Recently, the American Society of Association Executives (ASAE) honored the Coalition with the Power of A Summit Award for its commitment to solving problems and creating a stronger world. To learn more, go to endocrine.org/advocacy/DDRC.

We look forward to continuing this important work to address the growing diabetes epidemic and will update you on future initiatives in Endocrine News.

- Susan J. Mandel, MD, MPH, President, Endocrine Society

# Glucagon Regulation Immunoassays

	Dynamic Range	Sensitivity	Time	Sample
Glucagon (AL-157)	21 - 313 pg/mL	2.1 pg/mL	2.5 hr	50 μΙ
GLP-2 (AL-174)	140 - 7500 pg/mL	11 pg/mL	2.5 hr	50 μΙ
Oxyntomodulin (AL-139)	3 - 290 pg/mL	0.2 pg/mL	2 hr	25 <b>µ</b> L
MPGF (AL-175) Major Proglucagon Fragment	50 - 3000 pg/mL	3 pg/mL	2.5 hr	25 <b>µ</b> L

# Coming Soon: GLP-1, Glicentin

Ansh Labs' proglucagon peptide regulation assays are specific to target analytes and have neglible cross-reactivity to related peptides. The proprietary designs of the assays eliminate the need for special sample tubes or extraction procedures. Total incubation times do not exceed 2.5 hours thus results are available the same day. All assays have relevant dynamic ranges and sensitivities for the applicable research or clinical applications.





### FROM THE **EDITOR**

# **Diabetes Awareness: Focusing on the Patient**

his year, in honor of November being National Diabetes Awareness Month, we've decided to devote a large portion of our feature well to highlighting the various challenges faced by clinicians who treat patients with diabetes as well as some of the challenges those patients face in coping with this disease that continues to reach epidemic proportions year after year.

On page 18, Eric Seaborg discusses using older insulin formulations to combat the rising costs of newer formulations. In "Paying the Price: Coping with the High Cost of Insulin," he describes how one type 1 diabetes patient actually died because he couldn't afford his lifesaving medicine. He lays out the reasons why clinical practitioners have moved away from the older formulations - and with good reason - but if costs are too much for some patients to bear then perhaps with more guidance these older formulations could be an option. "It's the cost that is driving the whole picture. If cost wasn't an issue, we would not be having this conversation," says Dace Trence, MD, professor of medicine and director of the Diabetes Care Center, University of Washington, Seattle, in the article. "But a lot more teaching has to be done explaining how to use them."

On that same topic, Endocrine News is publishing an official statement from the Endocrine Society on increasing insulin affordability (page 30). This position statement identifies barriers to accessing affordable insulin and posits a variety of notable solutions to address this problem. Among some of the policy and practice changes that could help expand access to lowercost insulin are: more reasonable rebates for consumers; providers trained to use lower-cost human insulins; greater transparency in the supply chain; the federal government addressing regulatory barriers and value-based purchasing agreements; and many, many more.

In "Pump It Up" (page 48), Seaborg gives us a closer look at how diabetes technology is playing its part in revolutionizing care and discusses the advantages of "smart" technologies as well as potential pitfalls such as the potential threat that hackers could pose by compromising patient data. However, with these upgrades comes an additional challenge: educating patients who don't adapt well to new technology: Anne Peters, MD, director, clinical diabetes program and professor, clinical medicine, Keck School of **NOVEMBER 2018** 

# **Endocrine**

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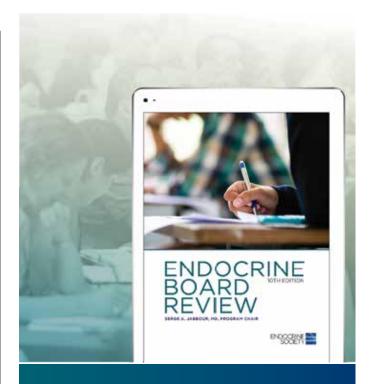
Medicine, University of Southern California, Los Angeles, says that she has seen amazing successes, but mainly with people who are "familiar with using technical tools," she says, adding: "I've had patients whom I have literally forbidden to wear sensors because they overreact so much to changes in their glucose."

On page 24 the Endocrine Society's associate director, content strategy & outcomes, Dennis Harris, PhD, attended the inaugural conference on "disrupting" diabetes that brought together professionals from a variety of disciplines to address the challenges of diabetes. The organizers brought together 12 teams to tackle unmet needs of patients with diabetes in a human-first, design-centric approach. "We are confronted with an evolving world in diabetes care that may benefit from some disruption in how we typically perceive and solve problems," Harris writes. "While it is true that the concepts presented were not fully developed, they were certainly disruptive."

In "Teachable Moments" (page 58), senior editor Derek Bagley details how the Phoenix Children's Hospital has instituted a game-like approach for its pediatric diabetes patients – and their families and caregivers – that has had very positive results. According to Marjorie Abele, MSN, RN, health education specialist, Emily Center at Phoenix Children's Hospital, it's not simply creating patient education content, but also a method to measure outcomes. "We know our nurses are doing a great job of teaching, but we also realize that documentation can be lax at times just with the hustle and bustle of healthcare," she says.

As usual, if you have your own treatment or research stories to share with the readers of *Endocrine News*, feel free to contact me at **mnewman@endocrine.org**.

- Mark A. Newman, Editor, Endocrine News



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# Endocrine Society Recommends Policies to Lower Costs for People with Diabetes

piraling insulin costs have created a dangerous barrier for many people with diabetes who need to access lifesaving treatments. The Endocrine Society is calling on stakeholders across the supply chain to help reduce out-of-pocket costs for people with diabetes.

More information about the factors driving cost increases is needed to effectively combat the trend, the Endocrine Society said in a position statement issued on Nov. 1 (and published on page 30). The complex interactions among insulin manufacturers, pharmacies, health plans, pharmacy benefit managers (PBMs), and wholesalers make it challenging to determine where in the supply chain costs continue to soar. The cost of insulin has nearly tripled in the past 15 years.

The current climate makes it difficult, if not impossible, to understand how much each stakeholder gains when costs to the patient increase. Research indicates that the net price increase insulin manufacturers earn has risen at a far slower rate than insulin list prices.

"Without clear information about expenses incurred by various players in the supply chain, we cannot fully understand what is driving costs up or how to best reduce insulin costs for people with diabetes in the future," says Society spokesperson Rita R. Kalyani, MD, associate professor of medicine at Johns Hopkins University School of Medicine. "High costs are forcing some people with diabetes to make the life-threatening decision to ration insulin. This is unacceptable for optimal patient care. Everyone needs to be part of the solution to this problem."

The three insulin manufacturers are taking steps to address this issue. On Nov. 1, insulin manufacturer Sanofi announced that it is expanding its VALyou Savings Program to include nearly all of its insulins. The program offers the company's insulins at one set price: \$99 for a 10 mL vial or \$149 for a box of pens. The company's combination insulin product is not included in the program. This summer, Eli Lilly launched a patient-focused



helpline to help individuals with high out-of-pocket costs reduce their financial burden. Novo Nordisk pledged to limit price hikes in 2016 and has kept annual list price increases in the single digits for the past two years.

The Congressional Diabetes Caucus is evaluating legislative action to address rising insulin costs, and its members held a hearing to examine what is driving cost increases and potential solutions to the problem. The Caucus released findings from its insulin probe today. Congress passed legislation last month that eliminated rules blocking pharmacists from informing patients whether they could purchase their medications for less money. The Trump administration has proposed having Medicare pay for certain medications based on the prices in other industrial nations.

More than 30 million Americans have diabetes, and an additional 84 million have prediabetes. Currently, 7.4 million children and adults use insulin to treat their diabetes. These patients use at least one vial of insulin per month, and some need to purchase multiple vials or multiple types of insulin each month. For people with type 1 diabetes, insulin is the only treatment for their lifelong disease. Many people with type 2 diabetes will eventually need insulin treatment as their disease progresses.

Individuals with diabetes need to stick to their medication regimen to avoid unnecessary hospitalizations and complications, but rising insulin costs discourage medication adherence. One study indicates that improved adherence among people with diabetes could prevent nearly 700,000 emergency department visits, 341,000 hospitalizations, and save \$4.7 billion annually.

As more insurance plans shift to a high-deductible structure, the cost of insulin falls more heavily on consumers. Patient Assistance Programs help some individuals, but they can be difficult to navigate and have been shown to increase medication prices overall. Rebate programs, another effort to reduce costs, are often used by employers to reduce health insurance premiums rather than patients' out-of-pocket costs.

# Society Elects Five Members to its Governing Council

embers have elected five new officers and Council members to lead the Endocrine Socity into the future. The new Officers and Council members are:

- President-Elect: Gary Hammer, MD, PhD
- Vice President (Physician-in-Practice): Whitney Goldner, MD
- Council (Basic Science Seat): Joy Wu, MD, PhD
- Council (At-Large Seat): Samantha Butts, MD, MSCE
- Council (At-Large Seat): Ghada El-Hajj Fuleihan, MD, MPH

The new officers and Council members will begin serving their terms following **ENDO 2019**, which will take place in New Orleans, La., from March 23-26, 2019.



Hammer will serve as resident-elect in 2019-2020 and then as president in 2020-2021. He is director of the Endocrine Oncology Program at the University of Michigan in Ann Arbor. Hammer has been a Society member since 1999, and has since served on

several committees and various journal editorial boards. These include the Governance Task Force, the *Endocrine Reviews* Editor-in-Chief Search Committee, the Strategic Plan Retreat, the *Endocrine News* Advisory Board, and the Committee on Governance Affairs. He's also served as the chair of the Annual Meeting Steering Committee and of the Scientific and Educational Programs Core Committee. His awards and honors include the Endocrine Society's 2013 Edwin B. Astwood Award Lecture for Outstanding Research in Endocrinology and the University of Michigan's 2005 Jerome Conn Award for Outstanding Research.



Goldner will serve a three-year term as vice president, physician-in-practice (2019-2022). She is a professor of medicine of the Division of Diabetes, Endocrinology and Metabolism at the University of Nebraska Medical Center in Omaha. Goldner has been a Society member

since 2002, and she currently serves as the chair of the Society's Clinical Endocrinology Update Committee and as a member of the Endocrine Educators Forum. Goldner has won the University of Nebraska, Department of Internal Medicine Top Teacher Award 12 times since 2005.



Wu will serve a three-year term in the basic science-designated seat on Council (2019-2022). She is an assistant professor of medicine at the Stanford University School of Medicine in Stanford, Calif. She's currently a member of the Society's Publications Core Committee

and previously served as a 2017 Strategic Plan Retreat member and a 2015 Leadership Development Task Force member. Her awards and honors include the Endocrine Society's Endocrine Scholars Award and Merck Senior Fellow Award, the NIH Director's New Innovator Award, and the John Haddad Young Investigator Award for Advances in Mineral Metabolism.



Butts will serve a three-year term as an atlarge member of Council (2019-2022). She is an associate professor at the University of Pennsylvania Perelman School of Medicine in Philadelphia. She's currently a member of the Society's Governance Task Force and

serves as an Editorial Board member for *The Journal of Clinical Endocrinology & Metabolism*. She was previously a member of the Advocacy and Public Outreach Core Committee from 2014 to 2016. Her awards and honors include the 2009 Penn Center for Excellence in Environmental Toxicology (CEET) New Investigator Award and the 2011 National Faculty Award from The American College of Obstetricians and Gynecologists and The Council on Resident Education in Obstetrics and Gynecology.



Fuleihan will serve a three-year term as an at-large member of Council (2019-2022). She is a professor of medicine at the American University of Beirut in Beirut, Lebanon. She currently serves as the clinical science chair of the Society's Annual Meeting Steering

Committee and was previously a Strategic Planning Task Force member from 2015 to 2016. Her awards and honors include the Endocrine Society's International Excellence in Endocrinology Award, the Harvard T.H. Chan School of Public Health Merit Award, and a lifelong appointment as a Lown Scholar for the Harvard T.H. Chan School of Public Health.

# **Legro Appointed** Department of Obstetrics & Gynecology Chair at **Penn State University College of Medicine**



■ ndocrine Society secretary-treasurer, Richard S. Legro, MD, has been appointed chair of the Department of Obstetrics and Gynecology at the Penn State University College of ■ Medicine. Legro had been serving as interim chair of the department since July 2017.

In his 25 years at Penn State, Legro distinguished himself as a respected clinician, investigator, educator, and leader in women's health services - all roles that will serve him well as he oversees the expansion of Women's Health in its new Labor and Delivery units that will be constructed, throughout the Penn State Health facility.

Legro is an associate editor for Fertility and Sterility and Human Reproduction Update and the co-editor in chief of Seminars in Reproductive Medicine. He has consulted extensively for the NIH, the Food and Drug Administration, the World Health Organization, and been selected for the Thousand Talents Program in China. He has received many awards including the Presidential Achievement Award of the Society for Gynecologic Investigation and has been elected an honorary member Ad Eundem of the Royal College of Obstetricians and Gynecologists in the United Kingdom.

Legro joined Penn State in 1993 and is professor and vice chair of research in the Department of Obstetrics and Gynecology as well as co-director of the Hub Resource Capacity Core at the Penn State Clinical and Translational Science Institute. Legro is recognized internationally for his research in polycysticovarysyndrome (PCOS) — diagnosis, treatment, and genetic/environmental causes, as well as on improving infertility diagnosis and treatment. He has designed and led many practice-changing multicenter comparative effectiveness infertility trials in the U.S. and China. He has been continuously funded by the National Institutes of Health (NIH) for more than 20 years as a principal investigator and currently has both NIH RO1 and U10 grant support. He has published more than 250 peer-reviewed articles in medical journals and has mentored numerous students, residents, and junior faculty in clinical research.

He graduated from Middlebury College with a degree in English Literature and received his MD from the Mount Sinai School of Medicine in New York City. His post-graduate work included a residency in Obstetrics and Gynecology at the University of Pittsburgh (Magee Womens Hospital) and a fellowship in reproductive endocrinology at the University of Southern California in Los Angeles.

# Woodruff, Santoro Named to National Academy of Medicine



Nanette Santoro, MD



Teresa K. Woodruff, PhD

n October 15, the National Academy of Medicine announced the election of 75 regular members and 10 international members during its annual meeting and among those inductees are Endocrine Society members Nanette Santoro, MD, and Teresa K. Woodruff, PhD.

Santoro, professor and E. Stewart Taylor Chair of Obstetrics and Gynecology, University of Colorado School of Medicine, Denver, was inducted due to her research discoveries in health predictors of midlife women and participation in cutting-edge clinical trial design and execution. Santoro is a 2016 Endocrine Society Laureate, receiving the Outstanding Mentor Award.

Woodruff, the Thomas J. Watkins Professor, and vice chair for research and chief, Division of Reproductive Science, Department of Obstetrics and Gynecology, Northwestern University, Chicago, was cited for her innovation in reproductive health, having cloned key regulators of ovarian and gonadotroph function; pioneering in vitro maturation of human oocytes; discovering roles for zinc in fertilization; and inventing microfluidic systems modeling human ovarian function, all relevant to her work on preservation of fertility in cancer patients, the field she named "oncofertility." She is an Endocrine Society past-president (2014 – 2015) and a 2017 Endocrine Society Laureate, receiving the Outstanding Leadership in Endocrinology Award. She also currently serves as the editor-in-chief of the Endocrine Society's journal, *Endocrinology*.

Election to the Academy is considered one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service.

New members are elected by current members through a process that recognizes individuals who have made major contributions to the advancement of the medical sciences, healthcare, and public health. A diversity of talent among NAM's membership is assured by its Articles of Organization, which stipulate that at least one-quarter of the membership is selected from fields outside the health professions — for example, from such fields as law, engineering, social sciences, and the humanities. The newly elected members bring NAM's total membership to 2,178 and the number of international members to 159.

# **Terry Davies is Co-Director of New NYC Thyroid Center**



erry Davies, MD, the Florence and Theodore Baumritter Professor (Endocrinology, Diabetes, and Bone Disease) at the Icahn School of Medicine at Mount Sinai, will codirect the new Mount Sinai Thyroid Center at Mount Sinai Union Square.

The new facility, located at 10 Union Square East, is the first and only center in Manhattan, and in the Northeast, to offer comprehensive thyroid care in

a single location. "It is one-stop shopping, which is what we all want when we go to the doctor," Davies says. "If your physician says you need to see another specialist, it's nice if he or she is in the next room."

Davies is also on the editorial board of the Journal of the Endocrine Society.

The Mount Sinai Thyroid Center at Mount Sinai Union Square provides multidisciplinary treatment to ensure an accurate diagnosis and the best possible treatment. Endocrinologists, surgeons (from general surgery and otolaryngology), radiologists, and pathologists are located under one roof and work together to create specialized treatment plans and seamlessly coordinate treatment. Lab tests, ultrasound, and biopsies are done on the spot to ensure quick diagnosis and expedite therapy.

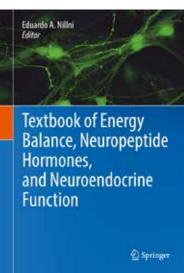
Additionally, the Mount Sinai Thyroid Center will lead breakthrough research in both clinical and lab settings. Having multidisciplinary physicians in one location will help enhance the understanding of thyroid disease by conducting new clinical trials. By combining their expertise, doctors hope to make discoveries about the biology of thyroid cancer and drive advances in managing this condition. They will also analyze outcomes of new, advanced surgical techniques.

Maria Brito, MD, an assistant professor of medicine (Endocrinology, Diabetes, and Bone Disease) at the Icahn School of Medicine will be co-director of the center with Davies.

# **Eduardo Nillni Edits New Neuropeptides**

Textbook

duardo Nillni, PhD, is the new book that takes a comprehensive look at the latest science on neuropeptides and their effects on energy balance.



Textbook of Energy Balance, Neuropeptide Hormones, and Neuroendocrine Function was recently published by Springer and is available both in print and as an eBook and can be used for teaching graduate students and medical school courses as well as a valuable resource for researchers in biochemistry, cell and molecular biology, neuroscientists, endocrine clinicians, and nutritionists.

The textbook includes an examination the history of the evolution of human society from a thin to the obese phenotype and, within that context, how modern society habits and industrial food production did not respect the evolutionary trait resulting in changes in the energy balance set point. It provides a novel conceptualization of the problem of obesity when considering the biochemistry of peptide hormones and entertaining novel ideas on multiple approaches to the problems of energy balance, as well as demonstrates and explains why alterations in pro-hormone processing are paramount to understand metabolic diseases.

Nillni is a professor emeritus in the Departments of Medicine and Molecular Biology, Cell Biology & Biochemistry at Brown University, where he has been on the faculty since 1989.

# TRENDS & INSIGHTS

# **Persistent Organic Pollutants May Affect Child Growth and Development**

xposure to persistent organic pollutants (POPs) is associated with thyroid hormone (TH) levels in placenta, which could explain how exposure to these chemicals affects child growth and development, according to a study recently published in Endocrinology.

Researchers led by Zhong-Min Li, MSc, and Meri De Angelis, PhD, both of Helmholtz Zentrum München-German Research Center for Environmental Health, Molecular EXposomics in Neuherberg, Germany, point out that POPs have been widely used in commerce and industry over the past few decades. These chemicals are transferred across the placenta during pregnancy and disruption of TH levels after POP exposure has been observed in vitro and in animal studies.

"The potential thyroid-disrupting effects of POPs in background exposed populations are of interest because THs act at extremely low serum concentrations (free concentration range, 8 to 30 pg/mL), and POPs can mimic or inhibit the response of the hormones at low doses (e.g., the low dose cutoff of BDE 99 is 0.3 mg/kg/d)," the authors write. "The purpose of this study was to investigate the possible association of background exposures of POPs [specifically, polybrominated diphenyl ethers (PBDEs), polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins and furans (PCDD/Fs), organotin chemicals (OTCs), and organochlorine pesticides (OCPs)] with placental levels of THs (T4, T3, and rT3) in a Danish population that gave birth to boys with and without cryptorchidism."

The researchers collected 58 placenta samples from mothers of boys born with and without cryptorchidism (28 and 30, respectively) and



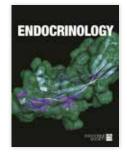
measured the concentrations a total of 82 POPs PBDEs, PCBs, PCDD/Fs, OTCs, and OCPs as well as the concentrations of T4, T3, and rT3. "No correlation between THs and the odds of cryptorchidism was found. Several POPs were significantly associated with THs: (1) T4 was inversely associated with BDEs 99, 100, ΣΡΒDE, and 2378-TeCDD, and positively associated with 1234678-HpCDF; (2) T3 was positively associated with 2378-TeCDF and 12378-PeCDF; and (3) rT3 was positively associated with PCB 81, 12378-PeCDF, and 234678-HxCDF, and inversely associated with tributyltin, ΣΟΤC, and methoxychlor," the authors write.

The researchers conclude that their results suggest background exposure to POPs is associated with TH levels in placenta. "Our results highlight the challenges of assessing effects on thyroid function, especially during pregnancy, due to the complexity of contaminant mixtures and the sensitivity of the thyroid system of the pregnant woman and the fetus," the authors write.

Findings: However, they also write that the results should be interpreted with caution because of the small sample size and the fact they only analyzed samples from mothers of boys, so they could not determine any sex-dependent effect. "The findings should be confirmed with more placenta samples from boys and girls," the authors write, "also including the deiodination enzyme activities and the hydroxylated metabolites of PBDEs and PCBs."



BY DEREK BAGLEY Senior Editor



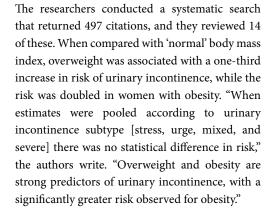
Our results highlight the challenges of assessing effects on thyroid function. especially during pregnancy, due to the complexity of contaminant mixtures and the sensitivity of the thyroid system of the pregnant woman and the fetus.

# **Overweight and Obesity Linked to Higher Risk of Urinary Incontinence for Women**

Overweight and obesity are strong predictors of urinary incontinence, with a significantly greater risk observed for obesity.

eing overweight or obese is linked with an increased risk of developing urinary incontinence for young to middle-aged women, according to a review and meta-analysis recently published in Obesity Reviews.

The researchers wanted to evaluate whether overweight or obesity are risk factors for young and middle-aged women developing incontinence. "Understanding these relationships during this life stage is important as early onset increases the risk for developing severe and persistent incontinence," the authors write.



The findings indicate that clinical advice to young women who are obese or at risk of becoming obese should not be limited to metabolic health but should also emphasize the role of excess weight on pelvic floor weakening and subsequent risk of incontinence.

Findings: "We know that urinary incontinence can be a complex issue, especially among younger women," says lead author Tayla Lamerton, of the University of Queensland, Australia. "Understanding overweight and obesity as a determinant of urinary incontinence could play a role in the way we counsel those affected by the condition, and our findings provide a building block to further explore lifestyle interventions for preventing and managing incontinence."



# **Review Examines Genome-Wide Association Studies' Effects on Understanding of Human Growth**

review recently published in The Journal of Clinical Endocrinology & Metabolism looks at how genome-wide association studies (GWASs) have impacted the medical community's understanding of the underlying biology of human growth.

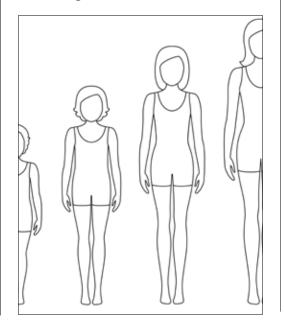
The paper, by Michael H. Guo, et al, of the Broad Institute of MIT and Harvard in Cambridge, Mass., summarizes key findings of GWASs for height and growth-related traits, since height is heritable and the genetic basis for height is of great interest to the medical field. "Understanding the genetic architecture of height — the number of genetic variants that contribute to variation in height, their frequencies in the population, and the magnitude of each genetic variant's effect (i.e., effect sizes)—can teach us lessons about how to study the genetic underpinnings of other complex genetic traits and disease," the authors write.

"Moreover," they continue, "understanding the genetics of height can illuminate the underlying biology of human growth and provide insight into disorders of growth, such as short stature."

The researchers examined GWASs related to height using PubMed and the GWAS catalog and found that these studies show that height is highly polygenic, with many thousands of genetic variants contributing to height. These studies have also uncovered previously underappreciated genetic pathways that may explain growth and height. "These height-associated regions of the genome are enriched for genes in known biological pathways involved in growth, such as fibroblast growth factor signaling, as well as for genes expressed in relevant tissues, such as the growth plate," the authors write.

They go on to write that these GWASs can provide further insight into Mendelian growth disorders and skeletal dysplasia, since the genes implicated in GWASs are the same genes that are the genetic causes of these disorders. "An important but more distant clinical application of GWAS findings is the discovery of new therapeutics for growth disorders," the authors write. "GWASs for height have clearly identified genes, tissues, and pathways that influence growth. Many of these genes might serve as prime therapeutic targets."

Findings: The review covers a lot of ground and ends with some perspectives for the future, further uses for these GWASs, including looking at how emerging technologies like CRISPR might help scientists translate GWASs findings into novel insights about human growth. "These insights into the biology of growth could play an important role in the translation of genetic findings into therapies for disorders of growth," the authors write.





**Understanding** the genetic architecture of height - the number of genetic variants that contribute to variation in height. their frequencies in the population, and the magnitude of each genetic variant's effect (i.e., effect sizes) can teach us lessons about how to study the genetic underpinnings of other complex genetic traits and disease.





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# **Translational Reproductive Biology and Clinical Reproductive Endocrinology Conference**

New York, New York, November 15 - 18, 2018

"Paradigm changes you may not hear about elsewhere" is the theme of the 2018 conference of the Foundation for Reproductive Medicine, encouraging attendees to think differently about clinical reproductive medicine driven by new discoveries in reproductive biology. The conference will recognize state-of-the-art developments in reproductive biology and their translational potential for clinical practice in reproductive endocrinology and infertility and look at changes in the evaluation of current popular infertility treatments in selected patient populations. This program is especially interested in facilitating attendance by postdocs, residents, fellows, and other professional junior staff members of research laboratories, academic departments, and IVF programs and offers greatly discounted registration fees to these junior staff members with presentation of a letter from their program director.

https://www.foundationforreprodmed.net/

# **Third United States National Conference on Prevention of Diabetes** Atlanta, Georgia, November 16 – 18,

The Third National Conference on Prevention of Diabetes is a global forum that will feature constructive debates around one of the most important public health issues, the prevention of

diabetes and its complications. Although there has been progress made toward the prevention of diabetes and its complications, there is still a long way to go and many lessons to be learned. This conference provides the opportunity for all attendees to participate in high quality scientific discussions on principles of diabetes prevention and listen to the experiences from diabetes prevention programs that have been implemented in various countries.

www.diabetes-prevention.us

# **World Congress Insulin Resistance Diabetes and Cardiovascular Disease**

# Los Angeles, California, November 29 -December 1, 2018

Offering three days of CME, the World Congress Insulin Resistance Diabetes and Cardiovascular Disease is a state-of-the-art program featuring distinguished global experts presenting unique topics and lectures on the most innovative clinical research and basic science in cardiometabolic disorders. The Congress is a premier global meeting dedicated to diabetes, obesity, lipids, cardiovascular disease, and energy balance.

https://www.wcir.org/

# **55th Clinical Diabetes and Endocrinology Institute Annual CME** Conference

Snowmass, Colorado, January 15 - 19,

The 55th Clinical Diabetes and Endocrinology Institute Annual CME Conference will address

gender affirming hormone therapy, gestational diabetes, precision medicine for thyroid tumors, Cushing's disease, neuroendocrine diseases, obesity therapies, the new ADA/EASD guidelines for type 2 diabetes management, menopause, diabetes technologies, and much more.

www.nihealth.org/diabetes-conference

# MEN 2019: 16th International **Workshop on Multiple Endocrine** Neoplasia

Houston, Texas, March 26 - 29, 2019

In keeping with the spirit of the original MEN workshop, MEN2019 will focus on emerging topics in the genesis and therapy of malignant endocrine tumors associated with multiple endocrine neoplasia. The goal of the workshop will be to provide an outline for basic and clinical research focused on these malignant manifestations. The meeting will bring together local and international experts on multiple endocrine neoplasia to focus on these subjects. A significant portion of the meeting will be spent in workshops centered on emerging topics and the development of an international roadmap for future research and clinical trials, and the remainder of the meeting will be composed of large group didactic sessions.

https://www.mdanderson.org/educationtraining/professional-education/cmeconference-management/conferences/ international-workshop-on-multiple-endocrineneoplasia.html



# ObesityWeek - The Obesity Society and American Society for Metabolic and Bariatric Surgery Joint Meeting

### Nashville. Tennessee.

### November 11 - 15, 2018

ObesityWeek is the largest obesity-centric conference in the world with the broad, comprehensive benchto-bedside and continuum of care content. This is an international event focused on the basic science, clinical application, surgical intervention, and prevention of obesity. By combining both American Society for Metabolic & Bariatric Surgery (ASMBS) and The Obesity Society (TOS) annual meetings, ObesityWeek brings together world-renowned experts in obesity to share innovation and breakthroughs around the globe. This year, the international conference will focus on the heart, the cardiac component of obesity.

This year's multi-track schedule offers a plethora of options for all attendees including pre-conference courses, hands-on skills labs, and an industry sponsored symposium. Interdisciplinary research, education sessions, and policy programming will focus on the latest breakthroughs in the science of obesity. Conference programming will cover the full interdisciplinary spectrum and features leading experts in their respective fields.

Attendees will have the opportunity to meet face-to-face with over 4,000 surgeons, researchers, physicians, and healthcare professionals from across the globe during the exhibit. Additional networking events offer further opportunities for attendees from all fields to collaborate with others who are part of other leading obesity organizations.

In addition, attendees will enjoy all Nashville, the City of Music, has to offer with a wide variety of dining options featuring Southern fare, endless entertainment in the home of country music, and countless attractions for

Make plans to attend ObesityWeek now at www. obesityweek.com.

# INTERNATIONAL ITINERARY

# 17th International Congress on Hormonal Steroids and **Hormones and Cancer**

# Stellenbosch, South Africa, November 26 - 29, 2018

The objective of this conference is to promote interaction and discussion within the field of steroid hormones and hormone-dependent cancers. The conference will consist of a keynote lecture, plenary lectures, and oral and poster presentations. This conference also includes built-in time for networking as attendees enjoy the Stellenbosch winelands.

www.ichshc2018.co.za

# 7th Asia-Pacific Osteoporosis Conference

### Sydney, Australia, November 30 - December 1, 2018

Health professionals in the Asia-Pacific are facing a rapidly aging population. At this conference, physicians, clinical researchers, and allied health professionals can look forward to learning how to improve the identification of high-risk patients, understand the similarities and differences in fracture risk and treatment response between Asia and the West, and assess quality of life in elderly patients with osteoporosis, osteoarthritis, or sarcopenia. Meet-the-Expert sessions will give delegates the opportunity to discuss with world experts, learn about the latest products and services, and mingle with colleagues from throughout the region. http://iof-regional.org/

# 18th International Congress of Endocrinology and 53rd **SEMDSA Congress**

# Cape Town, South Africa, December 1 - 4, 2018

The Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) is hosting ICE 2018 with the 53rd annual SEMDSA Congress. The Program Organizing Committee is currently putting together a stimulating program including cutting-edge academic endocrinology for basic scientists and clinicians.

www.ice2018.org

# **ThyroAlex 8**

### Alexandria Egypt, December 13 - 14, 2018

ThyroAlex 8 is organized by Alexandria Thyroid Association and Endocrinology. This meeting will address thyroid disorders in the elderly, the effect of smoking on thyroid disorders, anesthetic management of thyroid disorders, and thyroid and adrenal interconnections. Regional, as well as national and international speakers, will focus on these current topics from a practical and updated approach.

http://www.med.alexu.edu.eg/endounit/

## 1st BES-Mayo Course in Advanced Endocrinology 2019 Dhaka, Dhaka, Bangladesh, January 24 - 25, 2019

The Advanced Course in Endocrinology is a collaboration between the Bangladesh Endocrine Society (BES) and the Mayo Clinic, Rochester, Minn. It is a twoday intensive and interactive learning course covering all aspects of clinical endocrinology.

http://www.bes-mayo.com

# **ATTD 2019**

## Berlin, Germany, February 20 - 23, 2019

The 12th International Conference on Advanced Technologies and Treatments for Diabetes (ATTD 2019) focuses on technology in diabetes and how healthcare professionals and patients can use those technologies for the best outcomes in treatment. International experts will discuss breakthroughs in diabetes treatments, technological innovations, and showcase the latest developments in new insulin analogues, delivery systems, pumps, glucose sensors, closed-loop systems, and much more. Featuring the International Fair of New Technologies, this conference will highlight start-ups and emerging companies displaying cutting-edge technologies.

https://attd.kenes.com/2019#.W9CXKIWnHbg

# **DASHBOARD**

If you are looking at the older insulins, there has to be an understanding that a patient's lifestyle has to be more regimented. The peaks of these insulins and their actions require that patients not skip meals and ingest close to the same amount of carbohydrates at each meal consistently at the same time each day. Otherwise they are in trouble. The insulin is going to be in the system for quite some time, so there has to be that regimentation with regard to timing of meals as well as the amount of carbohydrate."

- DACE TRENCE, MD, professor of medicine and director of the Diabetes Care Center, University of Washington, Seattle, discussing the feasibility of diabetes patients using older, cheaper insulins to combat the higher prices of new formulations in "Paying the Price" on page 18.



Global life expectancy for virtually every nation will rise in the next 20 years, but Spain will be the big winner, overtaking Japan as the country with the longest-lived population according to new research from the University of Washington's Institute for Health Metrics and Evaluation. The average age expectancy for Spain is anticipated to be 85.8 years compared to Japan's **85.7** years. - SOURCE: AARP, THE MAGAZINE

According to the World Health Organization (WHO), there are some 60~million people with



diabetes in Europe, which equates to around 10.3% of men and 9.6% of women aged 25 years and above. WHO projects that, worldwide, diabetes deaths will have doubled from 2005 levels by 2030. (EAPM) - source: European alliance for personalised medicine (EAPM)

FROM THE CENTURY OF ENDOCRINOLOGY TIMELINE

1978:

First "Test Tube" Baby Born

The world's first "test tube" baby, Louise Brown, was born by caesarean section on July 25, 1978. Robert Edwards was awarded the 2010 Nobel Prize in Physiology or Medicine for the development of human in vitro fertilization (IVF) therapy.

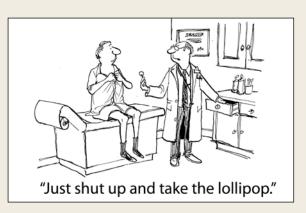


For more about the Century of Endocrinology, go to: www.endocrine.org/timeline.

The average American eats 17 teaspoons of sugar daily, about five more than they should when based on a 2,000 calorie diet. Some 68%of packaged foods have added sugars which "get snuck into our diet in ways that we would never really anticipate," said Oxiris Barbot, the acting commissioner of the New York City Department of Health and Mental Hygiene

> in reference to the newly announced National Salt and Sugar Reduction Initiative. - source: WALL STREET JOURNAL







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\*Dr. Swamy is a paid spokesperson of Dexcom, Inc., Dr. DeSalvo is a paid spokesperson of Dexcom, Inc., and a Dexcom user. For a list of compatible devices, visit www.dexcom.com/compatibility. "The Dexcom G6 Sensor and Transmitter are water-resistant and may be submerged under eight feet of water for up to 24 hours without failure when properly installed. "Separate Follow app required. Available by prescription only. Failure to use the Dexcom G6 Continuous Glucose Monitoring System (G6) and its components according to the instructions for use provided with your device and available at https://www.dexcom.com/safety-information and to properly consider all indications, contraindications, warnings, precautions, and cautions in those instructions for use may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If your glucose alerts and readings from the G6 do not match symptoms or expectations or you're taking over the recommended maximum dosage amount of 1000mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions. Seek medical advice and attention when appropriate, including for any medical emergency.





AS THE PRICE OF INSULIN INCREASES, THERE MAY BE A ROLE FOR OLDER FORMULATIONS FOR PATIENTS WHO STRUGGLE WITH THE COST. HOWEVER, PATIENTS NEED EDUCATION ON HOW TO SAFELY AND EFFECTIVELY USE THESE CHEAPER OPTIONS.

BY ERIC SEABORG

he price of insulin has soared to such levels that it could be costing lives. Consider the case of type 1 diabetes patient Alec Smith, who turned 26, aged off of his mother's health insurance policy last year, and was unable to afford his own policy. On his first visit to his pharmacy after his insurance lapsed, he was told his monthly diabetes supplies would cost \$1,300, an expense he needed to put off until payday a few days later. He apparently tried rationing his insulin, but in a matter of days was found dead in his apartment.

His mother, Nicole Smith-Holt, related his story at an August 21 hearing in Washington, D.C., convened by Senate Democrats to look at the impact of rising prices for prescription drugs.



A recent study by Yale University researchers found that one in four patients at a New Haven, Conn., clinic had cut back on the use of insulin because of cost. A study in *JAMA* reported a threefold increase in the cost of insulin between 2002 and 2013, and National Public Radio reports the costs doubled again since 2012. The increases have been for the newer, analog insulin formulations, which has brought attention to the possible use of older insulin formulations for patients who can't afford the skyrocketing costs.

# **A Hot Topic**

That question spurred the American Diabetes Association to hold a session at its June meeting on "Insulin Therapy—To the Future and Back" that considered this question. Regular insulin and neutral protamine Hagedorn (NPH) insulin cost \$24 a vial, whereas the newer analogs such as U200 lispro and U300 glargine cost \$280 to \$290 a vial, according to meeting speaker Dace Trence, MD, professor of medicine and director of the Diabetes Care Center at the University of Washington in Seattle.

"This topic is getting a lot of attention," Trence tells

*Endocrine News*, but clinicians need to remember that the newer formulations replaced the older ones "for one major reason, and that was decreasing hypoglycemia risk."

Wendy Lane, MD, a diabetes specialist at the Mountain Diabetes and Endocrine Center in Asheville, N.C., says she remembers when Lantus (glargine), the first FDA-approved long-acting, basal, recombinant human insulin analog, was approved in 2000: "I was a physician at a camp for kids with type 1 diabetes, and for the first time in history in that diabetes camp, everybody slept through the night because the kids weren't having hypoglycemic events at night from using NPH."

Trence and Lane both said that they have been practicing long enough to remember when the older insulins were the only formulations available, and therefore remember why the newer ones replaced them. Lane has not prescribed the older formulations for several years because the newer ones are better.

The newer formulations have been around for 15 years or more, and that time frame creates a barrier to the use of the older ones because younger endocrinologists have never seen or used NPH or regular insulin.

# **Limitations of Older Formulations**

To go back to using the older insulins, one needs to be aware of their limitations, and more teaching of both clinicians and patients is necessary, Trence says: "If you are looking at the older insulins, there has to be an understanding that a patient's lifestyle has to be more regimented. The peaks of these insulins and their actions require that patients not skip meals and ingest close to the same amount of carbohydrates at each meal consistently at the same time each day. Otherwise they are in trouble. The insulin is going to be in the system for quite some time, so there has to be that regimentation with regard to timing of meals as well as the amount of carbohydrate."

The newer formulations are more consistent and predictable in their activity, while the older formulations are of longer-acting and don't match peak effects of food as well.

# **Higher Insulin Needs**

Trence says that one category of patients who could do well on U500 regular human insulin are those who have high insulin needs — such as more than 200 units per day. Patients with high insulin requirements may do better on

46 It should be intuitively obvious to any practitioner why the standard of care has become the new analog insulins.

We don't have to rehash old data."

- WENDY LANE, MD, DIABETES SPECIALIST, MOUNTAIN DIABETES AND ENDOCRINE CENTER, ASHEVILLE, N.C.

# AT A GLANCE

- The prices of the newer insulin analog formulations have skyrocketed in recent years, in some cases putting their costs out of reach of some patients.
- The high prices have spurred discussion of whether some patients should consider using the more affordable, older insulin formulations, but clinical practice moved away from them because the newer analogs offer greater efficacy and usability.
- If costs give patients no choice but to fall back on the less expensive options, patients need more instruction on how to use them safely and effectively.



It's the cost that is driving the whole picture. If cost wasn't an issue, we would not be having this conversation.

...But a lot more teaching has to be done explaining how to use them."

- DACE TRENCE, MD, PROFESSOR OF MEDICINE AND DIRECTOR OF THE DIABETES CARE CENTER, UNIVERSITY OF WASHINGTON, SEATTLE. U500 because of the lower volume of insulin and because it can often avoid the need for multiple injections a day — a higher number of injections reduces adherence. Trence adds that the long-acting NPH insulin "has both a basal as well as a bolus effect. So you are not using the insulin for just one purpose, you are really getting two benefits from it."

She notes that there are also some "very specialized patient populations" who might do better on NPH, such as patients receiving high-or-medium-dose steroids or parenteral nutrition, but "usually these are hospitalized patients, so they will not be walking into your office."

# In the Literature

Trence and Lane both note that articles have begun appearing in the literature trying to justify the use of older formulations based on efficacy, but do not find the data convincing. For example, an article in JAMA in July used data from Kaiser Permanente of Northern California to compare results from patients with type 2 diabetes who began therapy with a basal insulin analog versus NPH insulin. The researchers concluded that "initiation of a basal insulin analog compared with NPH insulin was not associated with a reduced risk of hypoglycemia-related emergency department visits or hospital admissions or with improved glycemic control. These findings suggest that the use of basal insulin analogs in usual practice settings may not be associated with clinical advantages for these outcomes."

But Trence notes that using that article's own data, "If you look closely over time, you can begin to see marked differences in terms of glycemia between the two populations. This same research group reported in JAMA earlier this year that measuring just ER and hospitalization data does not give the full picture of hypoglycemia incidence — for example, medical records captured only about one in 20 of the hypoglycemic events Kaiser Permanente Northern California members reported in a survey conducted by the Diabetes Study of Northern California."

Lane says that as she read the article, she made a list of its shortcomings, which she was "relieved" to see an accompanying editorial: "It should be intuitively obvious to any practitioner why the standard of care has become the new analog insulins. We don't have to rehash old data."

Trence agrees: "It's the cost that is driving the whole picture. If cost wasn't an issue, we would not be having this conversation." If patients cannot afford their analog insulin, older formulations are better than no insulin at all, "but a lot more teaching has to be done explaining how to use them."

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# COSTRUCTIVE BY DENNIS HARRIS, PHD COSTRUCTIVE BY DENNIS HARRIS,



In its inaugural event, the Disrupt Diabetes Design Challenge brought together new perspectives to tackle the persistent challenges of diabetes with a human-first, design-centric approach.



# A mechanical engineer is sitting in a conference room at Stanford University.

At the table, he is joined by an emergency medicine

clinical pharmacist and healthcare designer. Across from them sit two medical students - one interested in psychology and the other in surgery. Their group is one of 12 teams spread throughout the room.

'hat kind of meeting is this? It is the inaugural Disrupt Diabetes event, a 10week design challenge brought to life by two undergraduates from Stanford University — Urvi Gupta and Divya Gopisetty. The program was shepherded with mentorship from Stanford Diabetes Research Center, Stanford's Medicine X program, the diaTribe Foundation, and IDEO.

The organizers brought together 12 teams to tackle unmet needs of patients with diabetes in a human-first, design-centric approach. Each team included a Patient Powerhouse, Designer, and Student Lead that identified a real-life challenge for people with diabetes and laid the groundwork for possible solutions. In the last leg of their journey, teams developed their concept in a day-long

design sprint that ended with a group pitch to a panel of judges on May 20, 2018.

# "Disruptive, Unpredictable, and Frustrating"

But before we jump to the winner's circle, perhaps we should ask "was this diabetes disruption needed?" In recent years, we've seen major advances in diabetes therapies and a booming field of diabetes technology that includes insulin pumps, continuous glucose monitors (CGMs), and apps that act as platforms for coaching, decision-making, and data integration. Why disrupt an already advancing field?

While these advances have led to powerful tools to treat and manage diabetes, many people continue to



Divya Gopisetty and
Urvi Gupta are two
undergraduates from
Stanford University who
brought to life the inaugural
Disrupt Diabetes event, a
10-week design challenge
created to tackle persistent
diabetes with a human-first,
design-centric approach.

struggle. This is not because patients and providers are unaware or uncaring. Diabetes is a challenging mess. Management isn't as simple as flipping a switch on new treatments and waiting for better glucose control. It is a complex disease that creeps into every aspect of life. On a daily basis, diabetes can be disruptive, unpredictable, and frustrating. As one participant put it, "being diagnosed with diabetes feels like someone is taking away your agency; it takes away your sense of normalcy." Although the medical community is steadily improving recognition of the emotional burden of diabetes, it is still a wearisome challenge that makes management more difficult.

Something else that is often forgotten is that much of diabetes management happens between office visits when patients are alone, and a provider isn't there to guide decisions. Yet, the information continues to pour in as day-to-day decisions become overwhelming. We must also recognize that access to newer therapies and technologies is a luxury that many cannot afford.

The Disrupt Diabetes Design Challenge was an interesting approach to deal with these persistent challenges. It brought perspectives you don't normally see in diabetes conferences and encouraged fresh ideas. In a single room, designers, developers, engineers, architects, researchers, nurses, and students discussed diabetes together. Many of them were living with diabetes themselves. Disrupt Diabetes gave the patient a voice like never before. Teams were solving real-life problems that were sitting right there in front of them and asking questions in real-time.

It was also the only diabetes-related conference with a "Hypo Table" replete with glucose tablets and juice boxes.

66 Individuals with diabetes are more than a collection of symptoms and targets. Individuals with diabetes are people first and each has a unique perspective and set of life challenges. It is a reminder that individuals with diabetes are at the center of their care and should be at the center of solutions."

Design Thinking projects "How might we..." "What if...." "What is the future of..." Stanford ME

# **Disrupting the Status Quo**

The day of the design sprint began with a reminder of the most pressing challenges and unmet needs in diabetes by Daniel DeSalvo, MD, a pediatric endocrinologist at Baylor College of Medicine. DeSalvo also happens to live with type 1 diabetes and spoke from firsthand experience of the diverse patients he cares for and the difficulties he faces. Larry Chu, MD, MS, anesthesiologist and executive director of Stanford's Medicine X program, followed with a powerful message on the value of empathy, perspective, and inclusion in our design process.

The group was then treated to presentations by innovators that shared personal stories of how they disrupted the status quo in diabetes healthcare. The breadth of innovations was impressive - from provider education (Project ECHO), patient coaching (Lark), decision-making (Sugar.IQ), and caring for underserved populations (NICH).

Primed with inspiration and direction, the design sprint began. Dennis Boyle, partner at the international design company, IDEO, led the groups through a process of brainstorming and prototyping in an intense afternoon of workshopping. At the end, each team gave a creative pitch for its concept. They used video, skits, or presentations to deliver their design solution in a five-minute window.

Notably, each group seemed to leverage digital platforms in a "behind the scenes" approach to minimize the burden of inputting and interpreting data. The concepts also sought to empower patients, to give them a sense of control in chaotic or unpredictable moments such as when they are eating outside their home, exercising, or experiencing hypoglycemia. The solutions also aimed to restore a sense of normalcy to an otherwise chaotic condition.

# AT A GLANCE

- The inaugural "Disrupt Diabetes" event took a unique health design approach to solving persistent challenges in diabetes
- Each of the 12 teams took different approaches to solutions that preserve a sense of normalcy by moving the complicated decisions in diabetes 'behind the scenes.'
- Although many of the ideas might not come to fruition, it was an important disruption in an area of medicine that can benefit from human-first, design-centric approaches to care.



Brainstorming Rules

Defer independ

Encourage wild ideas

Encourage wild ideas

Encourage wild ideas

Gray focused on topic

Gray focus

Although the medical community is steadily improving recognition of the emotional burden of diabetes, it is still a wearisome challenge that makes management more difficult."

# Concepts included tools that:

- Reduce the stress of new diagnosis
- Connect peer communities
- Make CGM alerts/alarms discrete and sharable
- Lower barriers to finding healthy food alternatives
- Integrate cultural sensitivities into coaching platforms
- Track and anticipate the impact of exercise
- Aggregate and simplify data across devices
- Leverage crowdsourced information on restaurant choices

After deliberation, the judges selected a combination of two teams as the winner. Each of the teams had presented concepts that build off existing CGM systems to give patients more control, support, and discretion while also building a sense of community and alerting others in emergency situations. The combined group received a monetary award and continued mentorship to further develop their concepts.

At the end of the design challenge, the teams were exhausted and delighted. As Bruce Buckingham, MD, pediatric endocrinologist at Stanford University and Disrupt Diabetes judge said, "The journey and process will be transformative to the way you work and treat others."

# "A Hectic, Unpredictable Life"

As technology and healthcare continue to blend, this transformation will likely be more powerful and lasting than the design challenge itself. Diabetes technology is reshaping how care is delivered and is putting more information and control in patients' hands for day-to-day treatment decisions. Designing solutions for patients — rather than providers — is an increasing demand in a world of self-care diabetes technology. However, the patient's voice if often absent when designing solutions despite more information and treatment decisions resting in their hands. Disrupt Diabetes is taking on the changing landscape with a new approach to solving problems that puts the patient "in the driver's seat."

As Dennis Boyle said, "to be truly patient-centric, perhaps the inspiration for solutions needs to come from the people facing the challenges rather than relying on past experiences."

A pessimist might say the concepts were too lofty or impractical to be taken seriously. However, several of the now successful Disrupt Diabetes speakers were likely told something similar along their own journey. It's also worth mentioning that one of the winning teams was able to develop a working prototype of their discrete CGM alert device in the 10-week span of the design challenge. The broader diabetes DIY community has also shown us that a motivated, tech-savvy group can make wild ideas into a reality. This is not fiction; it can be a reality.

This constructive disruption should be a welcome addition to the thought-space of innovative approaches to solving diabetes dilemmas. Throughout this atypical process, participants were repeatedly reminded that individuals with diabetes are more than a collection of symptoms and targets. Individuals with diabetes are people first and each has a unique perspective and set of life challenges. It is a reminder that individuals with diabetes are at the center of their care and should be at the center of solutions.

These are valuable reminders for practice and research. Invite patients to express their challenges. Seek to understand their perspectives and build solutions collaboratively. Then think about how those solutions are going to impact life between visits in a hectic, unpredictable life with diabetes. New solutions will hopefully emerge that are more sustainable, satisfying, and ultimately, successful.

We are confronted with an evolving world in diabetes care that may benefit from some disruption in how we typically perceive and solve problems. While it is true that the concepts presented were not fully developed, they were certainly disruptive.



HARRIS IS THE ASSOCIATE DIRECTOR OF CONTENT STRATEGY AT THE ENDOCRINE SOCIETY AND ATTENDED THE DISRUPT DIABETES EVENT AS AN EDUCATION DESIGNER AND PERSON LIVING WITH TYPE 1 DIABETES.



# DISTINGUISHED **DISRUPTORS**

The participants in the Disrupt Diabetes conference ran the gamut from clinicians to designers to nurses to engineers and pharmacists. Here are iust a few of the brainstormers:

- David Maahs, MD, a pediatric endocrinologist at Stanford University, shared his experience in expanding Project ECHO (Extensions for Community Healthcare Outcomes) into T1D with a collaboration between Stanford and the University of Florida.
- Julia Hu and Jeff Zira from Lark described their iterative design process when developing a Personal AI nurse in their Diabetes **Disease Management and Diabetes** Prevention Programs.
- Ilana Orloff and Matt Callery gave a walkthrough of Medtronic/IBM Watson Health's Sugar.IQ Personal Diabetes Assistant as an innovative use of CGM data for patient decision-making.
- Diana Naranjo, PhD, clinical assistant professor in the Department of Psychiatry and **Behavioral Sciences at Stanford** closed the panel with a look into lessons learned when implementing the Novel Interventions in Children's Healthcare (NICH) model of care for high risk patients at Stanford.

# Increasing Insulin Affordability:

AN ENDOCRINE SOCIETY POSITION STATEMENT



Hormone Science to Health

# Introduction

Insulin is a lifesaving medication for people with diabetes. However, its cost has nearly tripled in the past 15 years making it difficult for many patients to afford this medication and effectively manage their disease. This has put patient safety in jeopardy as patients opt to ration their insulin or forgo other medical care. Research indicates that a lack of transparency in the drug supply chain has made it challenging to identify the root cause of price increases. This position statement will identify barriers to accessing affordable insulin and potential policy solutions that could address this growing problem.

# **Background**

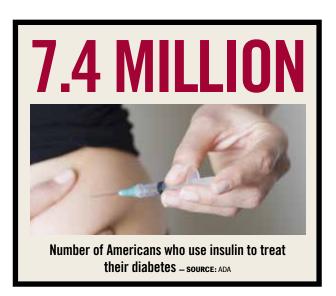
More than 30 million Americans have diabetes with another 84 million at risk for developing the disease. Having diabetes increases one's risk for serious health problems including heart attack, stroke, blindness, kidney failure, amputations, and death. Diabetes is also the most expensive chronic condition in the U.S. Average medical expenses are 2.3 times higher for people with diabetes. In 2017, the cost of diagnosed diabetes was estimated to be \$327 billion annually, with \$237 billion in direct medical costs. This equates to one-in-four healthcare dollars being spent on people with diagnosed diabetes.

since one-in-four are unaware they have the disease, <sup>8</sup> costs to the healthcare system are even higher than estimated.

Given the complex nature of diabetes, it is essential that patients adhere to their medication regimen to avoid unnecessary complications and hospitalizations. However, adherence can be difficult as people with diabetes often have co-morbidities that require them to take multiple, costly medications or they may be unable to make sustained lifestyle changes that could improve outcomes. One study indicates that improved adherence among people with diabetes could prevent nearly 700,000 emergency department visits, 341,000 hospitalizations and save \$4.7 billion annually. Recent increases in drug costs and changes to insurance design are some of the most common reasons for poor medication adherence, particularly for patients on insulin.

The true cost of insulin can be difficult to pinpoint because of a lack of transparency in financial agreements between stakeholders in the supply chain, geographical differences in cost, and insurance coverage. From 2001 to 2016, the list price of Novolog, a commonly used insulin, increased by 353% per vial. Humulin U500 increased from \$170 to more than \$1,400 since 1987. From 2001 to 2015, the price of Humalog increased 585% for a vial of insulin. GoodRx.com, a website

Given the complex nature of diabetes, it is essential that patients adhere to their medication regimen to avoid unnecessary complications and hospitalizations. However, adherence can be difficult as people with diabetes often have co-morbidities that require them to take multiple, costly medications or they may be unable to make sustained lifestyle changes that could improve outcomes."



that aggregates claims data to estimate the average list price of medications (the price of insulin without the negotiated discounts or rebates), published cost information per vial (1,000 units) for commonly prescribed insulins in August 2018. The following prices are averaged from Walgreens and CVS pharmacies:

• Lantus: \$302

Humalog: \$322

Novolog: \$336

• Humulin N: \$180

Novolin N: \$155

Basaglar: \$261\*

• Levemir: \$394

**Toujeo: \$338\*** 

Humulin R: \$180

Novolin R: \$155

Humulin 70/30: \$177

• Novolin 70/30: \$156

Novolog 70/30: \$338

• Humalog 75/25: \$351

Tresiba: \$388\*

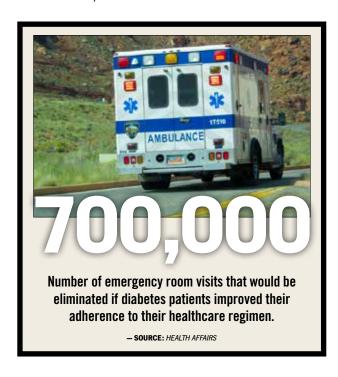
• Apidra: \$368

· Admelog: \$254

\*cost based on conversion to 1,000 units

Currently, 7.4 million Americans use insulin to treat their diabetes. <sup>16</sup> At minimum, these patients use one vial of insulin each month. However, some patients require multiple vials of insulin or use multiple types of insulins (which necessitates

multiple vials) each month. According to a survey conducted by the American Diabetes Association, 27% of respondents stated that insulin costs have affected their past year purchase or use of insulin. Thirty-four percent of families with children on insulin were impacted.<sup>17</sup> Those affected by rising costs were more likely to experience adverse health effects than those for whom cost did not impact their purchase or use of insulin and twice as likely to experience negative emotions like stress and anxiety. Many of these patients were also forced to forgo other needs such as transportation (32%), utilities (30%), housing (27%), doctor's visits (32%), or other medications (36%), <sup>18</sup> and were more likely to ration their insulin.



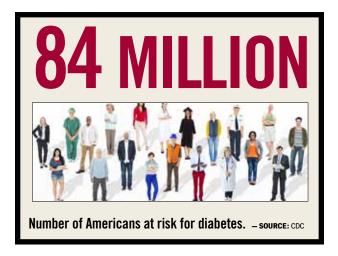
# **Patient Cost-Sharing**

Insurance plan design directly impacts out-of-pocket costs. Patients who are uninsured pay the list price of insulin. These individuals may be eligible for a manufacturer-sponsored patient assistance program (PAP), however, these programs are restrictive, difficult to navigate, and it is unclear how many patients are able to utilize them.

Patients on some forms of commercial plans may need to pay full price, depending on the plan design, for their insulin until they meet an annual deductible and then pay a fixed co-pay. They may also be required to pay co-insurance, a percentage of the cost based on the list price of insulin that does not include rebates or discounts negotiated by the

pharmacy benefit manager (PBM).

For patients with high-deductible plans (plans with a deductible greater than \$1,350 for an individual or \$2,700 for a family), out-of-pocket insulin costs are significant. Individuals



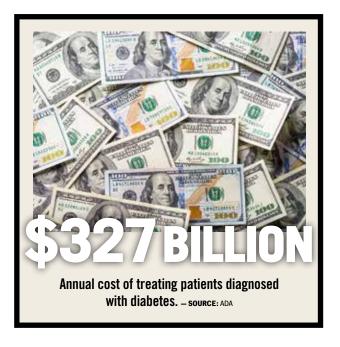
must pay for the full list price of insulin until they meet their annual deductible. In 2016, approximately 40% of Americans had a high-deductible health plan with an average annual deductible of \$4,358 for individual health plans and \$7,983 for family plans. <sup>19</sup> In the same year, 44% reported selecting plans with annual deductibles of \$6,000 or greater in 2016. <sup>20</sup>

Medicare beneficiaries with Part D coverage without a supplemental plan must also pay full price for insulin until they meet their deductible, after which point they will pay co-insurance until meeting their plan's initial coverage limit for prescription drugs (\$3,750 in 2018). At this point, they experience the Part D "donut hole," a coverage gap between the plan's initial coverage limit and when catastrophic coverage kicks in. While Medicare beneficiaries are in the donut hole, they will pay 35% of the plan's cost for covered brand-name prescription drugs until reaching their annual out-of-pocket limit of \$5,000 in true out-of-pocket spending. Catastrophic coverage will then begin, and the Medicare beneficiary will pay a small coinsurance or copayment for covered prescription drugs. 22

In some cases, purchasing medications outside of their pharmacy benefit allows patients to pay lower costs. So-called

"gag rules" have prevented pharmacists from counseling patients about options to take advantage of this cost-savings and should be eliminated.

There are many stakeholders across the drug supply chain who influence rising costs, including wholesalers, PBMs, pharmacies, health plans, and employers. While manufacturers establish the list price, each of these players impact the out-of-pocket cost to a patient on insulin through a complex series of negotiations and rebates not transparent to the public. The lack of transparency makes it difficult, if not impossible, to understand how much each stakeholder gains when costs to the patient increase. Research indicates that while list prices have skyrocketed, the net price increase



that manufacturers earn has risen at a far slower rate (3%-36% net increases).<sup>23</sup> Increasing transparency is critical to understand this divergence and other contributors to rising insulin costs.

# **Considerations**

### Complexity of the Supply Chain

The complexity of the supply chain makes it difficult to pinpoint the drivers behind increasing insulin prices. Manufacturers set the list price for the medication and typically sell their medications to wholesalers or PBMs. The process to get the medication from the manufacturer to the patient is rather straightforward, but the flow of money and the methodology to establish the price that the patient ultimately pays is much more complex. The net price manufacturers receive is based on the list price minus any fees paid to the wholesaler, discounts paid to the pharmacy, and rebates paid to the PBMs or health plans. Financial agreements between the stakeholders are confidential. For example, manufacturers are not privy to the PBM's negotiations with the health plans.

Despite significant financial incentives negotiated between the stakeholders in the supply chain, most of these savings are never shared with the consumer. As such, an individual's cost is largely based on the list price. As list prices grow at doubledigit rates, people with high-deductible plans, co-insurance, or no insurance suffer the effects.

### Net Price

The process to establish the net price involves the exchange of rebates, discounts, and other payments to encourage the purchase of a drug. For example, a manufacturer may offer distributor volume discounts to purchase their drug or provide financial incentives to a PBM for placement on the preferred tier of their drug formulary. Manufacturers cite these financial incentives as a major driver of high list prices; the more incentives provided to the players across the supply chain, the higher the list price must be for the manufacturer to realize any profit. In theory, the rebates offered to a PBM to place the drug on their preferred formulary tier should reduce costs for the patient. However, these rebates may be used by the employer or the health plan to reduce insurance premiums, not the cost of the drug at point-of-sale. However,

due to a lack of transparency, it is unclear the extent to which premiums are actually affected.

# Patient Assistance Programs and Discount Cards

To address high out-of-pocket costs, manufacturers offer patient assistance programs (PAPs) that provide insulin at low or no cost to low-income patients who qualify. These



requirements vary by company and patients must apply annually which can be problematic as PAPs can be difficult to navigate. Manufacturers also offer co-pay cards but these are typically used to incentivize the use of higher cost medications and have been shown to result in overall higher medication prices.

Competition in the marketplace for both brand name and generics typically drives down prices. This has not been the case with insulin. The price of modern insulins has continued to increase despite the availability of multiple competing insulins on the market. In a true free-market economy, this should promote greater competition and drive down costs."

#### Lower-cost Alternatives

Competition in the marketplace for both brand name and generics typically drives down prices. This has not been the case with insulin. The price of modern insulins has continued to increase despite the availability of multiple competing insulins on the market. In a true free-market economy, this should promote greater competition and drive down costs. Human insulins (i.e, NPH and regular insulins) have been available for decades, would be an effective therapy for some patients with type 2 diabetes, and can still be purchased at a significantly lower cost. However, most healthcare providers are no longer trained on how to use these.

#### Value-based Purchasing

Some experts believe that value-based purchasing (VBP) agreements have the potential to reduce drug costs. These agreements between manufacturers and health plans base payment on how effective a medication is at treating a disease and can be structured in different ways; if a drug does not improve outcomes or leads to poorer health among the health plan's patient population, the manufacturer will provide discounts, rebates, or refunds to the health plan. However, further research is needed to understand whether VBP agreements will reduce patient costs. Furthermore, regulatory barriers have limited the number of existing VBP contracts, thereby making it difficult to assess the real benefit of VBP on reducing drug costs.

#### **Positions**

Rising costs have made access to affordable insulin far more difficult for people with diabetes, especially low-income individuals, those on high deductible health plans, Medicare beneficiaries in the Part D donut hole, or those who are uninsured. Addressing insulin affordability is critical in ensuring that patients can effectively manage their diabetes and avoid unnecessary complications and hospitalizations. For many patients with diabetes, insulin is a life-saving medication. Policymakers should address drivers of rising insulin prices and implement solutions that would reduce high out-of-pocket expenditures for patients.

The Endocrine Society believes the following policy and practice changes could help expand access to lower cost insulin.

- ► Greater transparency is needed across the supply chain to understand rising insulin costs.
- ► Future list price increases should be limited, and reasonable financial incentives should be pursued by all stakeholders.
- ► To reduce out-of-pocket expenditures, cost-sharing should be limited to a co-pay. In addition, NPH and regular insulin should be available at no cost to the patient.
- ► Rebates should be passed along to consumers without increasing premiums or deductibles.

- ► Healthcare providers should be trained to use lowercost human insulins (e.g., NPH and regular), so they can prescribe as appropriate.
- ► When clinically equivalent options are available, physicians should consider prescribing the lowest cost insulin.
- ▶ The federal government should address regulatory barriers to create a more favorable environment for the testing of incentive programs that reduce cost and improve care (e.g., value-based purchasing agreements).
- ► Electronic medical records should include up-to-date formulary and price information.
- ► Co-pay savings cards should be eliminated as they have been shown to incentivize the use of higher cost medications and raise the overall cost of drugs.
- ▶ Patients should be educated about low-income assistance programs (e.g. the Extra Help program under Medicare) and to ask their physicians about alternatives if they cannot afford their insulin.
- ► Gag rules, which prevent pharmacists from helping patients find less expensive ways to pay for their medications, should be eliminated.

#### **End Notes**

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## CONGRATULATIONS TO THE NEW 2019 ENDOCRINE SOCIETY LEADERSHIP

We are pleased to announce the new Officers and Council members who will be joining our leadership team at the conclusion of ENDO in New Orleans, Louisiana. Please join us in congratulating and welcoming our future leaders!



President-Elect (Clinical Science) Gary D. Hammer, MD, PhD



Vice President (Physician-in-Practice) Whitney S. Goldner, MD



Council (Basic Science Seat) Joy Y. Wu, MD, PhD



(At-Large Seats)
Ghada El-Hajj Sam
Fuleihan, Bu
MD, MPH MD,



Council

Samantha Butts, MD, MSCE

## Way Down YONDER

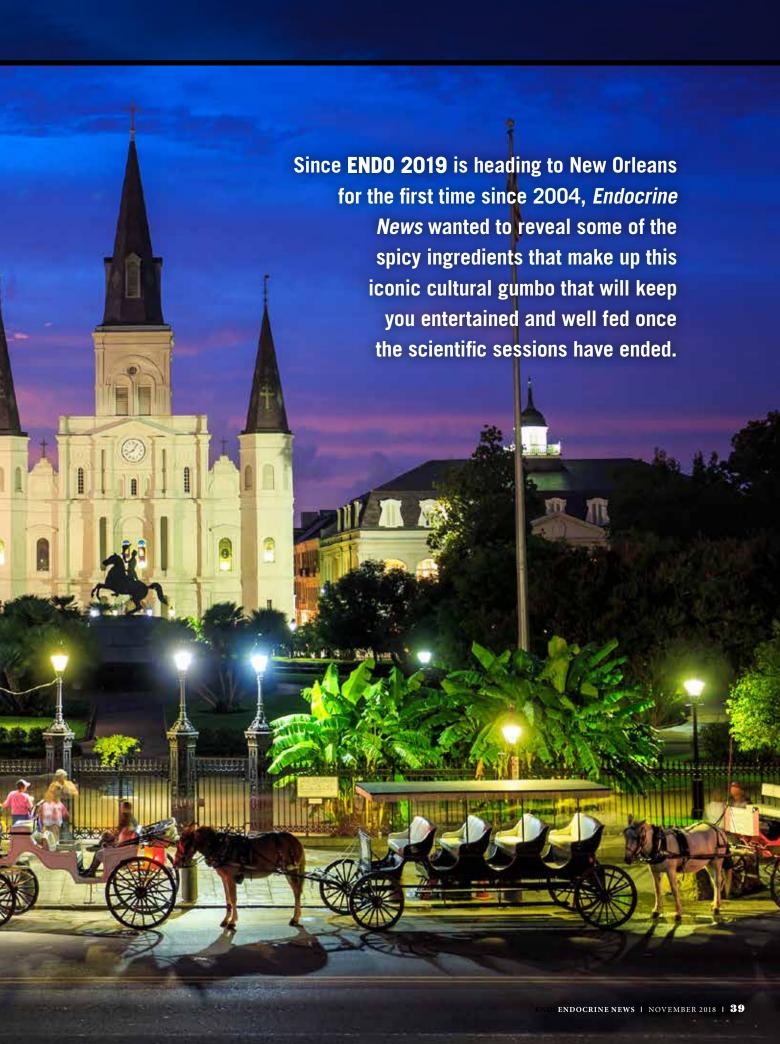
A New Orleans Travel Guide

BY COURTNEY CARSON



THE ENDOCRINE SOCIETY'S 101ST ANNUAL MEETING & EXPO

Iconic Jackson Square and St. Louis Cathedral, Photo credit: Shutterstock.com





he strains of jazz music stream down the cobblestone alleyway as the smell of warm powdered sugar drifts along the southern breeze. Travelers stop to take photos of a second line, the parade of a newly married bride and groom escorted by their wedding party and a brass band. Hungry diners line the street hoping to get a taste of the delicious fine dining at Galatoire's Friday lunch, a tradition in New Orleans society, drawing politicians, doctors, socialites, and travelers to the Bourbon Street icon.

One of the country's most unique cities, New Orleans will play host to ENDO 2019 in March at the Ernest N. Morial Convention Center. We couldn't be more excited to invite you to join us for the Endocrine Society's 101st Annual Meeting and Expo in a city that continues to top lists of the hottest travel destinations year after year.

> Make plans now to attend ENDO 2019, featuring an extensive program covering a broad array of topics, various networking opportunities, poster sessions, updates on new products and technologies at the ENDOExpo, and more. And plan to come early or stay late to enjoy all New Orleans has to offer. We guarantee it will be a trip you won't soon forget.

## **66** Laissez les bon temps rouler!"

#### **Born On The Bayou**

Founded by the French, ruled by the Spanish for 40 years, then purchased by the United States for pennies an acre in 1803, New Orleans, forever shaped by its European heritage, is a living history lesson. As one-time French Quarter resident William Faulkner said, in New Orleans, "the past isn't dead. It's not even past." The history of New Orleans has been preserved better than possibly any other U.S. city with entire neighborhoods, manhole covers along cobblestone streets, cemetery crypts, and ancient oaks seemingly untouched by human hands since they were created centuries long ago.

(article continues on p. 34)





Here's a look at some of ENDO 2019's most cutting-edge sessions that have been confirmed so far:

#### **Presidential Plenary: Whole Genome Approaches to Unraveling Diseases**

Francis S. Collins, MD, PhD, director, NIH, Bethesda, Md.

#### **Utilizing Big Data in Science and Clinical Care**

- Cori Bargmann, PhD, Rockefeller University, New York, N.Y., head, Chan Zuckerberg Initiative's science work
- Robert Califf, MD, Duke University School of Medicine, Durham, N.C., former FDA Commissioner

#### Gene Editing and Stem Cells: Using Reproductive Technology for Early Disease

- Juan Carlos Izpisua Belmonte, PhD, Salk Institute, La Jolla, Calif.
- Marisa Bartolomei, PhD, University of Pennsylvania, Philadelphia

#### **Novel Therapeutic Targets in Metabolic Disease and Cancer**

- Myles Brown, MD, Dana-Farber Cancer Institute, Boston, Mass.
- Peter J. Tontonoz, MD, PhD, University of California-Los Angeles, Los Angeles

#### **Hormone Science to Health: The Endocrine Society Goes to the National Academy of Sciences**

- Barbara B. Kahn, MS, MD, Beth Israel Deaconess Medical Center, Boston, Mass.
- Christopher Glass, MD, PhD, University of California San Diego, La Jolla
- Mitchell A. Lazar, MD, PhD, University of Pennsylvania

#### **Targeting Senescent Cells in Aging and Disease**

- Jan M. van Deursen, PhD, Mayo Clinic, Rochester, Minn.
- Sundeep Khosla, MD, Mayo Clinic College of Medicine



The Creole spirit is a part of New Orleans' history that is still very much alive. The Creole residents, American-born offspring of European settlers in the 1700s, created a world of their own throughout New Orleans. Creole flavors still dominate the cuisine with rich sauces, local herbs, red ripe tomatoes, and the prominent use of seafood, caught in local waters, while the architecture and cityscape of New Orleans, from the streets of the French Quarter to Creole cottages, reflect their French and European influences.

In the 1800s, the highest concentration of millionaires in the U.S. could be found in and around New Orleans. The elegant homes built during this period along St. Charles Avenue are still the crown jewels of New Orleans and many of the fine dining establishments that catered to the city's wealthy residents in the 1800s, including Antoine's and Commander's Palace, are still going strong.

Although the Jazz Age dominated the U.S. in the 1920s and 30s, it never really left New Orleans. Known as the birthplace of jazz, New Orleans is still the capital of that music genre with the forceful rhythms, creative improvisations, and toe-tapping tunes sounding out on almost every corner throughout the French Quarter today.

Top: Streetcars on Canal Street, photo credit: Shutterstock.com. Bottom: Booth with original art for sale at Jackson Square, photo credit: Catherine Neill

#### **Walking Through New Orleans**

A trip to New Orleans doesn't require a visit to one of the city's 45+ museums for visitors to soak up the rich history — it's apparent in all parts of the city. But New Orleans is home to a number of museums that history buffs dream of visiting. The New Orleans Jazz Museum celebrates the music in the city where it was born while the National World War II Museum brings "The War That Changed The World" to life through powerful, personal stories from the battlefront and the home front, rare artifacts, and even an exclusive cinematic experience from Tom Hanks.

The Audubon Nature Institute "celebrates the wonders of nature" in the heart of New Orleans. Made up of the Aquarium of The Americas, Audubon Butterfly Garden and Insectarium, Audubon Zoo, and more, the institute offers endless entertainment for children, families, and nature lovers of any age.



Lafitte's Blacksmith Shop bar in French Quarter. Photo by Andriy Blokhin / Shutterstock.com

For travelers looking for a more grownup getaway, New Orleans couldn't be a better fit - bars line Bourbon Street, the always bustling Harrah's Casino, dance clubs (from tame to risqué!), and endless options for live music. Pat O'Brien's offers the (in)famous Hurricane, a fruity concoction made famous in New Orleans while Lafitte's Blacksmith Shop invites guests to sip strong libations in a dimly lit building from the 1700s purported to have been a hideout of pirate Jean Lafitte. The Carousel Bar at Hotel Monteleone sends guests spinning (and not just because the drinks are strong!) while Arnaud's French 75 is an iconic New Orleans cocktail bar not to be missed.

And travelers looking for a slower pace can step in from the hustle and bustle of the French Quarter and relax in world-class spas that beckon travelers to stop and stay awhile. The spa at the Ritz-Carlton is the largest in the city and offers an impressive menu of more than 100 treatments, many locally inspired. The Waldorf Astoria Spa at The Roosevelt Hotel, one of the most sought-after spas in the South, offers indulgent signature treatments that combine local ingredients and contemporary techniques.

No matter your travel style, this city will not disappoint. History buffs, those looking to get away and relax, and adventurous families alike will find no shortage of activities during a trip to New Orleans.



#### Making a Scene in New Orleans!

The thriving arts and culture scene are a large part of what makes New Orleans such a special destination and an ideal backdrop for your night on the town when the sessions are finished. There are a number of events you might want to catch while you're in town to fully immerse yourself in all that New Orleans has to offer.

#### **Alvin Ailey American Dance Theater**

Returning to New Orleans for the first time in almost a decade, the Alvin Ailey American Dance Theater celebrates 60 years as one of America's most distinguished and famous companies bringing the African American experience and dance traditions to the world's stages. (March 22 & 23 only) www.alvinailey.org

#### **Hamilton: An American Musical**

If you missed it last March in Chicago during ENDO 2018, guess what? You don't have to throw away your shot: this sold-out show will be in New Orleans at the historic Saenger Theatre. This world-wide phenomenon won both the Tony Award for Best Musical as well as the Pulitzer Prize for drama so get your tickets while you can!

https://hamiltonmusical.com/us-tour



Clockwise from top left: Beignets and chicory coffee at Café Du Monde, photo credit: Shutterstock.com. Commander's Palace, photo credit: Suzanne C. Grim / Shutterstock.com. Oyster po-boy, photo credit: Shutterstock.com. Brennan's. Restaurant, photo credit: Brennan's.



#### **Eat Your Heart Out**

While activities abound for every kind of traveler, foodies hit the jackpot with endless options for culinary tourism.

New Orleans is home to 20 James Beard Award winners. A few highlights include August, featuring contemporary Creole with a focus on local ingredients, inspired by classical training and Southern Louisiana roots; La Petite Grocery, a bistro-style eatery that echoes the atmosphere of French restaurants of the past; and world-famous Chef Leah Chase's Dooky Chase, the family restaurant that serves up Creole-inspired soul food in an eclectic space featuring local art.

After a late night in New Orleans, diners getting a slow start will be pleased with the Sunday brunch offered around the city. Brennan's, a New Orleans icon that recently reopened, has been hailed as one of the best spots for brunch in America. Many of the brunch items are prepared tableside, including the dessert invented at Brennan's, Bananas Foster. Commander's Palace has been serving up one of New Orleans most iconic brunches since 1880. Items beloved by locals and tourists alike include the brandy milk punch and turtle soup, both of which are highlights at brunch here.

The po-boy is a staple in New Orleans — crusty French bread, most often filled with fried seafood, lettuce, tomato, pickles, and mayonnaise. Domilise's, a hidden Uptown dive, is known for its oyster po-boy. Gus's Po-boys single-room is an uptown joint that began as a pre-Depression corner grocery store that evolved into a favorite po-boy destination. Gus's is known for its off-menu favorite, the shrimp combo, that serves up fried and grilled shrimp on the classic po-boy set-up.

And a trip to New Orleans is never complete without a trip to Café du Monde, the renowned open-air coffee shop that serves fresh beignets, a deep-fried pastry topped with plenty of powdered sugar.

(article continues on p. 38)



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#### **Endocrine News Editors Pick** Their New Orleans' Favorites

Although senior editor Derek Bagley and I have both been with Endocrine News for over five years, in another life we both worked for a magazine based on the Gulf Coast for a number of years. As part of our duties, we would find ourselves in New Orleans on a regular basis (our office was only three hours away), so we feel like we have the chance to impart our expertise to make your ENDO 2019 after hours more enjoyable. Also, if you have any New Orleans recommendations, please share! As they say down yonder, "Laissez les bon temps rouler!" - Mark A. Newman, Editor [Photo credit: Catherine Neill]





"I still get a hankering for the eggs Benedict po-boy I had at Stanley Restaurant almost a decade ago! Located right on Jackson Square, this sun-filled upscale café gives you a great view of the Square and St. Louis Cathedral and all the hijinks that take place, which is like a show unto itself! You won't miss any ENDO sessions if you want breakfast food since they serve it all day long!" - M.A.N.

"You can get the best view of New Orleans by taking the Canal Street Ferry to Algiers Point, across the Mississippi River. Algiers Point itself has a much more residential feel than downtown New Orleans and the French Quarter, but there are still plenty of places to eat and explore. One of my favorite things to do is just take a leisurely stroll along the levee, taking in the New Orleans skyline." - D.B.



"I actually had to be talked into this one, but I'm so glad I gave in. The Preservation Hall Jazz Band performs every night in their tiny concert hall conveniently located next door to Pat O's. It's loud and crowded but listening to these musicians play is like watching and listening as history takes place." - M.A.N.

"Whenever I visit New Orleans, I make sure to have lunch at the Napoleon House. I order a muffuletta and a Sazerac, two very quintessential New Orleans menu items (the Sazerac is the official cocktail of the Crescent City) and try to sit in the courtyard if the weather is nice. The building that houses the restaurant was built as a refuge for the eponymous emperor, although he never made it to New Orleans. And the way the Napoleon House is decorated, its namesake would probably feel right at home dining there." - D.B.





"One of my favorite places to meet friends is the Carousel Bar at the Hotel Monteleone because it feels like you've stepped back in time. Yes, the bar stools revolve around the circular center bar, but not so fast that you'll spill your Pimm's Cup!" - M.A.N. Photo credit: jackanerd / Shutterstock.com

"New Orleans is definitely known for its food and drink, but it wouldn't be a trip there without checking out some jazz. My favorite place to go to hear jazz is Frenchmen Street, to the Spotted Cat or the Blue Nile in particular, but you honestly can't go wrong along that strip. It's a good way to cut loose or relax or just appreciate classic New Orleans." - D.B. Photo credit: cdrin / Shutterstock.com





"I don't think I've ever visited New Orleans without going to Pat O'Brien's for one of its signature hurricanes. Yes, it's a bit touristy but that's part of the fun. Whether it's with a large group or just by yourself, steal away and sip - slowly - on a bright red fruity concoction as you unwind in the courtyard." - M.A.N. Photo credit: Atomazul / Shutterstock.com

"A relative newcomer to the New Orleans culinary scene is Bacchanal Wine, and it's quickly become one of my go-tos ever since a friend took me there for dinner a few years ago. It's an interesting concept – you go into a small building and purchase a bottle of wine and/or a cheese board and then find a seat in the large courtyard where a jazz band plays at one end. Items from the Mediterranean-style menu are ordered at a window at the back of the building. Enjoy delicious food and wine and make some new friends in what essentially amounts to a backyard party in the Bywater." - D.B.



Top to bottom: Preservation Hall Jazz Band in the heart of the French Quarter (726 St. Peter Street), photo credit: f11photo / Shutterstock.com. New Orleans skyline at sunset, photo credit Shutterstock.com. Carriage ride passing Cafe Du Monde, photo credit: Catheirne Neill.

#### **Resting Easy in the Big Easy**

After a busy day seeing all the sights, hearing all the sounds, and filling your stomach with all the New Orleans fare, travelers will drift off to sweet dreams of the Crescent City in one of the city's acclaimed hotels.

The Ace Hotel, an outpost of Manhattan's famous original location, is one of the city's most sought-after destinations. The lobby is a mix of a lively music venue and cocktail bar that is always bustling. The Pontchartrain Hotel is located in the Garden District and features vintage interiors with modern (and luxurious) touches. The penthouse rooftop bar, Tin Roof, is known to offer some of the best views of the city.

Hotel Monteleone is one of the city's oldest luxury hotels that is said to be one of the most spirited places to stay in New Orleans. The hotel is known for its spirits, from the Carousel Bar, which revolves as guests sip signature libations, to the dearly departed guests who are rumored to have never checked out.

However, if you want to be as close to the Ernest N. Morial Conference Center as possible, you have your choice of quite a few notable lodging options. Aside from reliable chain hotels — Embassy Suites, Hyatt Place/Convention Center, Residence Inn, Hilton New Orleans Riverside, Marriott — there are a few unique to New Orleans. The Loews New Orleans offers a splash of luxury on the banks of the Mississippi River in a building that once housed a steamship company. If you're looking for a little bit of southern glitz and glamour, the Harrah's New Orleans is the ideal place for ENDO off hours with a casino and a variety of restaurants from the upscale Ruth's Chris Steakhouse to Manning's Sports Bar and Grill, voted one of the best sports bars in town by the readers of Gambit magazine.



Registration is now open for ENDO 2019! Begin planning your stay in New Orleans and make your reservations now at www.endocrine.org/endo2019. Registration will fill up quickly so don't delay in securing your spot. Join 7,500 of your colleagues for an educational experience that will shape the future of the field and enjoy a trip that is sure to become one of your all-time favorites.

#### The Music Scene in New Orleans!

#### **Jeremy Davenport at The Davenport** Lounge, Ritz-Carlton

Each week, Wednesday through Saturday nights, the place to be in the French Quarter is the Davenport Lounge in the Ritz-Carlton Hotel. What better way to unwind from a day filled with sessions and exploring ENDOExpo than listening to the smooth tunes from the talented trumpeter and crooner while sipping on a mint julep?

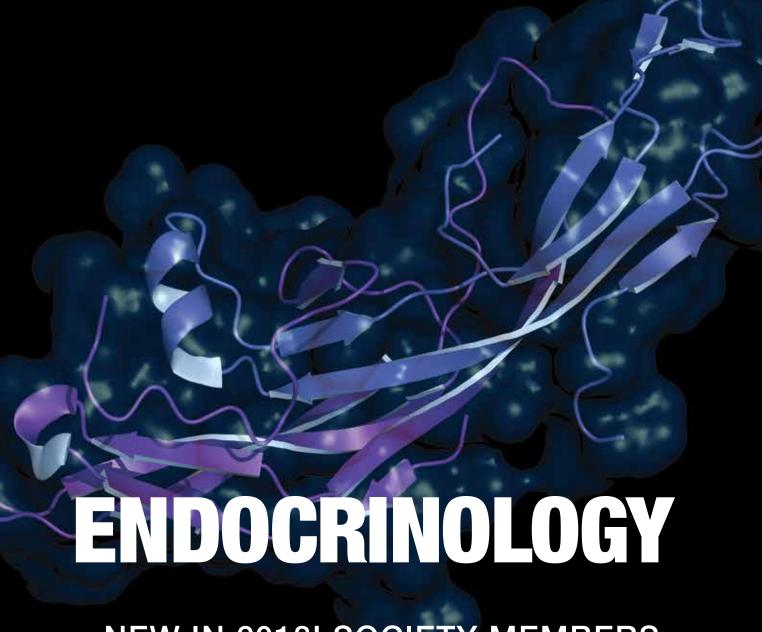
#### **Preservation Hall Jazz Band**

Since you're in one of the most historic cities in the U.S., why not have a taste of musical history and sit in on an intimate session by the Preservation Hall Jazz Band in the heart of the French Quarter (726 St. Peter Street). With nightly concerts, feel the city's spirit and joie de vivre as you sway along with the PHJB's vivid melodies.

www.preservationhalljazzband.com



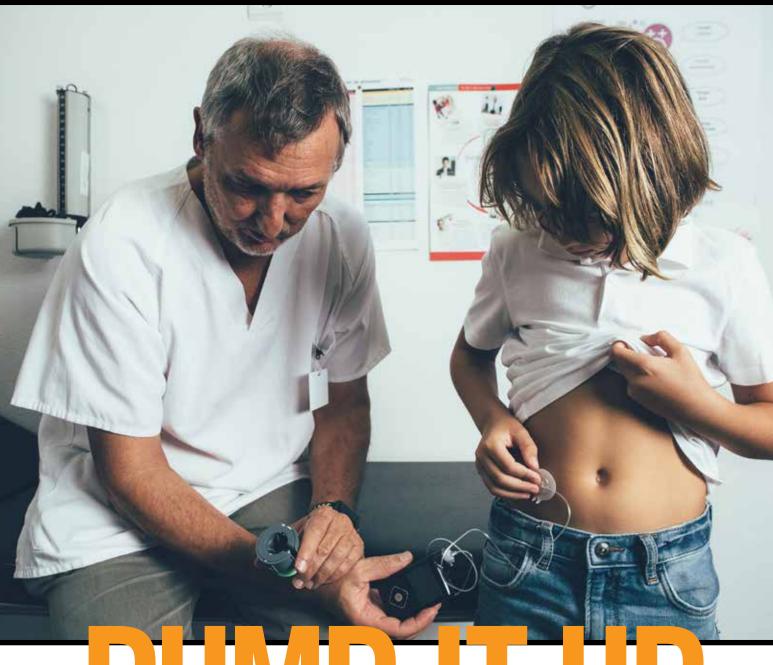
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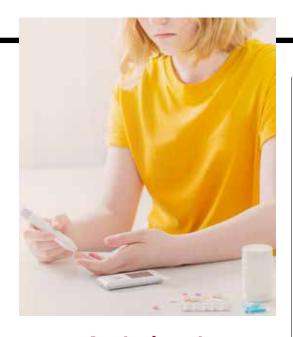
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### Diabetes Technologies Continue to Revolutionize Care

**BY ERIC SEABORG** 



As devices become smarter and smarter and smarter and smarter and improve patient outcomes, they also pose challenges for patient and clinician education. While clinicians ensure all patients are up-to-speed on the new technology, a new threat looms: Keeping data safe.

n an early episode of the CBS crime drama *Elementary*, a man is found dead of an apparent heart attack. But Sherlock Holmes deduces that it is a case of murder — the victim's pacemaker was hacked.

More than one Agatha Christie novel involves an unsuspecting victim succumbing to an insulin injection.

With diabetes patients now using continuous glucose monitors (CGMs) connected to insulin pumps via smart phones, could Dr. Evil combine these two plots and hack the pump's insulin delivery to commit murder most foul?

That apocalyptic vision may already be possible, some experts say, but it contrasts with a very positive real-world example related by a diabetes specialist: A type 2 diabetes patient over 80 years old was at his vacation home in Arizona when he passed out during a hypoglycemic episode. His wife was out of the house and without her phone. But when his CGM detected his perilously low blood sugar level, it caused an alarm to sound on his daughter's smart phone in Portland, Ore. She called the neighbors in Arizona, who found her father unresponsive and dialed 911. The first responders revived him.



#### **Fast-Changing Technology**

These wildly disparate scenarios illustrate the promise and the peril of new technologies that are rapidly improving the lives of many diabetes patients. CGMs and insulin pumps are becoming smaller, more accurate, and easier to use "off the shelf," with less need for patient or clinician intervention. Some CGMs are so reliable that they don't require calibration by the patient. One commercially available "hybrid closed-loop system" of a CGM interacting with a pump is nearing the goal of an artificial pancreas, while some tech-savvy patients are already using do-it-yourself systems. Even insulin pens are becoming smart enough to communicate with phones to deliver the correct amount of insulin.

It used to be that a patient would visit an endocrinologist every three or four months so the physician could adjust the treatment. But the new technologies "put the patient in the driver's seat and put decision-making tools in their hands to tweak their treatment," says Dennis Harris, PhD, associate

director of content strategy and outcomes at the Endocrine Society — and an early adopter of technology as a type 1 diabetes patient himself.

But there are concerns that those who could benefit the most from the technology could be the last to get it. "I work in Beverly Hills, in a practice where people have health insurance and are really well educated, and they are incredibly avid adopters of technology," says Anne Peters, MD, director of the clinical diabetes program and professor of clinical medicine at the Keck School of Medicine at the University of Southern California. "I also work in East Los Angeles where people are of lower socioeconomic status. Many have fifth-grade reading levels and don't speak English as a primary language. Their ability to adopt and use technology is much, much less. And, of course, it is much more needed because lower income patients have much poorer outcomes."

Better teaching tools are needed to reach these patients, and groups like the American Association of Diabetes Educators



I see amazing successes, but the vast majority of those successes are people who are familiar with using technical tools.

I've had patients whom I
have literally forbidden
to wear sensors because they
overreact so much to changes
in their glucose."

 ANNE PETERS, MD, DIRECTOR, CLINICAL DIABETES PROGRAM; PROFESSOR, CLINICAL MEDICINE, KECK SCHOOL OF MEDICINE, UNIVERSITY OF SOUTHERN CALIFORNIA, LOS ANGELES

are working on creating them, including multilingual instructions. Funded by a grant from the Helmsley Charitable Trust, Peters has created free online tools for less literate patients in English and Spanish (available at http://uscdiabetes.com/#pens).

Seniors are another subset particularly at risk because "they are more prone to hypoglycemia and more prone to the adverse outcomes from hypoglycemia, such as falls and fractures," says Andrew Ahmann, MD, professor of medicine and director of the Harold Schnitzer Diabetes Health Center at Oregon Health and Science University in Portland.

Peters agrees: "Even seniors who are more educated are much less comfortable with technology. They are not people who wander around with smart phones." Plus, issues of cognitive decline must be taken into account.

"If seniors are exposed to and carefully taught how to use technology, they get by their concerns," Ahmann says. "But you have to approach them a little bit differently. You have to get them to persist in its use long enough that they can get by those initial anxieties and uncertainties. I think the manufacturers are doing a good job of making their products simpler and simpler."

#### The Conundrum of Shared Data

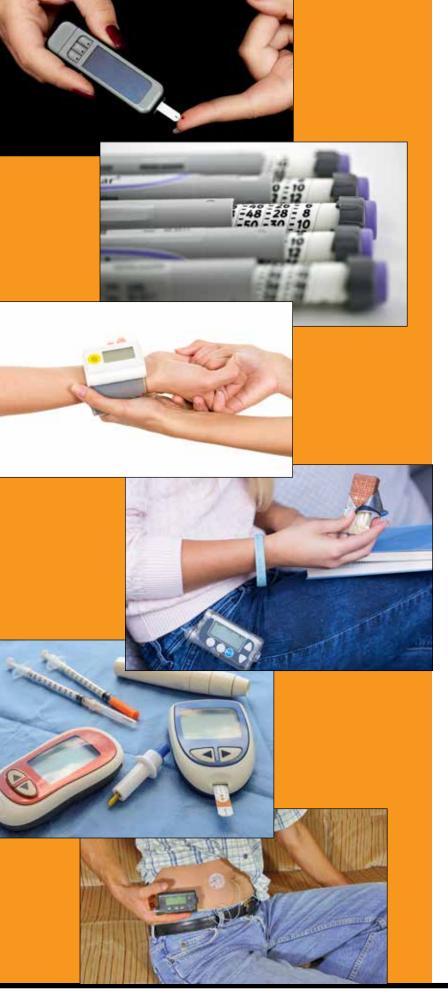
Ahmann says that he has been "surprised at how many patients, when they have the opportunity to share their information, are choosing not to. Or don't even want to put it on their phone and prefer to use a much simpler receiver."

But Ahmann can attest to the benefits of sharing. One family insisted that their



#### AT A GLANCE

- Advances in technologies like continuous glucose monitors and insulin pumps are transforming diabetes care.
- Although some patients are comfortable with new devices, clinicians face the task of spreading the benefits more equitably by introducing new technology to patients who find adapting to it a challenge.
- As devices incorporate the use of smart phones and cloud computing, issues of cybersecurity will increase in importance.



80-something father share his information, and the move paid off when he passed out on his large rural property - and a family member used the iPhone finder app to locate his unconscious body and get medical help.

#### **Sharing with Physicians**

By using smart phones, patients can tie into databases and algorithms that can help with their insulin dosing and also share their data with their physicians. Peters' patients' data is uploaded automatically, with no need for action by the patient, to a platform called Tidepool - open source software for a variety of devices distributed by a nonprofit organization. Jessica Castle, MD, an associate professor of medicine at Oregon Health and Science University, accesses her patients' data via several software systems, including Glooko (broadly compatible commercial software), Medtronic's CareLink, and Dexcom's Clarity. She says the Dexcom system is particularly handy because "once people accept the request to share data from a device with our clinic, I can access it without them doing anything further, which is really nice, because one of the barriers for being able to review data is for patients to have to download information from their devices."

She finds these systems particularly helpful for doing a weekly review of CGM and pump data from pregnant women with type 1 diabetes.

#### Issues of Cybersecurity

Of course, the use of cell phones and cloud computing to receive and share data raises questions of hacking and cybersecurity, issues beyond the control of clinicians and patients and left in the hands of the manufacturers of the devices. To guide manufacturers in making safer devices, the Diabetes Technology Society has developed a pair of cybersecurity standards, according to David Klonoff, MD, medical director of the Diabetes Research Institute at Mills-Peninsula Medical Center in San Mateo, Calif., who chaired the standards development committee.

Through the years, there has been a revolution in the development of technology to aid people with diabetes in managing their disease. From glucometers and injection pens to insulin pumps and artificial pancreases, this revolution will no doubt continue.

If you want to find out how to do anything, you go to YouTube. But the extension to medical applications must be done cautiously. We will have the challenges of separating out the ones that are done very professionally and scientifically from those done by self-appointed experts."

— ANDREW J. AHMANN, MD, PROFESSOR OF MEDICINE; DIRECTOR, HAROLD SCHNITZER DIABETES HEALTH CENTER,
OREGON HEALTH AND SCIENCE UNIVERSITY, PORTLAND

The first standard, called DTSec, is for information going to or from a connected diabetes device, such as a handheld, dedicated controller. The second standard, called DTMoSt, "is intended to help manufacturers understand what types of security features are needed when you have a mobile phone controlling a device — a situation so new that there is not even a product on the market yet that would need it," Klonoff says.

"If you give enough people enough time and enough equipment they can hack into anything," Klonoff says. "So the idea isn't for a medical device to be absolutely unhackable, because that is impossible. But there are levels of difficulty for hacking in. We have set a fairly high level because it is related to a medical product." For a device to be certified as meeting the standard, it is sent to a lab that does "penetration testing" to see how hard it is to hack. "One company has already had products verified as meeting DTsec," Klonoff says.

"I think at some point, patients are going to start demanding that products meet DTsec or DTMoSt, but right now, most patients don't know about it," Klonoff says.

#### Can Coverage Keep Up?

These kinds of standards may make it easier to get new devices approved for coverage by payers.

But payers are not always keeping up with the technology. For example, it took several years and concerted efforts by groups like the Endocrine Society working with the manufacturers to get Medicare to provide coverage for glucose monitors like the Dexcom G5 and the Abbott FreeStyle Libre Flash Glucose Monitoring System. But it was many months later that Medicare

agreed to extend coverage to the use of smart phones. And after the Food and Drug Administration approved the next step in the Dexcom family — the G6, which provides an upgrade over the previous model because it does not require calibration — it again took several months for it to receive Medicare approval. So Medicare patients will receive new units several months after privately insured patients receive theirs.

#### **Education Everywhere**

Education — for payers, patients, and physicians — is a key to effective adoption of the new technologies.

"I see amazing successes, but the vast majority of those successes are people who are familiar with using technical tools," Peters says. "I've had patients whom I have literally forbidden to wear sensors because they overreact so much to changes in their glucose."

The landscape is changing so fast that even clinicians have a hard time keeping up with it — and knowing how to teach their patients about it.

Ahmann says that professional societies are working on this problem, and the internet could be a key help: "YouTube is potentially going to be a significant player in patient education. If you want to find out how to do anything, you go to YouTube. But the extension to medical applications must be done cautiously. We will have the challenges of separating out the ones that are done very professionally and scientifically from those done by self-appointed experts."



# Hot Trock. Steps to Start Just like running any Your Own Lab

small business, putting together
a lab requires you to wear many hats.
Here are some tips that will help you
overcome many hurdles as you begin the
exciting and sometimes daunting process
of launching your own lab.

BY GLENDA FAUNTLEROY SHAW

he opportunity to start an academic research lab is an exciting time of independence and responsibility. For researchers overcoming the first hurdle of successfully negotiating funding to complete their research goals, the next steps can often be daunting. Now what?!

Running a laboratory is equivalent to running a small business — a business where you are in charge of it all. Glenn Rowe, PhD, of the Division of Cardiovascular Disease at the University of Alabama at Birmingham, knows this all too well. He has helped set up three labs during his 20 years of academic research, including his own lab at the UAB in November 2014. Rowe gave a lecture at this year's **ENDO 2018** on the very topic of the how to's of new laboratory set up.

"As a principal investigator, you're tasked with a new set of requirements, but all the training you've had up until that point really developed just one set of skills," Rowe says. "You became a scientist, you learned how to do science and how to ask very interesting scientific questions and execute them nicely."

"But now you must wear multiple hats all at the same time and you're your own little executive board," he adds. "You're the chief financial officer, the chief human resource officer, the CEO, and the chief scientific officer, and these other skillsets are all on-the-job training."

#### HAT #1: CHIEF FINANCIAL OFFICER

Once you have received a start-up package, planning your laboratory budget becomes top priority. Here's where one of your most critical "hats" gets the first test.

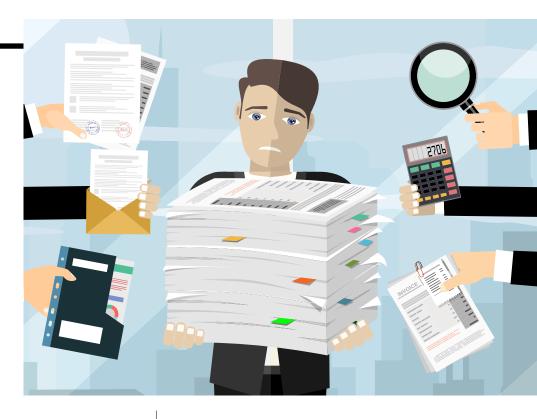
"You need to spend the money and get off the ground running as fast as possible," Rowe says. "It's not an investment account. You can't just put it in the bank and leave it. At some places you have to use it or lose it in three or five years."

Start by making a list of your important needs. The information used to negotiate your start-up package will provide the best data for your initial budget. Laboratory budgets usually fall into three major categories: 1. major equipment, 2. personnel, and 3. supplies/consumables.

As a principal investigator, you're tasked with a new set of requirements, but all the training you've had up until that point really developed just one set of skills. You became a scientist, you learned how to do science and how to ask very interesting scientific questions and execute them nicely."

- GLENN ROWE, PHD, DIVISION OF CARDIOVASCULAR DISEASE, UNIVERSITY OF ALABAMA AT BIRMINGHAM

#### **LABORATORY NOTES**



Major equipment can include anything from refrigerators and hoods to computer and printing equipment. Take the first step to learn if resources at your institution will allow you to save on major purchases.

"Let's say you get half a million dollars to start your program, but at your institution you have access to half a million dollars' worth of common or shared equipment. There's a lot of money you don't have to spend," Rowe advises.

After you determine what equipment you need to purchase, be sure to receive quotes from several vendors, especially when you do not need a specific model or brand. Ask other researchers at your institution for vendor recommendations and pour over product reviews online at sites such as www. labmanager.com.

After instrument costs, next comes personnel costs, which will make up a large portion of the budget. Typically, personnel include full or part-time laboratory technicians, graduate or undergraduate students, and post-doctoral fellows. Ideally, the post-doc or graduate student should have a fellowship or be funded through teaching assistantships. Consider salaries, benefits, and travel expenses.

#### **HAT #2: CHIEF HUMAN RESOURCE OFFICER**

Choosing the best team for your lab is one of the most important things lab managers do. How do you know who are the best people to complete your team?

"When starting out, you are the best at what you do within the lab," says Rowe. "Now you need to build a team to help execute on the scientific mission. So do you hire 'miniature' versions of yourself, which is an almost impossible feat starting out, or assemble a team of people who all bring something to the table?"

He believes the latter is best: "You probably wouldn't like working with you."

And while posting job announcements online is the standard method of choice, don't forget to tap referrals of trusted colleagues in the scientific community. This is where maintaining a professional network comes in handy. Colleagues at other institutions can alert you to people who are actively looking and can be potentially be a good fit.

#### HAT #3: CHIEF EXECUTIVE OFFICER

Finances, employees, regulatory matters, and equipment — it all falls to you as the chief executive officer. You're the boss and being a good one requires a personality and skillset that cause many bosses to struggle. A Forbes article analyzed a manager training program at Google and summarized it with the following: "Inspire. Teach. Protect. Remove obstacles. Be human. If you cultivate these characteristics, you'll become the unforgettable boss that your people will remember for the rest of their careers."

GLENDA FAUNTLEROY SHAW IS A FREELANCE HEALTH EDITOR/WRITER BASED IN CARMEL, IND. SHE IS A REGULAR CONTRIBUTOR TO ENDOCRINE NEWS.

## GETINVOLVED

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### *Teachable* Moments:

## Using Journey Boards for Pediatric Diabetes Patients

When children are first diagnosed with type 1 diabetes, there are myriad challenges for the patient and the parents. A new educational program developed by Phoenix Children's Hospital called *Our Journey in the Hospital* has proven to be an effective tool for patients, parents, and the clinical team.

> bout 12 years ago at Phoenix Children's Hospital, the nurses in the endocrinology unit started to realize that there's a lot to teach a child about his or her newly diagnosed type 1 diabetes – not just the child, but the parents as well. The child and the parents learn about a lifelong condition and they're told at the hospital that they basically have to become experts in the 48 to 72 hours before they're discharged.

> So, the hospital came up with a "journey board" concept called Our Journey in the Hospital, game board-like tools (now a free app) to help identify important questions to ask about treatment. The diabetes journey board breaks this overwhelming diagnosis into parts that the family can digest easily and concentrate on the areas that are most concerning to them.

66

The issue has always been how to efficiently educate young families of varying education levels, of varying resources just as efficiently as we can when you consider that we have many, many people helping care for these patients." - LESLIE TOUGER, MD, MEDICAL DIRECTOR, DIABETES PROGRAM, PHOENIX CHILDREN'S HOSPITAL, PHOENIX, ARIZ.

"What I love about the journey board concept is it's a lot of teams working together, including IT and the endocrine team, our Emily Center Health Information Library, marketing, [and so on]," says Marjorie Abele, MSN, RN, health education specialist at the Emily Center at Phoenix Children's Hospital. "It's bringing teams together to provide quality care."

Each box of the journey board represents an important step in caring for the patient with type 1 diabetes. Some are tasks requisite for safe discharge; some are on the continuum of care, the "journey," on the outpatient side. At the end of each section, there are teach-back questions. Abele says Phoenix Children's Hospital, by policy, adopted teach-back as their method for patient education, since it's an evidence-based process of evaluating understanding. "This practice is something the healthcare industry doesn't do very well at this time," she says.

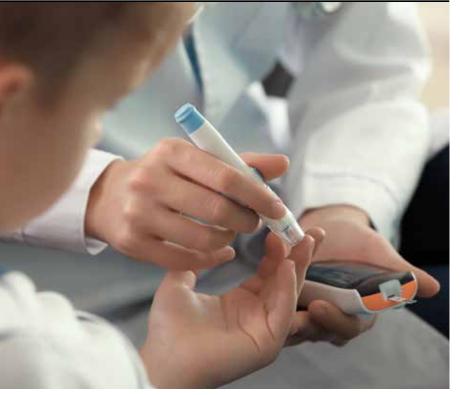
#### **Diabetes Care Checklist**

But this program isn't just about developing patient education content, it's helping the endocrine care teams streamline and

maximize their efforts to provide the best and most efficient care possible. The clinical team at Phoenix Children's can coordinate with the IT team to pull data at the time of discharge based on the journey boards' infrastructure, and the clinical team can see how well they documented, which is not always consistent in healthcare. It's a busy, fast-paced environment, and things can fall through the cracks.

"We're not just creating patient ed content," Abele says. "We're now looking at metrics and quality outcome data. We know our nurses are doing a great job of teaching, but we also realize that documentation can be lax at times just with the hustle and bustle of healthcare."

"The issue has always been how to efficiently educate young families of varying education levels, of varying resources just as efficiently as we can when you consider that we have many, many people helping care for these patients," says Leslie Touger, MD, a pediatric endocrinologist



We're not just creating patient ed content. We're now looking at metrics and quality outcome data. We know our nurses are doing a great job of teaching, but we also realize that documentation can be lax at times just with the hustle and bustle of healthcare."

- MARJORIE ABELE, MSN. RN. HEALTH EDUCATION SPECIALIST, EMILY CENTER AT PHOENIX CHILDREN'S HOSPITAL, PHOENIX, ARIZ.

and medical director of the Diabetes Program at Phoenix Children's Hospital.

Touger points out that the inpatient nurses work in shifts, and before this journey board model, efforts would be duplicated, and things would be left out. "This serves as a checklist that they talk about airline pilots having, so that everything does get indeed covered in a consistent way, so you can get good at it," she says.

"The nice thing is because it's now encoded electronically, if we ever want to change it because we have new insulins or new devices or something, it won't be like you then have old documents floating around that can mess people up," Touger says. "It's very uniform."

#### **Developing Survival Skills**

The journey boards have been instrumental in helping Touger's patients and their families develop survival skills. But the journey boards and the teach-back questions are on the back end of this process and introducing these families to these educational offerings and engagements can be challenging. For many of these families, it's their first time navigating a complicated healthcare system that can be extremely confusing. For example, part of the education is to teach them about different brands of insulin, that they're interchangeable like Coke and Pepsi, and the clinical team works to make sure they're prescribed the preferred product from their insurance.

Again, there's a 48- to 72-hour window from admittance to discharge, and some of these families may not even be aware that they have to go to the pharmacy to pick up their medications. Touger says that when the patient is first admitted, they meet with the endocrinologist, who lays out expectations and explains that they are in the hospital to learn about their diagnosis and how to tackle any issues that may arise because of it.

"We introduce a handwritten log that we talk with them about completing because our feeling is if the family can complete a log, three or four meals' worth of log material, then they can go home," Touger says. "We can do the rest of the support and education in getting into your target range over the next few weeks. It's really to set up so we can communicate, so we all





speak in the same language in terms of carb ratios, treatment of lows, how to treat lows, how to problem solve."

After that, the clinical team conducts classes at two weeks and then at four weeks after diagnosis, when they meet with physicians and educators. Then they see patients quarterly, but children grow, and they need dose adjustments between visits. "We teach families to contact our education team between visits with five or six days of data, either from the pump or from handwritten logs, so that they can get a dose adjustment," Touger says. "The hope is not only does the patient identify a doctor as their doctor but their team, their educator, and so forth."

#### **Rave Reviews**

Phoenix Children's Hospital's *Our Journey in the Hospital* program has produced results that show they are confident patients and families are properly educated, thereby ensuring post-treatment success. In February 2017, the hospital ran its first electronic medical records (into which journey board data are incorporated) report that showed only 40% compliance of documentation on the diabetes journey board, so the education group intervened and communicated with

nurses and staff and within two months, they brought that number up to 80%. "Then a few months later, we ran a five-month stretch at 100%," Abele says. "September 2017 to January 2018, we were 100% each month."

They also had a nurse educator survey 20 families who were admitted for new type 1 diabetes, asking basic questions about patient engagement and quality. "All 100% of those 20 families agreed that teach-back had been used to validate their teaching," Abele says.

"To me, it's a traditional way to do management where you provide what the patients need," she says. "It is not a revenue-generating activity. We are really fortunate to be at Phoenix Children's which supports this kind of diabetes education program."

Medicine is evolving from a fee-for-service environment to value-based care – patient satisfaction and reimbursement structures have a higher priority now. The journey boards program has not only seen 100% compliance rates, but it's also reduced the lengths of hospital stays and garnered glowing reviews from patients. "It's made the transition from inpatient to outpatient fairly seamless," Touger says.

### In Sequence

A look at some products to aid labs that perform single cell sequencing as part of their endocrine research.

#### COMPILED AND WRITTEN BY COURTNEY CARSON

Single cell sequencing is a growing area of focus in endocrinology research labs. This technique examines the sequence information from individual cells with optimized next-generation sequencing technologies, providing a higher resolution of cellular differences and a better understanding of the function of an individual cell in the context of its microenvironment. Recently published papers and ongoing studies use single cell sequencing to look at the development and function of the pituitary gland throughout life and as a way to understand and combat infertility.

This EndoGear features a few products labs are using in this powerful new set of technologies to study rare cells, delineate complex populations, and discover updated techniques for treating endocrine disorders.



**DISCLAIMER** INCLUSION IN THIS COLUMN DOES NOT SUGGEST AN ENDORSEMENT BY *ENDOCRINE NEWS* OR THE ENDOCRINE SOCIETY



The BD Rhapsody Single-Cell Analysis System is a platform for single cell analysis with the ability to detect rare molecules responsible for biological diversity that are often missed with whole transcriptome profiling. Developed using the company's patented unique molecular index (UMI) technology, BD Rhapsody is a complete system of reagents, instruments, and software for targeted gene expression analysis of tens of thousands of individual cells. www.bd.com

The DriverMap™ Human Genome-Wide Targeted Expression Profiling Assay enables researchers to simultaneously measure the expression level of almost 19,000 human protein-coding genes in a single assay. By combining highly multiplexed RT-PCR amplification with the depth and precision of next-generation sequencing (NGS) quantitation, the DriverMap assay provides a comprehensive, highly sensitive, and quantitative measurement of gene expression from total RNA without removal of rRNA or globin components. Any standard RNA sample for RT-PCR is suitable for DriverMap analysis, including total RNA from cells, frozen tissue, fine needle aspirate (FNA), whole blood, peripheral blood mononuclear cells (PBMCs), and mouse patient-derived xenograft (PDX) isolates. www.cellecta.com



As single cell sequencing continues to evolve, expect labs to use this powerful new set of technologies to study rare cells, delineate complex populations, and discover updated techniques for treating endocrine disorders.





#### **Society Names Co-Chairs of Congressional Diabetes Caucus Diabetes Champions**

he Endocrine Society awarded co-chairs of the Congressional and Senate Diabetes Caucuses with the Diabetes Champion Award for their outstanding work in promoting research and

prevention efforts for people with diabetes. Senators Susan Collins (R-ME) and Jeanne Shaheen (D-NH) and Representatives Tom Reed (R-NY) and Diana DeGette (D-CO 1st District) received the award for their work reauthorizing the Special Diabetes Program (SDP) at \$600 million over two years as well as championing other critical initiatives like coverage for continuous glucose monitors, the National Clinical Care Commission, and the Diabetes Prevention Program.

The SDP provides funding for type 1 diabetes research and prevention programs for at-risk populations, specifically Alaska Natives and American Indians. The SDP has resulted in important steps in finding a cure for diabetes, like the development of the artificial pancreas and beta cell replacement and has reduced complications from type 2 diabetes like retinopathy and kidney failure. The reauthorization of the SDP provides funding for these efforts through 2019.

The Society looks forward to continuing its work with the Diabetes Caucus on issues impacting endocrinologists and the patients they treat.





Susan Collins (R-ME Jeanne Shaheen (D-NH) Tom Reed (R-NY) Diana DeGette (D-CO)

#### **Endocrine Society Members Partner** with Patients and Caregivers to Advocate on **Diabetes**

n October 1, the Endocrine Society partnered with the Diabetes Patient Advocacy Coalition to advocate for increased access to diabetes selfmanagement training services and to educate members of Congress about ways to address rising insulin costs.

The joint Hill Day marks the first time that Society members have accompanied patients, caregivers, and diabetes educators to Capitol Hill to discuss issues impacting the field of endocrinology. We also conducted a Congressional briefing to provide policy makers with an overview of the impact of affordable access challenges to insulin and the need for increased utilization of diabetes self-management training. Society member Nazanene Esfandiari, MD, associate professor and service chief, Division of Metabolism, Endocrinology and Diabetes at the University of Michigan, moderated a panel composed of Jasmine Gonzalvo, PharmD, BCPS, BC-ADM, CDE, LDE, clinical associate

professor, College of Pharmacy at Purdue University and Stewart Perry, secretary of the National Diabetes Volunteer Leadership Council, and vice chair of the Diabetes Patient Advocacy Coalition. The briefing provided an opportunity for Congressional staff to learn about issues that make it challenging for people with diabetes to effectively manage their disease.

New Legislation to Cover Diabetes Self-Management Training - While patients currently have access to diabetes self-management training services, only 3% - 5% of Medicare beneficiaries utilize the benefit. To address these barriers, Congressman Tom Reed (R-NY) and Congresswoman Diana DeGette (D-CO) introduced the Expanding Access to Diabetes Self-Management Training Act. The Endocrine Society and DPAC advocated for cosponsorship of this legislation in more than 30 offices throughout the day.

Access to Affordable Insulin - In addition to discussing DSMT, members also educated Congressional offices about the need to address rising insulin costs. Over the past 15 years, insulin costs have nearly tripled. This has forced patients to make difficult, sometimes life-threatening, decisions about their treatment. The Endocrine Society released a position statement, featured in this issue of Endocrine News (page 58), outlining steps that stakeholders across the supply chain can take to address this issue.

The Congressional Diabetes Caucus is also investigating additional steps that can be taken and will issue a report in the coming weeks detailing these actions. We will include additional information on this report in a future issue of Endocrine News.

#### Rising Insulin Prices Fuel Anger; **Society Calls for Action by All Stakeholders to Ensure** Affordable Access



**Endocrine Society and Diabetes** Patient Advocacy Coalition members prepare to educate members of Congress on Capitol Hill.

ising insulin costs are drawing outrage from patients and policymakers alike.

Insulin was first discovered nearly 100 years ago, and as newer forms of the drug have been introduced, the price has climbed. According to the American Diabetes Association, the average price of insulin nearly tripled between 2002 and 2013, putting the lifesaving hormone out of reach for some people with diabetes.

Recent stories in the media of patients who could not afford their insulin have prompted scrutiny from members of both parties in Congress. In the House of Representatives, Diabetes Caucus Co-chairs Tom Reed (R-NY) and Diana DeGette (D-CO) have been conducting an inquiry into insulin pricing, with the intent of eventually unveiling legislation. In the Senate, the Special Committee on Aging chaired by Susan Collins (R-ME) has been examining the issue and conducted a hearing. In addition, the Senate Finance Committee Democratic staff has issued a report

on the broader issue of the drivers in the supply and payment chains for all prescription drugs. Calls for Congress to address rising drug prices led to the passage of bipartisan legislation last month to eliminate so-called "gag rules" that prevent pharmacists from telling consumers about lower-cost alternatives that are off formulary.

President Trump has also said reining in rising prescription drug costs is a priority of his administration. This year, the administration has taken a series of steps outlined in a drug pricing "blueprint" geared toward promoting lower prices through competition. Last month, the administration unveiled a proposed rule to require manufacturers to disclose the list price of a drug or biological product in all direct-to-consumer advertisements. Although experts in drug policy argued these steps are modest, they increase visibility of the problem and continue to put pressure on the industry to make changes on its own.

The Endocrine Society is deeply concerned about this issue and has worked for the last year and a half to identify ways to ensure affordable access to insulin. Last year, we worked on a resolution at the American Medical Association (AMA) House of

#### **ADVOCACY**

Delegates calling for greater transparency in how insulin prices are set. AMA is now advocating for the Federal Trade Commission and the Justice Department to monitor insulin pricing and market competition and take enforcement actions as appropriate.

CEU 2018 featured a session with Alvin Powers, MD, probing what is the responsibility all stakeholders in the insulin supply chain, including not only pharmaceutical manufacturers, but also physicians, medical centers and health systems, and the Society. We followed that session with special roundtable discussions with members to hear their experiences and recommendations concerning insulin affordability.

The Society's Clinical Affairs Core Committee has studied insulin pricing and talked with insurers and companies to instigate conversation on solutions. In September the Committee conducted a Hill Day to talk with Congressional offices about diabetes issues, including insulin affordability. The Committee also hosted a Congressional Briefing to educate Congressional offices about the problem.

In this issue of *Endocrine News*, we are sharing our new position statement on access to affordable insulin (page 58 ). The statement reviews the problem, describes certain policy issues that need to be considered when developing a solution, and provides several recommendations to address the issue. While we recognize that no single recommendation offered will resolve the problem, we hope that this statement will not only guide our advocacy, but also will be used as a catalyst to facilitate discussion on how best to develop policies that will take on and address this national public health crisis.

#### Sanofi Expands Insulins VALyou Savings Program to Help Make Sanofi Insulins More Affordable

We are happy to see manufacturers responding to our call for greater affordability. Most recently, Sanofi announced that as of November 1, 2018 it will expand its Insulins VALyou Savings Program for people living with diabetes to include all Sanofi insulins (with the exception of Sanofi's combination insulin product), helping patients get the insulin they need at a significantly reduced price. This program is available at U.S. pharmacies and offers all Sanofi insulins at one set price: \$99 for a 10 mL vial or \$149 for a box of pens.

All uninsured and commercially insured patients are eligible to participate in the Insulins VALyou Savings Program. This includes patients who don't qualify for



Nazanene Esfandiari, MD, discusses many of the issues that make it challenging for people with diabetes to effectively manage their disease at the Capitol Hill briefing.

traditional patient assistance programs and individuals who are commercially insured with a high deductible that they have not yet reached. Commercially insured patients can also check the website of their prescribed Sanofi insulin to see if they're eligible for co-pay cards which may limit out-of-pocket expenses to as low as \$0. While under current regulations pharmaceutical companies cannot offer this type of program to federally insured patients including Medicare and Medicaid recipients, Sanofi says it supports efforts that would expand this access program to all those who might benefit.

For some people, the program could offer a savings of up to \$3,000 per year. That support can assist people who need to control their diabetes but have found the out-of-pocket costs of their insulin unaffordable. Since its April launch, over 6,500 people living with diabetes have enrolled and taken advantage of the benefits of the program.

For more information, visit www.InsulinsVALyou.com. Sanofi also encourages anyone who is prescribed a Sanofi medicine, and who may be having financial challenges or trouble navigating their insurance, to call Sanofi Patient Connection at (888) 847-4877, where eligible patients can be connected to the medicines and resources they need at no cost.

For more information about our advocacy on insulin pricing, please visit www.endocrine.org/advocacy/diabetesadvocacy.

Endocrine Society and DPAC meet with staff from the office of Rep. Debbie Dingell (D-MI).

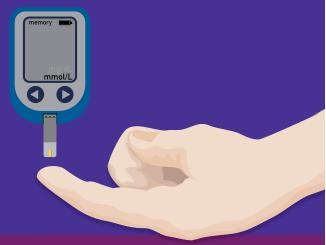


## **Understanding** Diabetes Complications

Two main types of complications that can occur are:

#### Microvascular

(Small blood vessels)



#### Macrovascular

(Large blood vessels)

Diabetes is the leading cause of blindness among adults in the U.S. For this reason, an annual eye exam is critical for people with diabetes so that your doctor can check for signs of plants. cataracts, or problems with the retina (retinopathy).

Retinopathy affects the back part of the eye, called the retinal This is where the eye receives images and converts them to electrical signals, which travel to the brain along the optic nerve. Diabetes is a major cause of retinopathy. More than 80% of people who have had diabetes 20 years or longer get diabetic retinopathy.



#### Cardiovascular Disease

Heart disease, peripheral arterial disease, and stroke are major concerns for people with diabetes. Heart disease is the No. 1 killer of Americans, and people with diabetes are twice as likely to have a heart attack or stroke as are people without diabetes. Two out of three people with diabetes die from cardiovascular disease.

The risk factors for cardiovascular disease include

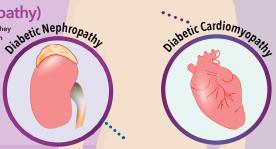
- High blood pressure
- Abnormal blood fat (cholesterol and triglycerides) levels
- Overweight or obesity
- Lack of physical activity
- Over the age of 50
- · Personal or family history of cardiovascular disease

#### Kidney Disease (Nephropathy)

Your kidneys are very important for your overall health. They remove waste and excess water from your body, maintain your body's chemical balance, and produce hormones that regulate the creation of red blood cells and blood

The body has two kidneys. You need at least one to work in order to survive

disease in the U.S. Among U.S. adults age 20 or older with diagnosed diabetes, 36.5% have chronic kidney



#### Neuropathy

About 50 percent of people with diabetes get some form of neuropathy. But not everyone has symptoms.

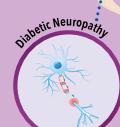
Those who develop neuropathy get one of two types: one that affects the limbs (distal polyneuropathy, or DPN), and the other that  $\,$  affects some of the internal organs (autonomic neuropathy).

DPN's symptoms can include:

- Pain, tingling, and burning
- Numbness or loss of feeling
- Muscle weakness
- Open sores (skin ulcers)

Autonomic neuropathy's symptoms can include:

- Bladder problems
- Digestive system problems
- Sexual problems
- Too much or too little sweating
- Dizziness when you stand up



#### **Coronary Heart Disease**

If your body has too much of certain blood fats, they can build up inside the arteries that carry blood to the heart. This buildup, called atherosclerosis, can lead to coronary heart disease, the narrowing or blockage of these important blood vessels.

If oxygen or blood supply is blocked or cut off to your heart, a heart attack may be the result.

Heart failure means your heart can't pump all the blood your body needs. A heart attack, coronary artery disease, and high blood pressure (hypertension) can all bring on heart failure.

A stroke is like a "brain attack"-the blood supply to part of your brain is suddenly stopped, usually by a blockage or blood clot. People with diabetes are 1% times more likely to have a stroke than are people who don't have diabetes.

The warning signs for stroke are:

- Weakness or numbness on one side of the body
- Sudden confusion or trouble understanding
- Trouble talking or walking, Reigheral Arterial Disease dizziness, loss of balance
- Trouble seeing out of one or both eyes
- Double vision
- Severe headache

#### **Peripheral Arterial Disease**

When the arteries in your legs become clogged with the buildup of blood fats, peripheral arterial disease (PAD) may be the result. It's estimated that one out of every three people over the age of 50 who have diabetes also have PAD.

The symptoms of PAD are:

- Leg pain, especially after walking or exercising (which goes away after a few minutes of rest)
- Numbness, tingling, or coldness in the lower legs
- Slowly healing sores or infections on your feet or legs

#### Microvascular

(Small blood vessels)

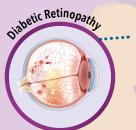
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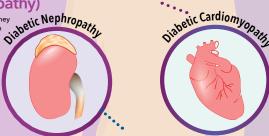
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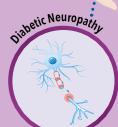
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#### **Prevention and Treatment**

It's important to understand that complications don't always happen. If you keep your blood sugar in the range your doctor recommends, you can reduce your chances of getting complications.







**Healthy Eating** 





Maintaining a Healthy Weight



**Doctor Prescribed** Drugs and Therapies to control Blood Sugar Levels

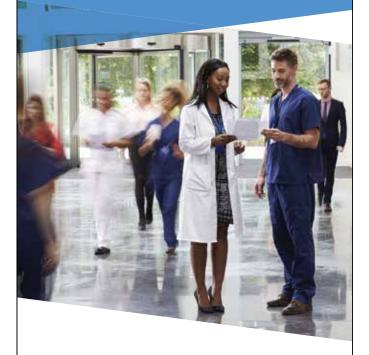


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#### ENDOCRINOLOGY CLINICAL INVESTIGATOR/SCIENTIST

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

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

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

Qualified applicants should contact:

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

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ADVANCE REGISTRATION: DECEMBER 7, 2018—JANUARY 31, 2019 LATE-BREAKING ABSTRACTS: JANUARY 16—FEBRUARY, 13, 2019

