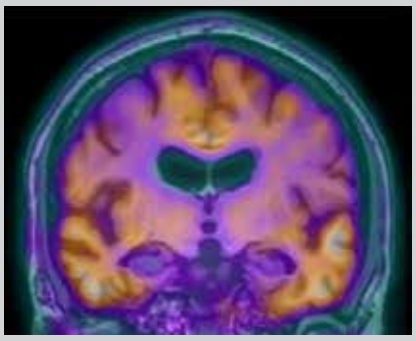
Serving Harris, Galveston, Brazoria and Fort Bend Counties

HOUSTON Medical Times

Bringing Healthcare News to the Forefront

March Issue 2016

Inside This Issue



Dementia Treatment Delayed Due to Misdiagnosis
See pg. 9

INDEX

First rapid detection Zika Test Now available
See pg 10

USING MEDICAL MARIJUANA TO STOP SEIZURES IN KIDS

For kids with uncontrolled seizures, a technically illegal drug offers hope. But is it scientifically sound?

By Christina Sumners
Texas A&M University Health Science Center

Desperate for relief, parents are taking unusual steps to help children plagued with seizures. The relief, however, comes in a most unlikely form: marijuana.

As many as 30 percent of people with epilepsy—or about one million Americans—still have seizures while on Food and Drug Administration (FDA)-approved treatments. It's left many who suffer from uncontrollable seizures—or their parents, as many of them are children—turning to medical marijuana and its derivatives in an attempt to take back control of a disease with no cure.

A seizure is an abnormal electrical storm in the brain that causes sudden alteration in consciousness, sensation and behavior that can manifest from an eye flicker to full-body convulsions. People with medication-resistant (also called intractable) epilepsy suffer from consequences of recurrent seizures, which could damage the brain and adversely impact their quality of life. This is commonly observed in children with certain types of devastating pediatric epilepsy, such as Lennox-Gastaut, Doose and Dravet syndromes.

Stories about desperate parents seeking anything to relieve their children's seizures abound, but how much scientific evidence is there for cannabis' effectiveness?

D. Samba Reddy, Ph.D., R.Ph., professor in the Department of Neuroscience and Experimental Therapeutics at the Texas A&M Health Science Center College of Medicine, studies novel therapies for epilepsy. He recentlypublished an article, with co-author Victoria Golub, in the Journal of Pharmacology and Experimental Therapeutics about the current state of research into medical marijuana for treating epilepsy.

"There was a lot of media attention about how medical marijuana is good for epilepsy," said Reddy, who is a fellow of both the American Association of Pharmaceutical Scientists (AAPS) and the American Association for the Advancement of Science (AAAS). "We became interested in finding out whether there was scientific evidence in the literature to support the claims of these people who have seen great benefits."

There are at least 85 active components of the plant colloquially known as marijuana, but two major ones of have been the focus of study: delta 9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the psychoactive component of the plant, while CBD doesn't cause any sort of a "high" and isn't thought to be addictive. Preliminary studies—largely in animal models—have shown CBD might have some anti-seizure potential.

Derivatives of marijuana high in CBD (but with negligible amount of THC) might offer some benefit for intractable epilepsy. CBD-enriched products, like Epidiolex and Realm Oil, exist, but their efficacy hasn't been proven and they exist in a sort of legal grey area. Homemade compounds exist, but since they don't go through rigorous best practice manufacturing procedures and haven't been approved by the FDA, it can be difficult for consumers to know exactly what they're getting.

Although THC is known to share the actions of anandamide (from the Indian Sanskrit word "anand" for bliss or happiness), a naturally

see MARIJUANA page 18

Mental Health

New Clinic Opens at UH for Adolescent, Family Counseling Therapy Focuses on Providing Support for the Transition to Adolescence

Adolescence is a difficult time. It's a time of transition for both adolescents and their parents. Better known for a variety of hormonal changes, adolescence also brings with it significant changes in brain structure and function.

"Adolescence is one of the two major transitional periods in childhood, where we see the most change in terms of biology and social functioning," said clinical psychologist Carla Sharp. "The hormonal changes are accompanied by changes in both gray and white matter development in the brain. This is in parallel with something called social reorientation, where teens' primary attachment expands from their parents more toward peers and romantic relationships. But since teens don't sever ties completely with parents, a tension often emerges between teens seeking autonomy while still being dependent on their parents. This is when relationship issues can emerge for teens and their families."

A new clinic at the University of Houston recently opened to address this transitional period, as it relates to family relationships. Under the direction of Sharp, who is both a researcher and professor in the Department of Psychology, the Adolescent Diagnosis, Assessment, Prevention, and Treatment Center (UH-ADAPT) addresses an unmet need in Houston. Sharp says there are not enough adolescent services available, and the ones that are often aren't affordable or accessible. She and her team are working to address this issue. UH-ADAPT is a low-cost provider, with fees set on a sliding scale based on family income.

The center focuses on assessing and treating adolescents ages 12-17 who struggle with emotional and relationship difficulties. There is also a research component that aims to develop more effective tools to identify areas of difficulty for adolescents, such as trouble with emotional intensity, family relationships, interpersonal relationships and thinking processes, as well as improving treatments for these problems.

The three types of disorders targeted by the clinic are emotional, behavior and emerging personality disorders. Emotional disorders include things like anxiety and depression, while behavior disorders result in externalizing behaviors, such as acting out, impulsivity and self-harm. Emerging personality disorders are a confluence of the two, manifesting in a severe way, with one of the quintessential personality disorders being borderline personality disorder (BPD). Sharp's lab is known internationally as having a great deal of expertise with BPD, which is at the severe end of the continuum.

"We provide services on a sliding scale, since we're a university clinic and have students in training doing much of the treatment under supervision. That means we can provide services to an underserved population who are falling through the cracks right now," Sharp said. "Studies have shown the onset for most psychiatric disorders is in adolescence, so it's this vulnerability period where we need systems in place to catch these kids. They are falling through the cracks partly because there are very little outpatient opportunities for emerging personality disorders, and the outpatient opportunities that exist are cost prohibitive, so we want to address that gap in the market for mental health services in Houston."

One of Sharp's goals with this clinic is to help adolescents build a stronger sense of "self" that will ultimately help patients be stronger when life throws something at them.

see Mental Health page 20

How does COPD care by physicians compare with nurse practitioners/ physician assistants?

Researchers from The University of Texas Medical Branch at Galveston investigated differences in care given to chronic obstructive pulmonary disease patients by medical doctors compared with nurse practitioners and physician assistants. This study is currently available in the journal, PLOS ONE.

The United States is experiencing a shortage of primary care physicians; stemming from growth in the population of older adults, increased rates of chronic diseases and an additional 13 million newly insured patients needing medical services under the Affordable Care Act.

To meet this growing need for primary care providers, many health systems are looking at alternate models of care by expanding the workforce of advance practice providers, or APPs, which include nurse practitioners and physician assistants.

APPs are increasingly contributing to the care of those with health conditions requiring lifelong management such as chronic obstructive pulmonary disease, diabetes, high blood pressure and others. However, some physician organizations say that APPs have less training and experience managing these type of conditions and can't deliver services of as high quality or as safe as those of physicians.

UTMB's study is the first to examine the quality of COPD primary care delivered by physicians versus APPs on a national level. For the study, records of 7,257 Medicare COPD patients who had at least one hospitalization in 2010 were reviewed. Researchers were looking for differences in the medical care given by the two types of providers and outcomes of patients.

The researchers looked at which health care professionals administered tests to check breathing capacity, flu and pneumonia vaccines, COPD medications and referrals to a pulmonary specialist. Outcome measures were emergency department visits, number of hospitalizations and readmissions within the first month after being released from the hospital.

"We found that APPs were more likely to prescribe short-acting inhalers or oxygen therapy and to consult with a pulmonary specialist, but less likely to give flu and pneumonia vaccinations compared to physicians," said Amitesh Agarwal, MD, lead author and fellow in the UTMB division of pulmonary critical care & sleep medicine. "Patients receiving care from APPs had lower rates of ER visits for COPD and a higher follow-up rate with a pulmonologist within 30 days of hospitalization for COPD than those cared for by a physician."

Agarwal said that the more frequent specialist consults with APP care may be due to the recognized need for expertise and skills outside of the APP's scope of practice for complex patients. Lower use of influenza vaccination in the APP group is likely related to the lower age group of the COPD patients under their care.

The study also found lower rates of follow-up clinic visits after hospitalization for sudden COPD flare-ups in the APP group than in the primary care physician group. However, patients cared for by APPs had more clinic follow-up visits with a pulmonary specialist than the patients of physicians. Higher follow-up rates with a pulmonologist following hospitalization in the APP group may partly explain the lower trends in emergency visits and readmission. ▼

MEDICAL WORLD AMERICAS CONFERENCE AND EXPO

MAY 18-20, 2016 | GEORGE R. BROWN CONVENTION CENTER | HOUSTON,TX

Produced in collaboration with:

TMC TEXAS MEDICAL CENTER

CORNERSTONE SPONSORS

GE

pwc

INSTITUTIONAL SPONSORS

MEMORIAL HERMANN

Texas Children's Hospital

utmb Health

HEALTH SCIENCE CENTER TEXAS A&M UNIVERSITY

SUPPORTING SPONSOR

OPPORTUNITY HOUSTON

CONTRIBUTING SPONSORS

FKP Architects

Houston Community College Coleman College for Health Sciences

HOAR CONSTRUCTION

Houston Medical Journal

McCOY Workplace Solutions | Steelcase Health

JobMedic

WHR ARCHITECTS the healthcare practice of EYP Inc.

MEDIA PARTNERS

The Citizen

Cypress Creek Mirror

HealthCareBusiness news

el Hospital

Bellaire | River Oaks Texas Southwest Examiner

Memorial Examiner

Houston Medical Times

Houston Community Newspapers & Media Group

HoustonPress

The Journal Pearland

MPO

ODT Orthopedic Design & Technology

TEXASMD

TMC NEWS

INNOVATE

TRANSFORMING HEALTH
Through Disruption and Discovery

Earn up to 10 hours of face-to-face, continuing education credits by attending interactive sessions from top medical professionals and industry experts.

EARN UP TO 10 HOURS OF CONTINUING EDUCATION

Don't Miss Our Distinctive Keynote!
Dean Kamen, Innovator/Inventor
Founder, DEKA Research
Disruptive Innovation
Thursday, May 19 | 10:00AM - 11:30AM

REGISTER TODAY!

VISIT WWW.MEDICALWORLDAMERICAS.COM

Legal Health

FIVE THINGS PROVIDERS SHOULD KNOW ABOUT CMS'S FINAL RULE REGARDING REPORTING AND RETURNING OVERPAYMENTS

Mark S. Armstrong, J.D. and Meghan Weinberg, J.D.
Epstein, Becker & Green, P.C.

Section 6402(a) of the Affordable Care Act ("ACA") requires a person who has received an overpayment to report and return the overpayment to the Secretary of Health and Human Services, the state, an intermediary, a carrier, or a contractor, as appropriate, by the later of (i) 60 days after the date on which the overpayment was identified or (ii) the date on which any corresponding cost report is due (if applicable). CMS recently issued the final rule regarding reporting and returning of overpayments (the "Final Rule"), six years after the enactment of the ACA. The Final Rule becomes effective on March 14, 2016 (the "Effective Date").

1. Look-back Period Shortened to Six Years

In the Final Rule, CMS pulls back from its proposed ten-year look-back period stating that overpayments must be reported and returned only if a person identifies the overpayment within six years of the date that the overpayment was received. CMS further noted that it is amending the reopening rules to accommodate the six-year look-back period for reporting and returning overpayments.

2. "Identified" Means Exercising Reasonable Diligence

CMS revised the earlier proposed standard for identifying an overpayment and replaced actual knowledge, reckless disregard or deliberate ignorance of the overpayment with a reasonable diligence standard and provides much-needed clarity regarding the actions that providers and suppliers must take when an overpayment has been "identified." In particular, the Final Rule clarifies that "a person has identified an overpayment when the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment." While the Final Rule itself does not use the phrase "credible evidence," this phrase is used throughout the preamble and reflects that reasonable diligence is demonstrated through the timely, good faith investigation of credible information. CMS further states that the time period should be at most six months from the receipt of the credible information, except in extraordinary circumstances. "Extraordinary circumstances" may include unusually complex investigations (e.g., physician self-referral law violations that are referred to the SRDP), natural disasters, or a state of emergency.

see Legal Health page 20

Oncology Research

The tumor microenvironment in melanoma: Challenges and opportunities for immunotherapy

By Jorge Augusto Borin Scutti, PhD
Houston Medical Times

Cancer of the skin is by far the most common of all cancer and melanoma accounts for less then 2% of skin cancer cases but causes a large majority of skin cancer deaths. Melanoma is one of the oldest known forms of malignant tumors in humans, although historical evidence for its occurrence in antiquity is scarce. In 1960s, a reported examination of nine Peruvian Inca mummies, dated approximately 2400 years old, showed apparent signs of melanoma, such as melanotic masses on the skin and diffuse metastases to the bones. Cutaneous melanoma is a tumor of neuroectodermal origin that results from the proliferation and malignant transformation of pigment producing cells, the melanocytes, which originate from neural crest progenitors and migrate to the skin and hair follicles during embryogenesis. Malignant melanoma is the most aggressive and treatment-resistant type of skin cancer with increasing incidence in the last decades. Several risk factors can make a person more likely to develop melanoma. About 86% of melanomas can be attributed to exposure to ultraviolet radiation of the sun. Although the precise etiology of malignant melanoma remains obscure, evidence strongly suggests that genetic and environmental interactions play a role in melanoma development. However, moles (also know as nevus – dysplastic nevi, dysplastic nevus syndrome and congenital melanocytic nevi), fair skin, light hair, freckling, family history, older age, male gender, xeroderma pigmentosum and immune dysfunction can contribute to melanoma initiation. To date, melanoma susceptibility genes CDKN2A, CDK4 and pathways involving RAS, BRAF, PTEN and PI3K have been identified and protects melanoma cells from anoikis (a form of programmed cell death induced by anchorage-dependent cells detaching from the surrounding extracellular matrix – ECM). Approximately 40%-60% of cutaneous melanoma carries mutations in BRAF, which induces constitutive activation of the MAPK pathway. The standard treatments for patients with melanoma are surgery (> 2mm), chemotherapy (Cisplatin, Vinblastine, Dacarbazine, Paclitaxel, Temozolomide, Carmustine and Carboplatin), radiation therapy, biologic and targeted therapy. The successful surgical removal of tumors depends on the early diagnosis of the disease. Unfortunately, the available treatment options have not been translated into significant improvement in the survival of patients with metastatic disease. Metastasis remains the major driver of mortality

in patients with melanoma and cytokine resistance is an obstacle to immunotherapy. Moreover, melanoma can modulate the immune response by releasing immunosuppressive factors and immunoediting. Furthermore, macroscopic metastasis can be seen decades after a primary tumor has been surgically removed or treated by conventional strategies. The newly introduced immunotherapies target critical regulatory elements of the immune system in an attempt to promote an effective antitumor response. Immunotherapy refers to a number of approaches intended to active the immune system to induce objective responses and disease stabilization. New agents, including cytokines (TNF, IFN-α and

see Oncology Research page 22

Healthy Heart

Your Annual Well-Women Visit: Take it to Heart

By: The American Heart Association

Do you know what causes heart disease in women? What about the survival rate? Or whether women of all ethnicities share the same risk? Heart disease is the No. 1 killer of women, causing 1 in 3 deaths each year. That's approximately one woman every minute!

But it doesn't affect all women alike, and the warning signs for women aren't the same in men. There are a several misconceptions about heart disease in women, and they could be putting you at risk. The American Heart Association's Go Red For Women movement advocates for more research and swifter action for women's heart health for this very reason.

of prevention is worth a pound of cure." Today that applies more than ever to women's health. Medicare and most private health insurance plans are now required to cover preventive services such as cholesterol and blood pressure checks, and help to quit smoking. These are covered at no added cost to you. As a patient, you won't even be charged a copayment or deductible for these services when provided by a health care provider in your network.

One of the covered preventive services is a Well-Woman Visit – sometimes also called an annual physical, wellness visit, or well woman exam.

What exactly is the Well-Woman Visit? It's an annual physical and

One of the best weapons against heart disease is to get to it before it gets to you. Early detection can make all the difference in a successful battle against the No. 1 killer of women.

The American Heart Association encourages all women to schedule a Well-Woman Visit with their health care provider. It's an annual check-up that gives a woman's doctor the chance to spot the signs of heart disease while there's still time to take necessary steps to conquer it. The Well-Woman Visit is also a great opportunity for your doctor to be on the look- out for other health concerns.

As the old saying goes, "An ounce

discussion about your health that all women should get to help identify serious health concerns before they become life threatening – such as heart disease and stroke. Your Well-Woman visit will be tailored to your age, family history, past health history, and need for preventive screenings. Some services – such as checking your blood pressure, height, weight, and temperature – will be provided as needed, based on your medical and family history. (For example, if you had your cholesterol and blood sugar levels checked last year and they were normal, you likely will not need to have these screening

see Healthy Heart page 22

Dementia Treatment Delayed Due to Misdiagnosis

Frontotemporal dementia often misdiagnosed as Alzheimer's disease

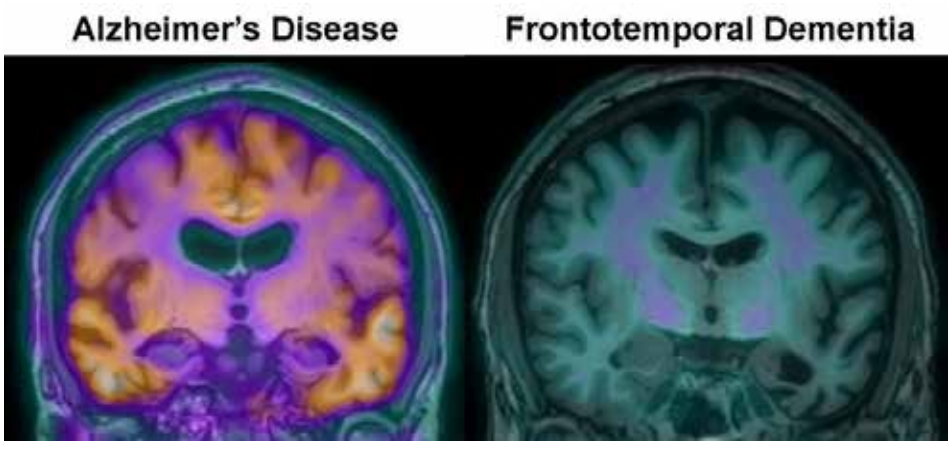
Many patients showing signs of dementia are quickly diagnosed with Alzheimer's disease when they might actually suffer from frontotemporal dementia, delaying the appropriate treatment for them.

"Some people cannot tell frontotemporal dementia from Alzheimer's disease," said Joseph Masdeu, M.D., director of the Nantz National Alzheimer Center at Houston Methodist Hospital. "However, these diseases have different symptoms and treatments. And with advances in neuroimaging, we can see a clear difference in how frontotemporal dementia manifests in the brain."

in Alzheimer's clinical trials can skew that data and prevent the advancement of those treatments."

Masdeu adds that a good treatment is not yet available for frontotemporal dementia, but that the symptoms can be treated. While memory loss is the primary symptom of Alzheimer's, patients with frontotemporal dementia begin to be less concerned or organized in their daily activities, say or do inappropriate things that they usually would not, or have difficulty finding the right words.

Frontotemporal dementia is estimated to affect more than 50,000 people in their 50s to 70s annually,



In Alzheimer's disease, the accumulation of the protein beta amyloid can induce the excess production of an abnormal form of the important brain protein, tau. In frontotemporal dementia, beta amyloid is not present and a different abnormal form of tau is detected. Houston Methodist Hospital is the only center in Houston offering tau imaging to aid in the diagnosis of frontotemporal dementia.

"A misdiagnosis of Alzheimer's can prevent a person with frontotemporal dementia from participating in future trials for this group of disorders" Masdeu said. "And since potential Alzheimer's treatments would not help a patient with frontotemporal dementia, misdiagnosed patients participating

whereas Alzheimer's disease affects more than 5 million people between the ages of 60 and 90 each year.

Emmy Award-winning sports commentator, Jim Nantz, partnered with the Houston Methodist Neurological Institute to create the Nantz National Alzheimer Center. Jim and his wife, Courtney, work tirelessly to increase funding for research and generate awareness of dementia and Alzheimer's disease, as well as the possible effects that concussions and traumatic brain injuries have on these diseases. Courtney and Jim have made a generous lifetime commitment to aggressively support research to find a cure for Alzheimer disease as a lasting tribute to Jim's father, Jim Nantz, Jr. who battled Alzheimer's for 13 years. ▼

First rapid detection Zika test now available through collaboration with Texas Children's Hospital and Houston Methodist Hospital

Collaboration between two Texas Medical Center institutions has resulted in a release of the country's first hospital-based rapid tests for the Zika virus.

Pathologists and clinical laboratory scientists at Texas Children's Hospital and Houston Methodist Hospital developed the Zika direct test in a matter of weeks as part of the L.E. and Virginia Simmons Collaborative in Virus Detection and Surveillance. This sponsored program was designed to facilitate rapid development of tests for virus detection in a large metropolitan area. The tests are customized to each hospital's diagnostic laboratory and will provide results within several hours. They can be performed on blood, amniotic fluid, urine or spinal fluid, according to James Versalovic, M.D., Ph.D. pathologist-in-chief at Texas Children's and leader of the Texas Children's Zika test development team along with James Dunn, Ph.D., director of medical microbiology and virology at Texas Children's.

Zika virus, which is mostly transmitted through mosquitoes, is a flavivirus that contains RNA as its genetic material. The new diagnostic test identifies virus-specific RNA sequences to directly detect Zika virus.

"With travel-associated cases of the Zika virus becoming more prevalent in the United States, coupled with the looming increase in mosquito exposure during spring and summer months, we must be prepared for a surge of Zika testing demand," said Versalovic. "We must provide answers for anxious moms-to-be and families who may experience signs and symptoms or may simply have travel history to endemic areas."

Before this test was developed, physicians faced the possibility of long delays of testing in local and state public health laboratories and the Centers for Disease Control.

"Hospital-based testing that is state-of-the-art enables our physicians and patients to get very rapid diagnostic answers. If tests need to be repeated or if our treating doctors need to talk with our pathologists, we have the resources near patient care settings," said James M. Musser,M.D., Ph.D., Chair of the Department of Pathology and Genomic Medicine at Houston Methodist Hospital and leader of the Houston Methodist test development team along with Randall J. Olsen, M.D., Ph.D., director of the molecular diagnostics laboratory.

Musser said the test was designed to detect the genetic material of the virus, its

RNA, so that virus is directly detected in pregnant women and any other adult or child with this virus infection. This test is specific and can distinguish Zika virus infection from Dengue, West Nile or Chikungunya virus infections. Every viral particle contains genes in its RNA and these RNA sequences are directly detected during pregnancy in amniotic fluid or anytime in blood, spinal fluid or urine.

"This is a significant development as health authorities are recommending all pregnant women who have traveled to a place with a Zika virus outbreak get tested," Musser said.

At the current time, only registered patients at Texas Children's or Houston Methodist hospitals can receive the test but the labs will consider referral testing from other hospitals and clinics in the future.

The test will be initially offered to patients with a positive travel history and symptoms consistent with acute Zika virus infection such as a rash, arthralgias or fever or asymptomatic pregnant women with a positive travel history to any of the affected countries. The World Health Organization is now advising pregnant women to consult their doctors before traveling to places with Zika virus outbreaks and consider delaying travel. The CDC issued similar guidelines to American women last month.

The collaboration between Texas Children's and Houston Methodist Hospital was made possible by philanthropists, Virginia "Ginny" and L.E. Simmons who created the program after the 2014 Ebola virus scare highlighted the need for more focus on these infectious diseases.

"It is so great to see the progress these teams have made in such a short time. The work they are doing has such an impact on so many lives," Simmons said. "I am so grateful to know that the funds we donated are being used to make these types of advances in the Texas Medical Center."

SIMPLE SOLUTIONS TO REDUCE HAI'S

By Rayne Guest, Health & Safety Specialist, R-Water

R-Water is a small business based in San Marcos, TX that specializes in environmentally-friendly disinfectants. Their mission is to reduce preventable infectious diseases. Their solutions are generally nonhazardous to nurses, staff, patients, and doctors, and only require a few simple ingredients to make. R-Water's popular disinfectant, TK60, and powerful cleaner, FC+, have a unique chemistry that is produced on site and ready to use in minutes, using patented technology.

The TK60 disinfectant has a dwell time of only 60 seconds, a very competitive contact time compared to traditional disinfectants, which often have contact times ranging from 3-10 minutes. By having a short dwell time, cleaning procedures are shortened, saving valuable time and money. Not only does TK60 have a short contact time, but it can also be used on multiple surfaces including counter tops, flooring, and different types of metals; making it a very versatile disinfectant. TK60 is also safe on food contact surfaces and can be used as a sporicidal, which adds to TK60's versatility. Since TK60 has nonhazardous ingredients, it is generally not harmful to people, releases no volatile organic compounds into the air, improves air quality, decreases chemical related injuries, and is environmentally friendly.

Alongside TK60, is R-Water's general purpose cleaner, FC+,that can easily replace most other cleaners based on its versatility. Not only can FC+ be used on hard surfaces, it can also be used on carpets, upholstery, and virtually on any material.

Both R-Water's disinfectant and cleaner are conveniently made, RTU (ready-to-use,) in their TC-RU wall-mounted technology. The TC-RU utilizes the chemistry of electrolyzed water. To simply make their solutions on-site, all you need is pure salt, water, and electricity.

TESTING AND COLLABORATION

Microchem Laboratory helped R-Water bring this innovative product and disinfectant to market by assisting with careful laboratory testing. Microchem scientists helped R-Water determine different types of screen testing for TK60. By doing so, R-Water obtained valuable information about their disinfectant. The types of screen testing performed at the lab included germicidal spray test, germicidal and detergent sanitizing action of disinfectants, and a suspension time kill test.

Once the different screen testing was complete, the next process was to perform various GLP studies to substantiate efficacy claims. Per EPA rules, R-Water's device is classified as a pesticide device. Therefore, the company has latitude to carry out testing as it sees fit. Nevertheless, Microchem guided R-Water to test according to EPA's performance criteria for healthcare disinfectant claims, so the TK60's efficacy could not be questioned. Microchem performed various GLP tests, such as the AOAC germicidal spray test, in compliance with EPA requirements to help R-Water meet all performance criteria necessary for healthcare disinfectant claims. Their TK60 solution passed the equivalent tests for EPA-registered, hospital use disinfectants by achieving "disinfection" or total kill on test surfaces in 60 seconds.

With Microchem's guidance and support, R-Water successfully obtained their healthcare disinfectant claim and the product is now on the market. We continue to support and guide R-Water in their products even after all testing has been completed and furthermore, have provided them with accurate and reliable information about their healthcare grade disinfectant.

Lab reports conducted by our EPA registered laboratory, Microchem Labs, are downloadable from R-Water's website. For more information email Rayne Guest at rayne@r-water.com and visit www.r-water.com ▼

The Framework

UH Getting Second Health and Biomedical Sciences Building

Facility will be New Home to College of Pharmacy and House a Primary Care Center

The University of Houston is getting a second Health and Biomedical Sciences Building (HBSB2). The new nine-story, 300,000-square-foot facility is the next phase of the development of UH's biomedical district. While construction is already under way, a ceremonial groundbreaking will take place 10 a.m. Monday, Feb. 29.

HBSB2 will be the new home of the UH College of Pharmacy, unifying faculty and students currently housed in the Texas Medical Center and Science and Research 2 buildings. This consolidation will help integrate teaching, research and clinical programs, as well as provide a state-of-the-art infrastructure needed to enhance the delivery of new models of teaching and patient care. It also will promote faculty collaboration and increase research funding, as well as greatly expand the capacity to graduate highly trained pharmacy professionals and conduct basic, clinical and translational research.

Located in the southeast quadrant of campus, in what will become known as the biomedical district, the new building will be connected to other surrounding health science buildings – current and future – via four of its floors. Currently, this includes the Health and Biomedical Sciences Building 1 (HBSB1), J. Davis Armistead College of Optometry building and Campus Recreation and Wellness Center. Shepley Bulfinch, the architectural firm that completed HBSB1 in 2013, is the architect of HBSB2.

With a project budget of $145 million, HBSB2 will be home to specialized research and teaching labs, faculty and staff offices, an expanded health sciences library and a mix of teaching spaces, including large auditoriums and smaller learning spaces for group and individual study.

Another important component of HBSB2 will be an integrated health care clinic to serve faculty, student, staff and the surrounding community. The clinic will be made possible by partnering with a federally qualified health center (FQHC) that will have primary care, OB-GYN, family practice and pediatric physicians.

WHAT:

Groundbreaking Ceremony for New Health and Biomedical Sciences Building at UH

WHEN:

10 a.m. Monday, Feb. 29

WHERE:

Future site of Health and Biomedical Sciences Building 2 at northeast corner

Wheeler Avenue between Spur 5 and Calhoun Road behind the College of Optometry

Complimentary parking available in Lot 2A and Welcome Center Garage

WHO:

Speakers will include UH President Renu Khator, UH College of Pharmacy Dean Lamar Pritchard and donor David Sparks, the chairman and majority owner of the Professional Compounding Centers of America, which gave a $500,000 gift to name the compounding sterile products laboratory in HBSB2.▼

We pledge to help build your business.

Equipment Loans as low as 3.95% up to 60 months

Member FDIC

3.95% fixed rate for new equipment for up to 60 months. Used equipment eligible for 4.95% fixed rate for up to 48 months. Some restrictions may apply based upon the make and model of equipment purchased. Subject to credit approval. Rates and financing are limited to equipment model years 2008 or newer and are subject to change without notice. LIMITED TIME OFFER.

We're dedicated to boosting your bottom line. So now for a LIMITED TIME, we're offering tremendous financing rates for the medical equipment you need to keep things moving onward and upward.

AllegianceBank

We Practice What We Pledge.

www.AllegianceBank.com/Med

Call 281 894 3200

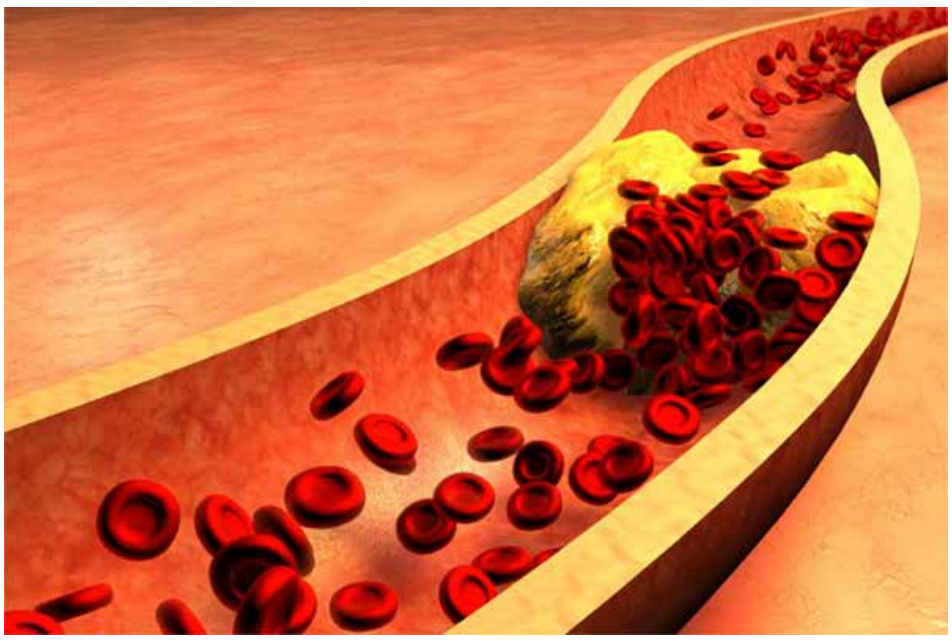
Nutrition Corner

SOLUBLE FIBER

TOP FIVE FOODS TO LOWER LDL CHOLESTEROL

By Denise Hernandez, MS, RD, LD
Houston Medical Times

Heart disease is the number 1 killer in the United States. One risk factor for heart disease is high cholesterol, particularly LDL cholesterol. A nutrient that has shown to be beneficial in lowering LDL cholesterol is soluble fiber.



Soluble fiber may help lower LDL cholesterol by playing a role in the production of short-chain fatty acids (SCFAs). SCFA's have been linked to low blood cholesterol levels. This works because soluble fibers are prebiotic, which means they serve as food for the beneficial bacteria in the human gut. This type of fiber is fermented by bacteria in the colon, which in turn produces gases and SCFAs.

In order to reap the benefits offered by soluble fiber, you need to consume 3 grams per day. Combine this with other dietary fibers and a diet low in saturated fat and cholesterol, and you've made your diet cardio-protective.

The best dietary sources of soluble fiber include the following:

1. Beans: One cup of black beans has 4.8 g of soluble fiber, while Navy beans have 4.4 g and light-red kidney beans have 4 g. All beans are good choices.
2. Oats: A bowl of oatmeal made from 3/4 cup of dry oats contains 3 g of soluble fiber.
3. Vegetables: Brussels sprouts contain 2 g per 1/2 cup. Sweet potatoes have 1.8 g. Asparagus has 1.7 g.
4. Fruit: Oranges contain 1.8 g of soluble fiber. Apples provide 5.5 g and pears provide 6 g.
5. Nuts/Seeds: Flaxseeds have 1.1 g per tablespoon, while chia seeds have 2 g per tablespoon. One tablespoon of peanut butter offers 0.3 g of soluble fiber ▼

Types of soluble Fiber

TYPE	SOURCES
Beta-glucan	Grains (oats, rye, barley)
Pectin (sugar acids)	Fruits, vegetables, legumes, sugar beets
Natural gums	Seeds (guar, locust), trees (gum acacia), seaweed (carrageenan), microbes (xanthum gum)
Inulin	Chicory, onions, wheat, Jerusalem artichokes

Nora's Home Board of Directors Elects Transplant Patient Michael Trevino

Nora's Home, an official member institution of the Texas Medical Center, recently elected Michael Trevino as a member of its board of directors. Like his fellow board members, Trevino has direct insight into the unique challenges transplant patients face on a day-to-day basis. Trevino was personally affected by the mission at Nora's Home after a lengthy battle against hepatitis C contracted from his service in Vietnam. In November 2014, he received the gift of life and became a fortunate liver transplant recipient.

"I was exceedingly blessed to have a supportive family and a network of friends in Houston," said Trevino. "People who travel to Nora's Home from all over the nation find that same support they need during critical health conditions. There couldn't be a better time for me to join the board of directors at Nora's Home because it's about to launch an expansion of facilities and services; I want to help."

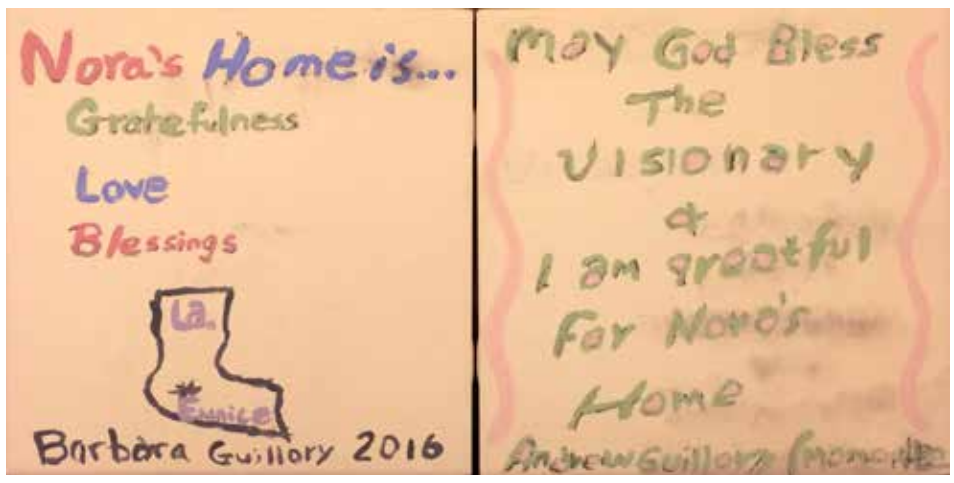
Trevino serves as the Managing Director of Trevino & Company, where he specializes in public-private partnerships, business-to-business development, public and government affairs and corporate communications. Trevino has more than 30 years of experience in government relations and corporate communications work, of which 24 were supporting all aspects of the oil and natural gas industry's domestic and international operations at the federal, state and local level.

Trevino serves on the advisory boards of the Houston Arts Alliance, Kellogg National Fellowship Alliance, the Mickey Leland Kibbutzim Foundation and the Houston BARC Foundation.

NORA'S HOME
FOR TRANSPLANT PATIENTS AND THEIR FAMILIES

About Nora's Home

Opened in 2013 as the first transplant hospitality home in the Gulf Coast region, Nora's Home welcomes patients and their families at any stage of the transplant journey. The hospitality home aims to ease burdens many patients face by helping reduce the immense expense and stress incurred while undergoing transplant care by providing affordable lodging in a loving, home-like environment. Located at 8300 El Rio Street in Houston near the Texas Medical Center, the self-supporting facility includes 16 private bedrooms and baths, a fully-equipped kitchen, community room, meditation room, education center, and provides free shuttle services to and from the medical center. For more information, visit www.norashome.org, call 832-831-3720 or follow us on Facebook, Twitter and YouTube. ▼



MARIJUANA

Continued from page 1

occurring compound in the brain, the exact mode of anti-seizure action of CBD is unclear. "It is critical to know how CBD controls seizures, so pharmaceutical companies can design novel synthetic compounds for epilepsy that could surpass the hurdles of mixed CBD extracts," said Reddy, who directs an epilepsy research lab at Texas A&M. These compounds might provide the benefits without some of the risks—or the legal issues—associated with the marijuana plant.

A standard manufacturing process and clinical trials might help answer some of these questions, but conducting one isn't easy, and there are currently only 19 clinical trials going on to test the use of cannabinoids for epilepsy. For one thing, cannabis is still listed as a Schedule I substance by the federal government, meaning gaining permission to use it in research on human participants is extremely difficult.

Still, change is occurring at the state level. Recreational marijuana use is legal for adults in four states (Alaska, Colorado, Oregon and Washington) and in 23 states and Washington, DC, medical marijuana is allowed. Texas, in a law passed during the last legislative session in 2015, legalized low-THC cannabis oils for people with intractable epilepsy while still prohibiting medical marijuana more broadly.

A new study at the University of Colorado Anschutz Medical Campus is enrolling Dravet epilepsy patients who have tried Charlotte's Web, a specific strain of medical marijuana that is low in THC and high in CBD. The researchers will compare the genetics of those who have seen seizure activity decreased dramatically (at least 50 percent) in response to the drug versus those who did not. Although this research could yield useful information about how CBD and genetic factors interact in a Dravet population, it is not the gold standard of scientific drug trials: the randomized, placebo-controlled, double-blinded clinical trial in which patients were randomly assigned to either CBD or a placebo.

As for experts like Reddy, who is a Texas board-certified pharmacist, most are taking a cautious wait-and-see approach.

The American Epilepsy Society (AES) has released a statement on the use of medical marijuana in the treatment of epilepsy stating that due to the lack of data, no conclusion can be drawn at present.

The Epilepsy Foundation doesn't specifically discourage cannabis use, but urges anyone exploring treatment for epilepsy to work with their treating physician to make the best decisions for their own care and to follow applicable laws.

"Despite all of the controversy about medical marijuana as a potential therapy for epilepsy," Reddy said, "most people agree that what we need is greater rigorous scientific study into cannabinoids to prove or disprove their safety and efficacy." ▼

Mental Health

Continued from page 3

"Adolescence is a time of identity formation where, for the first time, teens possess the cognitive skills to start putting together their identity," Sharp said. "To be there when kids are building themselves from the bottom up is a real privilege. We can help them tweak that picture of who they are, which will then help them later on in life to be able to withstand adversities and have that resilience to not fall apart when things get tough."

She uses the movie "Inside Out" as an example to illustrate how personalities are built. She says each new experience builds a new structure and becomes part of who you are, but when stress happens, those structures are threatened and get colored by emotions. If it's something really sad, the teen could build a whole sad structure, but if a counselor can help modify this, a different structure can be built. She says that's where their clinic comes in.

"We see it as a window of opportunity to catch a teen and not let them fall, because once they fall, you have a whole bunch of problems on your hands, such as addiction," Sharp said. "Adolescents' brains enjoy pleasure and risk more, so if there's not a net to catch them as they go through this stressful period, they may fall and then you have extra problems by 15 and 16 that you didn't even think of when they were 11."

Sharp says UH-ADAPT will be seeing a broad spectrum of adolescents, offering them three types of services. Clients will be offered comprehensive assessments, individual therapy and group therapy.

The one-day diagnostic/relational assessments will give adolescents and their families a comprehensive, integrated psychological report that covers such things as cognitive functioning, symptoms, family functioning and the teen's aspect of resilience that gauges how good they are at emotion regulations and social relationships. This written report will not only help the parent understand what's going on, but also can be given to other mental health providers for further treatment. The individual therapy comes with a mini standardized assessment to help families make decisions of what to do next. The treatment for each adolescent is specifically tailored to their individual needs and strengths. The group therapy, which is planned to start in March, focuses on gaining a better understanding of difficulties with emotional intensity, as well as developing skills to better manage strong emotions. Sessions last 90 minutes, with 5-10 participants, over the course of 18 weeks. Parents are encouraged to participate in a parent-focused group that runs at the same time to help them gain insight into the therapy their children are receiving. ▼

Legal Health

Continued from page 6

3. Addition of Quantification to Standard for Identification

The 60-day time frame for returning an overpayment begins when the overpayment is identified or after the potential overpayment has been "quantified." In the Final Rule, CMS specifically recognized that statistical sampling and extrapolation are appropriate components of a provider's reasonable diligence in investigating an overpayment and can serve as an appropriate way to calculate an overpayment amount, stating that "[p]art of conducting reasonable diligence is conducting an appropriate audit to determine if an overpayment exists and to quantify it." The

see Legal Health page 21

Legal Health

Continued from page 20

inclusion of "quantified" is a significant improvement from the proposed rule, which suggested imposing no such requirement. Notably, on August 3, 2015, in United States ex rel. Kane v. Health First, Inc., the U.S. District Court for the Southern District of New York, in issuing the only reported opinion on the False Claims Act's reversed false claim overpayment provision, determined that the 60-day clock for repaying "identified" overpayments began ticking "when a provider is put on notice of a potential overpayment, rather than the moment when an overpayment is conclusively ascertained." That ruling, which was perceived as a significant victory by government enforcers and qui tam relators, has been tempered by the provision in the Final Rule that quantification be part of "identification."

4. Tolling the 60-Day Rule

The Final Rule further allows providers and suppliers who report overpayments through CMS's Voluntary Self-Referral Disclosure Protocol ("SRDP") and the OIG Self-Disclosure Protocol ("SDP") on or after the Effective Date, to toll the 60-day deadline for returning overpayments. The deadline will be tolled while the provider or supplier is negotiating a potential settlement under these protocols. CMS declined, however, to extend this treatment to self-disclosing entities outside the SRDP and SDP.

5. Significance of the Effective Date

The Final Rule is not retroactive. However, the regulatory overpayment requirements extend to overpayments received before the Effective Date, even though the obligation to report and return such overpayments under the Final Rule will not be begin until the Effective Date. CMS notes that providers and suppliers who attempted to comply with the statutory overpayment requirements in the absence of regulatory interpretation "may rely on their good faith and reasonable interpretation" of the statute.

Key Takeaways for Providers and Suppliers:

a. You must have both a proactive compliance program to monitor the receipt of overpayments and a process to investigate potential overpayments in a timely manner.

b. You should prioritize overpayment investigations; completing such investigations will require the devotion of resources and time.

c. You should maintain records that accurately and fully document your investigation efforts to demonstrate that you acted in a diligent and timely manner.

d. You should be able to demonstrate that you have devoted appropriate attention, time, and resources—including both internal and external resources, when appropriate—to resolving whether an overpayment exists. This includes demonstrating that any proactive and investigative overpayment determination activities should be conducted by "qualified individuals."

e. You should retain your refund documentation in the event that a Medicare contractor or other Medicare authority conducts an audit of such claims at a later time.

f. You should use reasonable diligence and follow-up audits if you identify a single overpaid claim to determine whether there are more overpayments on the same issue.

g. You may use claims adjustment, credit balance, or self-reported refund process, or another appropriate process, to report and return overpayments. You can either submit a check when reporting the overpayment or request a voluntary offset from the contractor.

h. You should anticipate that in the context of False Claims Act cases, both the government and relator's counsel will promote a broad definition of the term "reasonable diligence". Moreover, you can expect to face challenges when you argue that there are "extraordinary circumstances" justifying additional time to determine whether an overpayment exists, and you should be prepared to challenge vigorously, where appropriate, any effort made to limit your investigations to six months simply because that time frame was identified in the preamble to the Final Rule. ▼

Oncology Research

Continued from page 7

IL-2), biochemotherapy (Cisplatin, Vinblastine and Dacarbazine combine with IFN-α and IL-2), monoclonal antibodies to PD-1 and CTLA-4 inhibition (Pembrolizumab, Nivolumab and Ipilimumab), signal transduction inhibitors (Vemurafenib, Dabrafenib and Trametinib), oncolytic viruses, vaccination with autologous dendritic cells pulsed with multiple tumor antigens such, adoptive cell transfer (ACT), transgenic TCR, chimeric antigen receptor (CART cells) and some angiogenesis inhibitors have been tried. Efforts to combine molecularly targeted targets and immunotherapy strategy have already begun. The above-mentioned approaches can mediate complete tumor regression in a proportion of patients, however many patients do not respond with this strategies. This effect could be explained by the fact that the tumor microenvironment (TME) can inhibit immune responses leading a suboptimal responses. The TME plays a major role in melanoma development and progression but the accurate function of each component and how they are relating to one another remains unknown. A range of infiltrating immune cells such leukocytes, fibroblasts and endothelial cells (blood and lymphatic) provide pivotal functions in sustaining activating mutations in oncogenes, cell proliferation, promoting survival, evading growth factors, inducing angiogenesis, enabling replicative immortality and activating invasion and metastasis. Critical evidences that makes the microenvironment essential to melanoma initiation, progression and metastasis and how the immunotherapy can not only modulate the TME but also used as promising tool to combat cancer are currently under investigation. ▼

Healthy Heart

Continued from page 8

tests done every year.) The exam will also screen for other health problems that are unique to women including mammograms for breast cancer, pap smears for cervical cancer, prenatal care, bone-mass measurements for osteoporosis; plus "gender-neutral" screenings and services such as colon cancer screening, obesity screening and counseling, and shots to prevent flu, tetanus, and pneumonia.

The American Heart Association estimates that 80% of all cardiovascular disease may be preventable, and it's always better to prevent it than treat it after it becomes life threatening. You can expect your Well-Woman Visit to include tests such as cholesterol screening, body mass index, blood pressure, and other evaluations specifically designed to help assess your heart health. It's a great way to help lower your risk of heart attack or stroke, and give you an added boost for your peace of mind.

Why is the Well-Woman Visit something you should schedule every year? There are lots of good reasons. If you go several years between physical exams, you run the risk of a health problem going undetected and causing your body far more damage than if you catch it early. Annual physical exams also strengthen the relationship between you and your regular physician, helping your doctor be better informed on what's going on with your health and in your personal life.

Take the time to educate yourself, and other women, by learning these three tips about heart disease and healthy living before it's too late.

1. **Know your risk, no matter your age**

No matter how small your health issues may seem, find out if you're at risk, and what you should do to reduce it.

2. **Get regular checkups**

The importance of this cannot be stressed enough. Don't wait until you feel symptoms. Make getting regular checkups an annual priority.

3. **Make your lifestyle a heart-healthy one**

Making healthy changes in your life can reduce your risk for heart disease by as much as 80 percent. That means getting at least 40 minutes of physical activity each day. It doesn't have to be strenuous – walking, swimming, gardening and house cleaning all count. It also means eating well and including more fruits, vegetables, whole grains and fish in your diet, and cutting back on foods high in fat, cholesterol and sugar. A heart healthy lifestyle also means learning to relax. So make it a priority to carve out plenty of time for yourself.

The more a woman knows about heart disease, the better chance she has of beating it. Learn more about the American Heart Association's Go Red For Movement and find out how you can be involved in local efforts in Houston. Find us online at: houstongored.heart.org or on Twitter and Instagram @ahahouston #GoRedHouston. Or call us at: 832-918-4039 ▼

Houston Medical Times
Bringing Healthcare News to the Forefront

Published by Texas Healthcare Media Group Inc.

Editor
Sharon Pennington

Director of Media Sales
Richard W DeLaRosa

Creative Director
Lorenzo Morales

Distribution
Vincent DeLaRosa

Accounting
Liz Thachar

Writers
Jorge Augusto Borin Scutti, PhD
Denise Hernandez MS,RD,LD

Office: 713-885-3808
Fax: 281-316-9403

For Advertising
advertising@medicaltimesnews.com

Editor
editor@medicaltimesnews.com

Houston Medical Times is Published by Texas Healthcare Media Group, Inc. All content in this publication is copyrighted by Texas Healthcare Media Group, and should not be reproduced in part or at whole without written consent from the Editor. Houston Medical Times reserves the right to edit all submissions and assumes no responsibility for solicited or unsolicited manuscripts. All submissions sent to Houston Medical Times are considered property and are to distribute for publication and copyright purposes. Houston Medical Times is published every month

P.O. Box 57430
Webster, TX 77598-7430