PANHANDLE HEALTH

A QUARTERLY PUBLICATION OF THE POTTER-RANDALL COUNTY MEDICAL SOCIETY

WINTER 2021 | VOL 32 | NO. 1

Pharmacy Research, Education & Practice

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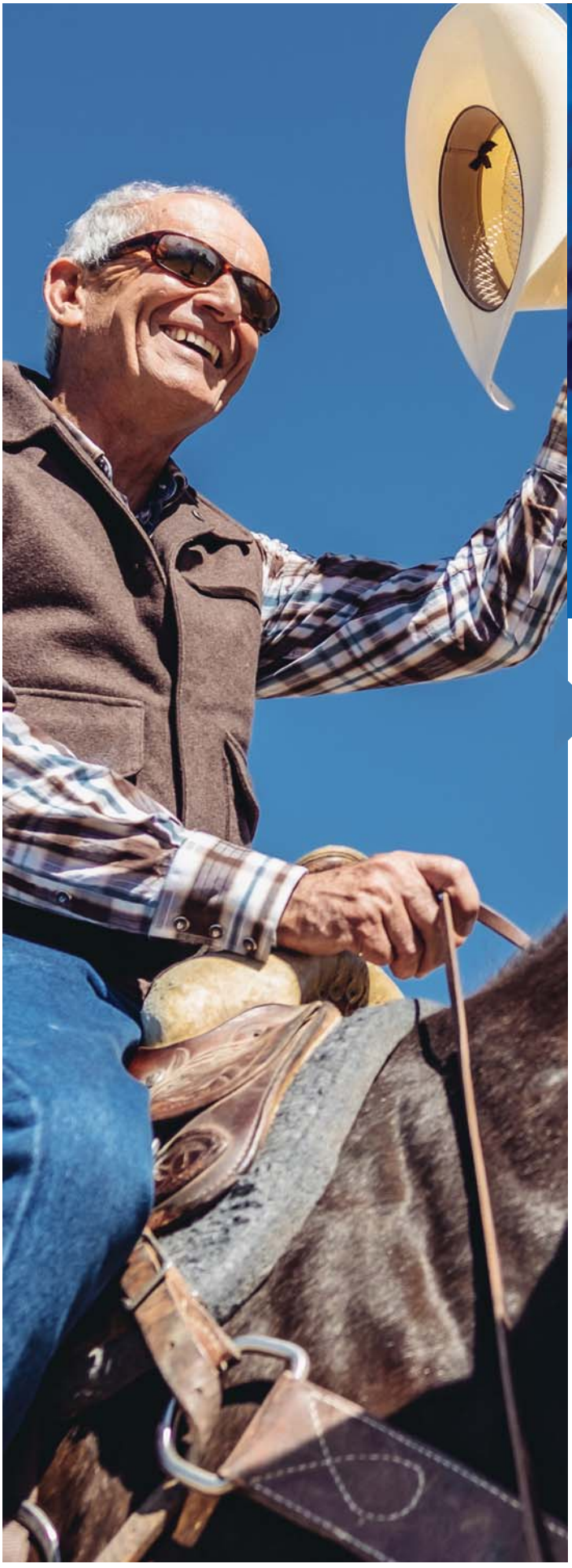

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President's Message

by Neil Veggeberg, MD

We are now coming around for our 3rd year of COVID. I am finishing my second year as President, during which COVID has been front and center. I did not think it was going to last this long, but we now have good vaccines and are developing effective medications to treat the acute illness. If we can get back to a place of near normalcy, it gives us an opportunity to look toward the future needs of COVID survivors.

One of my mentors at Baylor College of Medicine was Dr Carlos Vallbona. He was a 3rd year pediatric resident in 1955 when he began working at the Southwestern Poliomyelitis Respiratory Center in Houston, later to become the Texas Institute for Rehabilitation and Research (TIRR). He originally worked with the paralytic victims of polio. The polio epidemic had become especially fierce during the early 50's. Eddie Cantor, a comedian in the 30's, proposed that everyone send a dime to FDR to help with research and treatment of the polio epidemic. He used a takeoff on the popular newsreel at that time called the March of Time to call this the March of Dimes. In 1938, Roosevelt set up the National Foundation for Infantile Paralysis in order to help fund research into the treatment and prevention of polio. The crippling effects of polio were widespread and affected young, healthy people disproportionately. The March of Dimes played a pivotal role in the acceptance of the vaccine. There were campaigns supporting the use of vaccinations. Debbie Reynolds and Elvis Presley even joined in on the cause. Donald Anderson was reputed to be the first poster child. It was easy to garner sympathy with his case.

The Salk vaccine was first released in 1955. One of the companies that produced the vaccine did not fully inactivate the virus, and this led to the exposure of 200,000 children to live polio. 40,000 got the disease, 200 became partially paralyzed and 10 died. Eventually, the reason for failure to deactivate the virus was found and the vaccination program restarted.

In 1960 Dr. Albert Sabin's oral vaccine was approved. In this case he used a live attenuated virus. Patients developed antibodies in the GI tract as well as the circulatory system, providing better herd immunity. After passing through the GI tract, some of the poliovirus would revert to the live form and cause a mild form of the disease. Nonetheless, after the vaccination program began, cases of paralytic polio went from a high of over 50,000 cases in 1952 to 900 in 1962. The difference in acceptance between this vaccine program and the COVID vaccine was, in my opinion, that a well-respected organization with significant marketing techniques was able to make a case. The paralyzing effect of polio created such graphic effects that it made the disease seem more real. The way polio indiscriminately went after people regardless of their health took away the notion that you were somehow protected if you were healthy.

Since there were so few cases in 1962, the Southwest Polio Center began to change its mission. Dr. Vallbona continued his interest in polio; over a period of time, he recognized that survivors began having new and recurrent symptoms. Much of the original repair process of the nerves began to unravel as the body experienced the usual forms of aging. This was described as post-polio syndrome.

There is concern that the survivors of COVID may also have long term, yet to be fully described, symptoms. In the rehab component of long COVID, we work on strengthening and endurance. The long COVID cases we have seen have significant problems with respiratory and cardiac systems, as well as fluid balance, all of which are critical in order maximize performance. Time will tell what other complications we can expect.

Our Next Issue Of *Panhandle Health*

Features:

Updates in Oncology

Guest Editor's Message:
Texas Tech School of Pharmacy after 25 Years

by Quentin Smith, PhD

Texas Tech School of Pharmacy arose as a "special project" of Amarillo community leaders in the early 1990's. The ups and downs of the agriculture and oil/gas industries prompted thoughtful leaders to seek economic diversification and greater stability from other sources. The biomedical industry was high on the list, given its importance in meeting local health needs and travel distances for Panhandle citizens to healthcare centers elsewhere in the state. Texas Tech University Health Sciences Center already held a strong presence in Amarillo through the combined operations provided by the regional offices of the Schools of Medicine and Allied Health. Multiple steps were necessary to create a new pharmacy school in Amarillo with all the required faculty, teaching facilities, and infrastructure to meet the requirements of a state-of-the art doctoral program in the United States. The new school was unique in that no publicly funded pharmacy school had opened in the United State for 40 years. To move this forward, community leaders raised over $12 million to provide the building and hire a visionary leader as well pioneering faculty willing to undertake such a project. They also had to gain approval from the Texas Higher Education Coordinating Board as well as secure legislation supporting the new program by the Texas state legislature. Primary credit for the project went to a forward-thinking group of community leaders including Teel Bivins and Jerry Hodge. Years later, Hodge was recognized for his landmark activity on this project when the Texas Tech Board of Regents renamed the School the "Jerry H. Hodge School of Pharmacy" in 2019.

Dr. Arthur Nelson was recruited from Idaho State University as the inaugural dean. To him fell the incredible responsibility of planning the School, gaining approval for the curriculum, and ushering in the first classes of students. The faculty and leadership of the School sensed tremendous pride from the community that saw this as "their School." Equally, the School's faculty reflected that pride by creating a flagship of modern pharmacy education on the plains of Texas. My goal in this article is to convey the breadth and nature of the scientific and practice areas that make up the School. Our quarter century of achievement provides a lot for which the Panhandle of Texas can be very proud.

The first step, in such an effort, is to explain the differing fields in pharmacy that make up the core structure of the School. Pharmacy as a field relating to the identification and preparation of mostly medicinal agents for the treatment of human disease goes back thousands of years. One well-known example was the use of willow tree bark for the treatment of pain and inflammation. These trees were later found to have high levels of "salicylates" (from the Latin *salix,* for willow) which had anti-inflammatory properties. However, they also were very hard on the stomach, leading Felix Hoffmann, working at the Bayer company in Germany, to synthesize acetylsalicylic acid (aspirin) in 1897, which is used for the same purpose to this day. The science of drug discovery and development has blossomed over the last 100 years, leading to the modern fields of medicinal chemistry, pharmaceutics, and pharmacology as well as the clinical practice of pharmacy.

The critical "conceptual" element behind almost all of these fields was receptor theory. Receptors are the biological elements within the body where drugs bind and initiate their effects. In my lifetime, receptors have evolved well beyond their initial beginnings as conceptual elements determined mostly by structure-activity relationships. In the last 40 years, receptors have been isolated and identified *in vivo*, mapped to certain gene elements that determine their structure, visualized in 3D, and formulated with computer modeling so that the best drug agents can be designed *de novo* just from knowledge of the receptor. One of the breakthroughs in the 1970s was the discovery of endogenous opioids in humans and their binding to the "opiate receptor." Since then, molecular biology has catalyzed the identification and characterization of literally hundreds –to-thousands of new receptors in the body, expanding the scope of "drugable" sites for the treatment of disease by more than an order of magnitude. Further, receptor biology has been linked to a matching explosion of knowledge relating to how diseases arise in the body from genetic differences and how the environment, pathogens (including viruses!) and behavior combine with genetics to impact human health over one's lifetime.

There are four or five scientific areas that are the pillars of Pharmacy and are the essence of our field. The core science of this area of study is Pharmacology, which covers drug action. It similarly is a pillar in Medicine. I was trained in a Pharmacology Department that was shared between the Schools of Medicine and Pharmacy. Aligned with Pharmacology is Pharmaceutics, which relates to the preparation of safe and effective dosage forms to deliver an agent orally or by other means to the site of action. Many of the essentials of Pharmaceutics relate to physical chem-

| *continued on page 8*

istry and the effects of solvent, pH, ions and organic matrix on drug solubility and stability. A major problem at the turn of the last century (2000) was the heightened clinical failure rate of many new drug agents coming out of computerized mass screening efforts. Closer examination revealed that the drugs were failing due to problems in drug handling by the body (i.e., drug absorption, distribution and elimination) or from heightened adverse reactions. Follow-up showed that the agents selected from high affinity mass screening tended to be extremely "lipophilic" (i.e. fat soluble) which led them to have poor handling by the body. From this evolved the concept of good "drug-like" structural properties that favor reasonable absorption, biodistribution and elimination. Pharmacokinetics is the name of the field that studies drug absorption (usually from the GI tract) and how long drugs persist in the body before undergoing elimination, either by excretion or metabolism.

For a single disease, there can be multiple companies in the pharmaceutical industry competing to produce the most attractive clinical agent for treatment. While each agent acts at the same receptor, they can each be very distinct. A series of drugs that bind with similar affinity to the same receptor may differ greatly in rate of elimination by the liver or kidney, access within cell or tissue due to influx or efflux transporters, interaction at other receptors for alternate or competing effects, or ease of administration. Furthermore, critical genetic differences (linked to genetic changes in drug metabolizing enzymes) can cause individuals to vary tenfold or more in metabolic rates for drugs. The future may allow us to better target therapeutic action by taking into account genetic differences, as has been shown in several examples in cancer therapy.

And finally, there are Medicinal Chemistry and Molecular Biology which provide the tools and reactions that generate new drug agents. These are the science pathways that lead to the formation of transformative healing agents. Paul Ehrlich created the first of these agents around the turn of the previous century (1900) with "606," or Salvarsan (known as 606 because it was the 606th compound tested by Ehrlich for activity). 606 was the first chemically synthesized and developed therapeutic agent. Since then, over 8,000 such agents have been synthesized and developed as prescription drugs to treat human disease. Each differs from others in small ways. It is the science of Pharmacy to know the key agents and how to use them to best effect. Whereas a medical practitioner may use 200-500 therapeutic agents routinely, the clinical pharmacist needs to know several times more, particularly where science has validated differences that are important for their rational application. It takes most students ~2.5 years to master the basic sciences of Pharmacy. The last 1.5 years are spent further growing their applied clinical knowledge and

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Editorial Policy and Information for Authors

Purpose *Panhandle Health* strives to promote the health and welfare of the residents of Amarillo and the Texas Panhandle through the publication of practical informative papers on topics of general interest to most physicians while maintaining editorial integrity and newsworthiness.

Spectrum *The Journal* seeks a wide range of review articles and original observations addressing clinical and non-clinical, social and public health, aspects as they relate to the advancement of the state of health in the Texas Panhandle. Pertinent letters to the editor, news submissions, and obituaries listings are accepted pending editorial review. The Editorial Board accepts or rejects submissions based on merit, appropriateness, and space availability.

Submission process Material should be e-mailed to the editor at prcms@suddenlinkmail.com or mail a hard copy to Cindy Barnard, PRCMS, 1721 Hagy, Amarillo, TX 79106. A recent photograph of the author (optional) and a curriculum vitae or a biographical summary are also to be submitted.

Conflict of Interest Authors must disclose any conflict of interest that may exist in relation to their submissions.

Journal Articles Manuscripts should be double-spaced with ample margins. Text should be narrative with complete sentences and logical subheadings. The word count accepted is generally 1200 to 1500 words. Review articles and original contributions should be accompanied by an abstract of no more than 150 words.

References References to scientific publications should be listed in numerical order at the end of the article with reference numbers placed in parentheses at appropriate points in text. The minimum acceptable data include:

Journals: Authors, article title, journal, year volume, issue number, inclusive pages.

Books: Author, title, place of publication, publisher, year.

Web sites: URL of the site and the date the information was accessed.

Other sources: Enough information must be included so that the source can be identified and retrieved. If not possible, the information for source should be included parenthetically in the text.

Illustrations Illustrations should be black and white only with complete-sentence legend.

Previously Published Material Short verbatim quotations in the text may be used without permission but should be quoted exactly with source credited. Otherwise, permission should be obtained in writing from the publishers and authors for publishing extensive textual material that was previously published.

Editing Accepted manuscripts are edited in accordance with the *American Medical Association Manual of Style.*

Letters Letters will be published at the discretion of the editor and editorial board. The length should be within 400 words. References should not exceed five. All letters are subject to editing and abridgment.

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Obituaries Listings of deceased members of PRCMS with highlights of their contributions are published when adequate information is available.

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skills before graduation. In reality, the two areas are intertwined from the first day the students enter school.

The TTUHSC Pharmacy School grew from ~20 faculty at the start of the School (1997) to closer to 80-85 now. Faculty in each of the primary science areas comprise about one-third of the faculty. We have recruited a far larger component of clinical practice faculty who are generally residency-trained and board certified. These faculty members work along with medical teams in hospitals and clinics, not just to perform "drug distribution" but to counsel and advise on therapeutic progress. It has been estimated that approximately three-fourths of patient visits to medical clinics result in the prescription of a medicinal agent. The goal is for the agent to lead to a positive outcome with minimal to no adverse effects. In reality, approximately 2 million people each year are hospitalized as a result of drug adverse reactions. Deaths from these reactions are reported at the level of 100,000 – 200,000 per year.

The objective of the clinical pharmacist is to work as part of the medical team to ensure that therapy proceeds in the appropriate direction and that the best therapeutic agent is selected for the case on hand. Studies have repeatedly found that, when pharmacists are added to the health care team, treatment success rises, adverse effects fall, patient quality of life improves, and total cost to the health care team is reduced. One strength of community pharmacy is the proximity of patients, in that three-fourths of all American are estimated to pass through a pharmacy each week. Both practice elements are valuable in addressing the totality of modern therapy. The goal of the School in both these areas is to be a shining beacon to pharmaceutical science and pharmacy practice across the state.

Within clinical pharmacy, a range of sub areas exists, ranging from community pharmacy, ambulatory care, adult medicine, critical care, pediatric and geriatric pharmacy, and on. Of particular interest in the panhandle of Texas is rural pharmacy and pharmacy by telehealth. In this issue, several authors give glimpses as to how these separate clinical areas function and lead to advances in health. When I started my career in the mid 1970's, most pharmacists worked retail pharmacy or in hospitals, and contact between patient and pharmacist was limited. There were very few clinical pharmacists. In 2020, the number of new clinical pharmacy positions in both Texas and the nation exceeded that of retail pharmacy. We are coming closer to what was dreamed 30 years ago in the founding of the Texas Tech School of Pharmacy. The dream is getting close to a reality.

Performance outcomes are commonly used to assess the quality of training programs across the state. For pharmacy schools, those that are most commonly referenced include: a) pass rate on the national board exam (NAPLEX), b) performance on the national Pharmacy Curriculum Outcomes Assessment (PCOA) exam at the third year of the program, covering training in the first three years before the student transitions to advanced pharmacy practice rotations, c) the percentage of graduates who go on to competitive pharmacy residency training, d) ratio of students to faculty members in the School, and e) the level of extramural grant funding from faculty pushing forward the level of knowledge and discovery of new therapeutic measures. In our school, our scores on most of these measures are close to the top 25th percent of pharmacy schools in the country. A survey (1) published using multiple parameters of performance ranked the School 18th in education and 39th in research with an overall total score of 24th in the nation (out of 143). Although we are in the uppermost quartile of pharmacy schools in the country, we still have a way to go.

Since its inception, our School has graduated over 2,000 Doctors of Pharmacy, with 95% practicing in Texas. We are proud on this strong performance. Our graduates have gone on to lead major pharmacy organizations in the state and to hold important administrative positions in healthcare organizations. It has been an honor for me to serve the School these past 10 years. The Jerry H. Hodge School of Pharmacy at Texas Tech represents the collective effort of the all its members and those in the community who help support us. To you we offer our thanks. We would not have been able to attain what we did without your help and assistance.

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Quentin Smith is Dean of the School of Pharmacy as well as University Distinguished and Murray Professor. After receiving his Ph.D. in pharmacology, he worked for 17 years at the National Institute on Aging prior to coming to Texas Tech in 1997 to help build the School of Pharmacy.

Executive Director's Message

by Cindy Barnard, Executive Director

Texas pharmacy history closely follows the history of American medicine. A Spanish explorer, Cabeza de Vaca, was one of the first Europeans to practice pharmacy AND medicine in Texas. He was captured by Native Americans and made to treat their victims of epidemic diseases. By the late 1600's, El Paso missionaries were dispensing medicine in villages to the sick because physicians only administered to citizens of large communities. Spanish physicians were highly dependent on Native American medicine men as they had extensive knowledge of medicinal plants and herbs. Finally, some physicians decided to make up large amounts of certain medicines and kept them on their shelves in their offices or homes—thus, the term "drug store" was coined.

By the late 1800's, the Texas Pharmaceutical Association was created in Dallas. In 1889, the Texas Pharmacy Law passed, and the UT School of Pharmacy was created as well. In 1907, the first State Board of Pharmacy was established, helping to create consistency in standards in record-keeping and assisting in the control of access to drugs (Texas Health Law). New schools were created, and in 1993, the Texas legislature authorized the first publicly supported pharmacy program in the United States in fifty years, specifying that it be located in Amarillo. No state funds were allowed so the Amarillo Economic Development Corporation, the Harrington Regional Medical Center, and private donors contributed to the goal of 13 million (reached in 1995). Sixty-five students were in the founding class in August of 1996! In 1998, Lubbock's campus opened; in 1999, the Dallas-Fort Worth Regional Campus opened in two locations. Abilene followed in 2004. TTUHSC Jerry H. Hodge School of Pharmacy has become nationally known as one of the best programs for "practice-ready pharmacists" in the county.

It has been said that the history of pharmacy in the United States is a tale of new pharmaceutical combinations from Europeans as well as Native Americans. The Philadelphia College of Pharmacy (PCP) was modelled after a French pharmacy and was finally organized in 1821 with 68 pharmacists signing its constitution. Pharmacists found their way into the profession through apprenticeship, training under established pharmacists. The American Pharmaceutical Association followed the founding of the PCP, just as the Texas Pharmacy Law followed the Texas Pharmaceutical Association's founding. William Proctor, Jr. graduated from the PCP and then taught there; he was so influential that he is now considered the "Father of American Pharmacy." Major Eastern cities followed Philadelphia's lead, and finally in the 1860's, pharmacists arrived on the West Coast (California). Harry and Robert Borun founded Borun Brothers, LA pharmaceutical wholesalers, and that store became the model for our modern "chain stores", selling "drugs, sundries and household wares".

The Affordable Care Act identified "millions of newly insured patients needing primary care". This shortage allowed pharmacists to "expand their scope of practice". In many states, the pharmacists have been granted "the ability to perform certain tasks under a collaborative practice agreement (CPA) with a physician". For example, this could include assessing a patient, prescribing medications, ordering lab tests, etc. Inside many clinics are prescribing pharmacists. "The role of pharmacists has come full circle from colonial times, but today's highly auto-

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If you, or a physician you know, are struggling with addiction, depression or burnout and are unsure what to do or whom to contact, the Potter-Randall County Medical Society is here to help. We offer face-to-face confidential sessions with the PRCMS Physician Health and Wellness Committee, made up of your physician peers who know and understand recovery. Please don't struggle alone when help is a phone call or an email away. Whether you are calling for yourself, your practice partner, or as a family member of a physician, contact Cindy Barnard, PRCMS Executive Director, at 806-355-6854 or prcms@suddenlinkmail.com. Membership in PRCMS is not required.

mated and computerized pharmacies are quite different from yesteryear's nostalgic apothecaries. Pharmacists now can focus on disease and chronic condition management, medication management, health and wellness, and other services that help improve patients' quality of life." (Rosanna Sutherby, PharmD)

As the year ends, I want to thank the 2021 Board of Directors for their service and dedication to our Society. Under the leadership of our President, Dr. Neal Veggeberg, and despite the continuation of Covid, your Society has enjoyed an exceptional year. The following physicians deserve an enormous thank you for their support.

Executive Committee 2021: Neil Veggeberg MD, President; Evelyn Sbar MD, President-Elect, Nicole Lopez MD, Secretary/Treasurer

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Another thank you goes to the 2021 *Panhandle Health* Editorial Board led by Steve Urban MD. Other Editorial Board members are Steve Urban MD (Copy Editor), Rouzbeh Kordestani MD, Paul Tullar MD, Zane Grodman MD, Skye McLaurin-Jiang MD, Sheryl Williams MD, Jeffery Hanrahan MD, Marge Weis PhD

A final thank you goes to our 2021 "Circle of Friends" for their continued financial support and generosity. Their commitment is absolutely essential to the success of all our events. They are Amarillo National Bank, Baptist Community Services, Neely, Craig & Walton Insurance Agency, Texas Medical Association Insurance Trust, Texas Medical Liability Trust, Happy State Bank, ColorArt-Amarillo, Daryl Curtis, CLU, CHFC, Physicians Financial Partners, Boxwell Brothers Funeral Home, and Leslie Massey, Farmers Insurance Agency.

Their abiding confidence and encouragement continues to fuel us thoughout our journey, and we remain grateful to all of you.

UPCOMING EVENTS 2022

Winter Conference
Jan. 28-29, 2022
Hyatt Regency
Austin, TX

TexMed 2022
Apr. 29-30, 2022
Hilton Americas-Houston
Houston, TX

Message from the Potter-Randall County Medical Alliance

By Tricia Schniederjan, President

It's that time of year when we all reflect and share gratitude. After almost two years of the COVID pandemic, we know that physicians and medical families have done so much for our community. Whether it was directly taking care of patients or helping our community through these times, we are blessed to have a strong and dedicated medical community. We are so thankful for the medical community and look forward to getting everyone back together.

The Alliance hosted a wonderful Fall Social at the Amarillo Country Club this past November. We enjoyed having physician couples together for an evening of drinks and hors d'oeuvres. This event was a success; and we plan to host another couples' social in the spring.

As we get ready for the holiday season and new year, the Medical Alliance and Medical Society will give back to our community with the Hard Hats program. Every December, the Northside Toy Drive hosts an annual event to give toys and gifts for Christmas to kids who wouldn't otherwise get gifts. Hundreds of bikes are given away, and we want to ensure that all kids who receive a bike will be safe with a helmet. The Medical Alliance and Medical Society will be there fitting and providing over 150 bike helmets. If you'd be available to help, we'd love for you to join us! This year it will be held on December 18th. Please email me (tschnied@gmail.com) and let me know. This will be a great volunteer community event in which to get involved and bring joy to kids in our community.

Training a New Generation of Pharmacists: An Overview of the Department of Pharmacy Practice

by Eric J. MacLaughlin, PharmD and Krystal K. Haase, PharmD

A founding pillar of the Texas Tech University Health Sciences Center Jerry H. Hodge School of Pharmacy (SOP) has been innovation and the advancement of pharmacy practice. Once thought of as a profession responsible solely for medication preparation, dispensing, and counseling, the roles of pharmacists today have expanded considerably over the past several decades. Pharmacists administer medications, modify treatments under a protocol, and coach patients to optimize outcomes from drug therapy. Clinically-trained pharmacists are integrated into a variety of healthcare teams to provide clinical pharmacy services, team-based care, and comprehensive medication management (CMM). The TTUHSC Department of Pharmacy Practice has been a leader in innovation, collaboration, and expansion of pharmacist roles since its inception. Below is a brief overview of the department and how we are helping to train the next generations of pharmacists.

The Department of Pharmacy Practice is the largest in the school of pharmacy, with 53 faculty members located across four campuses (Amarillo, Abilene, Lubbock, Dallas/Ft. Worth). Due to its size, diversity, and geography, the department is further organized into five divisions (Adult Medicine, Ambulatory Care, Clinical and Translational Research, Pediatrics and Geriatrics, and Practice Management). Led by a division head and ultimately by the chair, the division structure helps foster communication, practice and research/scholarship collaborations, and faculty mentorship. Practice faculty balance multiple responsibilities, including teaching, maintaining an active practice, conducting clinical/translational research, and engaging in professional and academic service.

Pharmacy practice faculty teach the clinical application and use of drug therapy across the classroom, laboratory, and experiential settings, building on a strong foundation of basic sciences (e.g., the pathophysiology, molecular foundation of drug therapy including medicinal chemistry, pharmacology, pharmacokinetics, pharmacodynamics, etc.). As the "drug therapy experts," our faculty work with physicians and other colleagues to help design, manage, and monitor medication therapy regimens. That requires considering numerous factors such as a patient's medical history, concurrent medications, and social determinants of health (e.g., cost, health literacy, adherence, etc.). Simply put, they help find the right drug, at the right dose, for the right patient.

When the school of pharmacy was founded in the mid-1990s, there was a significant shortage of pharmacists in all practice settings in West Texas, particularly in community and hospital settings. However, this shortage was especially notable in clinical pharmacy practice. Originating as a field in the early 1970s in hospitals, "clinical pharmacy" at that time was seen primarily in larger metropolitan areas. Very few pharmacists fulfilled these roles in West Texas, and advanced clinical pharmacy services were largely non-existent.

Clinical pharmacists work with physicians and other health care providers to optimize drug therapy (1). With additional training in direct patient care environments, pharmacists who provide clinical services typically assess patient problems and medication needs, evaluate current drug therapy and appropriateness, identify unmet medications needs, collaborate with the patient's other healthcare providers to optimize drug therapy, and monitor the patient for anticipated response (2). An example of clinical pharmacy services in a hospital setting would be several of our faculty who work with one or more of the inpatient teams providing care to patients who are acutely ill. Our faculty work with several TTUHSC School of Medicine departments including Family and Community Medicine, Pediatrics, Internal Medicine, and Surgery in both the general hospital service and intensive care units. They round with the interprofessional teams and provide clinical pharmacy services, often working as a liaison with hospital-based staff pharmacists. Similarly, clinical pharmacists are contracted to provide care in many of the major inpatient healthcare systems across the state.

Likewise, in the outpatient setting, our faculty work with other departments to provide team-based comprehensive medication management services. Working under a protocol approved by collaborating physicians and the Texas State Board of Pharmacy, the pharmacist will see patients referred to them by prescribers to help co-manage common chronic diseases such as high blood pressure, diabetes, and venous thromboembolism (i.e., anticoagulation management). In this setting, the patient will see the pharmacist in the same clinic, and the pharmacist may independently modify and prescribe drug therapy, order laboratory tests, and follow up with the patient. All patient care plans are then shared back with the referring provider. In this manner, team-based care is provided in a coordinated manner. Numerous studies have demonstrated that a team-based approach to care with pharmacists improves outcomes for patients with chronic disease states. As a result, newer clinical guidelines strongly support the inclusion of pharmacists to provide team-based care.

The department of pharmacy practice also oversees two Class A pharmacies (Amarillo Pharmaceutical Care Center and TTUHSC Pharmacy in Lubbock). Both serve as community pharmacies for patients seen in TTUHSC clinics. They also provide additional services, such as vaccinations and administering intramuscular injections of long-acting medroxyprogesterone acetate and antipsychotic medications under a physician

protocol. The Lubbock pharmacy also has a USP-800 compliant sterile compounding cleanroom which is used to provide various intravenous medications (e.g., chemotherapy, intraocular injections, furosemide drips, etc.) for other TTUHSC departments.

Despite being relatively young and located in a region where practice innovation has historically lagged other areas of the country, the TTUHSC Jerry H. Hodge School of Pharmacy has quickly demonstrated leadership both in Texas and in the nation. Faculty routinely participate in professional service activities, and several have held national elected office in major pharmacy organizations. Dr. Cindy Raehl, the founding department chair, was the past president of both the American Society of Health-System Pharmacists and the American Association of Colleges of Pharmacy. In addition, several faculty members have held elected national leadership roles as members of boards of regents or boards of directors, participated in national guideline development committees, and served in credentialing and accreditation roles. At regional and state levels, department faculty members are leading the way as well. Dr. Mary Klein is the past president of the Texas Society of Health-System Pharmacists, and many have served or are currently serving as elected officers in local or regional organizations including the Panhandle Society of Health-System Pharmacists, Lubbock Society of Health-System Pharmacists, and West Texas Pharmacy Association.

While the department is dedicated to advanced clinical pharmacy practice in all settings (community, hospital, and clinic), it is also focused on educating the next generation of pharmacists. The department is home to the residency training program, which works with our partner institutions to provide post-graduate training for pharmacy residents in a variety of health care settings including ambulatory care, community practice, geriatrics, pharmacotherapy, general inpatient pharmacy practice, and oncology. With 39 TTUHSC and TTUHSC-affiliated residency slots, we have one of the largest programs in the country.

Lastly, research and scholarship in pharmacy practice and education are core value of the department of pharmacy practice. The department is home to a Cancer Prevention and Research Institute of Texas (CPRIT)-funded Clinical Pharmacology Core lab in Dallas and has several funded grants in pharmacoepidemiology. Likewise, throughout the years it has participated as a site in several funded National Institutes of Health cluster randomized trials, hundreds of observational studies, and numerous papers or studies on the scholarship of teaching and learning.

During the past 25 years, the practice of pharmacy in West Texas has evolved considerably, and the Department of Pharmacy Practice has played a leading role. Over the next 25 years, we look forward to continuing to pioneer the way, advancing the practice of pharmacy in all health care settings and improving the care of the patients we serve through innovation and collaboration.

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Eric J MacLaughlin, Pharm.D., FASHP, FCCP, BCPS is Professor and Chair, Department of Pharmacy Practice at the Texas Tech University Health Sciences Center (TTUHSC), Jerry H. Hodge School of Pharmacy. He is also a Clinical Professor in the Departments of Family Medicine and Internal Medicine at the TTUHSC School of Medicine. In addition to teaching, research, and scholarship, Dr. MacLaughlin practices in family medicine, providing team-based comprehensive medication management services for patients with hypertension, diabetes, and other chronic diseases.

Krystal K Haase, Pharm.D., FCCP, BCPS, BCCCP is Professor and Head of the Adult Medicine Division at Texas Tech University Health Sciences Center (TTUHSC), Jerry H. Hodge School of Pharmacy. She practices in the Medical and Cardiac Intensive Care Units at Northwest Texas Hospital where she precepts students and residents. She has taught in a range of different classroom and laboratory courses with emphasis on critical and acute care disease states. She also developed and directs the two-year Pharmacotherapy residency at Texas Tech in Amarillo.

Cutting-Edge Biomedical Research on the Amarillo Campus of TTUHSC: History and Outlook

by Ulrich Bickel, MD

While there had been commendable research efforts by colleagues associated with the Texas Tech School of Medicine in the 1990s, it is probably fair to associate the development of major preclinical research programs with the establishment of the TTUHSC School of Pharmacy (now Jerry H. Hodge School of Pharmacy, in the following just "SOP") in the late '90s. In the 21st century, experimental research in the biomedical field (bench research), including *in vitro* and animal studies, is dependent on technology. While projects should be driven by innovative ideas and not by whatever instruments are available, access to state-of-the-art equipment is an indispensable condition to be competitive in today's publication and funding climate. This article will give a brief overview of how our research infrastructure has evolved on the Amarillo campus over the past 20 years and will highlight the future challenges and opportunities from the perspective of a faculty member who had the privilege to participate in this endeavor.

In 2000 there was a single building on the current TTUHSC Amarillo campus, namely the SOP at 1300 S. Coulter Street. Around the same time, hiring of new faculty members with significant research expertise and track records as independent investigators picked up (see related article in this issue by Tom Abbruscato and Desmon Dunn). Research infrastructure available at the time consisted of about 5,000 square feet of lab space containing basic equipment, including cell culture hoods and incubators, -80°C freezers, a high speed ultracentrifuge, a cryostat, several HPLCs, a gamma and liquid scintillation counter, basic light microscopes, and a dark room. Many of the new faculty members would bring pieces of essential equipment with them from their previous institutions to enable them to carry on with their projects. Over the following decade, research programs and infrastructure saw significant growth. Without doubt, this expansion was facilitated, especially in the early 2000s, by a more favorable funding situation at the federal level (i.e., the doubling period of the NIH budget was still ongoing). A first milestone in these early years was the installation in 2004 of a confocal microscope system at a cost of about $250,000, which was made possible by pooling institutional funds with monies available as part of a NIH R01 grant.

With the gradual addition of faculty with active bench research programs, and the expansion of the Graduate Program in Pharmaceutical Sciences, significantly more lab space on the Amarillo campus was required. In addition, the old animal facility, which was located half a mile away and was operated under unsuitable infrastructural conditions, needed an urgent upgrade. This prompted to the construction of a new building, adjacent to the buildings of the School of Medicine and Pharmacy. The two story "Amarillo Research Building" was opened in 2007; with its 2 floors of labs, along with faculty offices and desk space for graduate students and post docs; it more than tripled the available lab space on the Amarillo campus. It also featured a state-of-the-art animal facility with ventilated cage systems and procedure rooms.

While securing grant funding from federal agencies, in particular from the NIH, became increasingly difficult in the late 2000s, a major boost for biomedical research was provided by the creation in 2010 of the Cancer Prevention and Research Institute of Texas (CPRIT) by the Texas legislature. Besides providing significant funding opportunities for individual investigators, CPRIT has implemented outstanding grant mechanisms for major equipment and core facilities. For comparison, these exceed equipment grants available from NIH. The SOP benefitted from a "Shared Instrumentation Award" in 2011 with the funding of a proposal to obtain a "Multiphoton Laser Scanning Microscope for Cancer Research and Drug Discovery" worth $929,000. In addition, the purchases of a small animal *in vivo* imager based on

bioluminescence and fluorescence (IVIS), a new flow cytometer and a flow sorter, a highly sensitive liquid chromatography-mass spectrometry (LC-MS/MS) instrument, and an NMR spectrometer elevated the quality and quantity of major research equipment available to faculty and students in Amarillo to the next level.

While such instruments are expensive to buy (the above items had an aggregate value of about $2.4 million at the time of installation), the cost of maintenance and service contracts is a significant challenge for all public research institutions. The SOP spends $150-200,000 per year for service contracts on the Amarillo campus alone. In most instances there is no choice, because only highly-trained service technicians and engineers from the manufacturer have the training and expertise to diagnose and repair these sophisticated instruments. Another consequence of the ever-accelerating technical progress in the biomedical field is the fact that most of these instruments nowadays are becoming obsolete within 10 years or less. This has gone to the point where manufacturers will not even offer service contracts or guaranteed supply of spare parts beyond such periods. In essence, this forces users to purchase a new model of all these instruments every 10 years or earlier. There is, however, not a financial mechanism in place at a public institution like Texas Tech to provide for the bulk of maintenance costs, not to mention replacement costs. The collection of user fees can support maintenance costs to a small degree, but this is very much dependent of how extensively an instrument is being used. Clearly, a small community of researchers, like the group of faculty on the Amarillo campus (currently with fewer than 15 active PIs between the Schools of Pharmacy and Medicine) will be at a disadvantage compared to large research-intensive institutions when it comes to recovering costs for maintenance and replacement.

The recent opening of the TTU School of Veterinary Medicine (SVM) in Amarillo, however, provides a tremendous opportunity to keep and expand our current excellent research infrastructure. With agreements of mutual support and good communication, unnecessary duplication can be avoided, and strategic investments in complementary equipment can be planned, to the benefit of all researchers on the Amarillo campus. A first major success in this direction occurred in 2020 with the submission of an application to CPRIT which was supported by both TTU and TTUHSC. This "Core Facility Support Award", funded at $2.83 million, has allowed us to establish an Imaging Core Facility for the Amarillo campus over the course of 2021. This includes the installation of 3 major new imaging instruments, one of which is a state-of-the-art super-resolution confocal microscope, allowing visualization of cellular structures 10 times below the limit of resolution of conventional light microscopes. Currently, there are only a handful instruments of that brand-new model installed worldwide. Another prime example of the developing synergy between the SOP and SVM is the recent acquisition of a new LC-MS/MS system, which was the first instrument of this latest generation installed in Texas. This purchase, on the order of half a million dollars, was only made possible by pooling funds from both schools to match a generous contribution of infrastructure funds by the TTUHSC administration, and it is already in use by faculty from SVM and SOP.

In conclusion, building infrastructure for biomedical researchers in Amarillo over the last 20 years has been a success story. It will be a shared responsibility of the institutions, as well as the PIs who use the available equipment, to provide the financial support required to keep these technical resources available and, hopefully, to further expand the research mission of Texas Tech in Amarillo.

Ulrich Bickel, MD has a background in Clinical Pharmacology. He joined the faculty of the Department of Pharmaceutical Sciences in 1999 and has been a tenured Professor since 2004. Since 2019, he has served as Associate Dean of Sciences in the School of Pharmacy. Ulrich's research focus is on transport mechanisms at the blood-brain barrier, pharmacokinetics, and drug delivery to the CNS. Besides motorhome trips with his family, he enjoys photography as a hobby.

Specialty Training and the Role of Clinical Pharmacists

by Kenna Payne, PharmD

Each year, a portion of pharmacy graduates make the decision to pursue clinical pharmacy practice by obtaining postgraduate training in a pharmacy residency or fellowship. Pharmacy residencies are accredited by the American Society of Health-Systems Pharmacists (ASHP) in order to ensure that residency graduates demonstrate a high standard of quality. The majority of accredited first year (PGY1) residencies are pharmacy practice residencies, which are somewhat similar to an intern year for medical residents as they focus on providing direct patient care and obtaining experience in the management of a variety of disease states. Pharmacy practice residencies are usually in a hospital setting, with longitudinal ambulatory care experiences. Depending on the institution, some pharmacy practice residencies are in a more specialized setting, such as pediatrics or ambulatory care. All accredited PGY1 residencies require the resident to meet standards set forth by ASHP, including conducting a research project.

After the PGY1 year, some resident graduates enter the workforce, while others go on to a PGY2 specialty residency. ASHP accredits 24 different PGY2 specialty residencies, including ambulatory care, critical care, emergency medicine, geriatric, pediatric, and solid organ transplant. The PGY2 year is focused on gaining knowledge and experience in that specialty area of pharmacy.

After completion of training, residency-trained clinical pharmacists are prepared for a variety of patient care activities.

Ambulatory care pharmacists work very closely with physicians in clinic to optimize drug therapy for a variety of chronic disease states such as diabetes, hypertension, and heart failure. Infectious disease pharmacists are often leaders in hospital antimicrobial stewardship and infection prevention and control. Many collaborate with Infectious Disease physicians in outpatient settings to provide pharmacotherapy management for patients with HIV, TB, and viral hepatitis. Critical care pharmacists round with physicians in the intensive care unit, focusing on optimizing medication therapy in critically ill patients. A position paper published by Society of Critical Care Medicine (SCCM), along with other organizations, states that "critical care pharmacists are essential members of the multiprofessional critical care team" (1). Transplant pharmacists are an integral part of the transplant team and help detect medication adverse effects, identify drug-drug interactions, and assist with drug therapy selection for complex cases. In order for transplant centers to meet CMS accreditation standards, they must document the participation of either a clinical transplant pharmacist or a pharmacology expert on the multidisciplinary transplant team (2).

Pharmacists also have the opportunity to become board certified in multiple specialty areas. The Board of Pharmacy Specialties (BPS) maintains rigorous standards to ensure that certified pharmacists are qualified to contribute at advanced practice levels. The BPS maintains 14 areas of certification, including ambulatory care, infectious disease, critical care, and pharmacotherapy. Candidates for certification must meet the eligibility requirements for their specialty area and must pass a BPS specialty examination. Eligibility requirements for clinical specialty pharmacists often include either residency experience or proof of multiple years' practice experience in that specialty area.

In Amarillo, several pharmacy residencies provide extensive training for our

pharmacy graduates: four in pharmacy practice, one in family medicine, and four in pharmacotherapy. The pharmacotherapy residency is a two-year residency that provides patient care experiences in areas such as ambulatory care, geriatrics, pediatrics, critical care, and family medicine, while also focusing on academic and teaching experiences.

Board-certified, residency-trained clinical pharmacists in Amarillo round with the hospitalists, attendings, and residents in the hospital setting, both in the ICU and on the floor. They evaluate newly admitted patients for potential medication adverse effects contributing to admission. They also review medication orders for optimal efficacy and potential dosage adjustments, taking into account clinical considerations such as severity of illness, renal function, hepatic function, and drug-drug or drug-disease state interactions. They assist with drug therapy selection and dosing, especially for antimicrobial agents. Their familiarity with CMS Core Measures and accreditation standards allows them to assist the physicians in complying with those standards, thereby improving billing and reimbursement. In addition, ambulatory care pharmacists practice in several clinics in the Amarillo area, providing outpatient services such as anticoagulant dosing and monitoring, hypertension management, and management of insulin pumps.

Rigorous standards for pharmacy residency accreditation ensure that residency-trained pharmacists receive quality training. Board certification ensures that these pharmacists are knowledgeable about current pharmacotherapy management in their area of specialty. While the traditional pharmacy roles of safe and effective dispensing of medications, patient education, and provision of immunizations are vitally important to the community, the value of the cognitive services of clinical pharmacists is also integral to patient healthcare. Clinical pharmacists are able to provide pharmacy services that assist physicians, provide cost-savings, and improve the quality of patient care.

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Dr. Kenna Payne is an Associate Professor and the Associate Dean for Professional Development at Texas Tech University Health Sciences Center School of Pharmacy in Amarillo, Texas. She received her Pharm.D. from TTUHSC School of Pharmacy in Amarillo in 2005, then completed a two-year ASHP-accredited Pharmacotherapy Specialty Residency at TTUHSC School of Pharmacy in Dallas in 2007. She is a Board Certified Pharmacotherapy Specialist, and she practices clinical pharmacy with the Family Medicine team at BSA Health System.

Hospital Pharmacy Practice: An Evolving Field

by Lori Henke, PharmD, RPh

My career in hospital pharmacy began before I even entered pharmacy school. I had just been accepted to the Bachelor of Science in Pharmacy program at Southwestern Oklahoma State University when I became a pharmacy technician at St. Anthony's Hospital (later merged with High Plains Baptist Hospital to form Baptist St. Anthony's Health System). My goal of becoming a pharmacist was motivated by my desire to help people in the community, and I was able to shadow an independent retail pharmacist, who convinced me that working in a role like hers would allow me to fulfill that dream. Not long after entering the hospital world, however, my goal became quite different. With great mentorship and support, the door to a career in hospital pharmacy was opened, and now, more than 35 years later, I have been fortunate to be part of a remarkable and rewarding field.

Upon graduation I was able to transition into a staff pharmacist role and soon was asked to lead the development of clinical programs. Until then, my training and experience had focused on medication preparation and distribution, so implementing clinical activities for pharmacists became an exciting and lofty aspiration. With the goals of standardizing care when appropriate and improving medication safety and patient outcomes, I instituted therapeutic interchange protocols and order sets, but I soon discovered that my training had not adequately prepared me to make a greater impact. Recognizing that further education was necessary to cultivate a clinical pharmacy career, I entered the Doctor of Pharmacy program at the University of Texas, then an intense and intimate two-year curriculum that prepared me for my career's next steps.

Having focused on oncology while at the University of Texas, I returned to Amarillo to work with the oncology team at then High Plains Baptist Hospital (now Baptist St. Anthony's Health System) to expand its cancer treatment programs and develop a bone marrow transplant unit. Over time my position evolved into that of a Clinical Manager and, later, Director of Pharmacy. While I never planned to fill the role of Director, dedicated mentorship, support from senior leadership and participation in the Executive Management Program for Pharmacy Leaders at The Wharton School at the University of Pennsylvania gave me the skills and confidence for the role I have served for the past 15 years.

In my various roles in hospital pharmacy practice over the past several decades, and currently as the Director of Pharmacy at Northwest Texas Healthcare System (NWTHS), I have seen an exciting evolution. Pharmacists providing clinical services, once such unchartered roles, are now integral members of health care teams in the hospital setting. Among my staff of 33 pharmacists (and 4 TTUSOP faculty members) are many with residency training or extensive experience in special patient populations and even specific disease states. For example, the emergency department at NWTH is staffed with pharmacists experienced in the immediate management of stroke, heart attack, and sepsis, providing on-the-spot expertise for the medical teams. As the medication experts, their contributions can significantly benefit patients and also shape a foundation of medication knowledge for medical students, residents and physicians with whom they round.

Jessica Hernandez, PharmD, RPh, is a clinical pharmacist at NWTHS. As a clinical pharmacist, Jessica collaborates with physicians to provide the optimal dosing and monitoring of medications with narrow therapeutic indexes such as warfarin and vancomycin. She participates in emergency codes, providing medication recommendations, preparing medications at bedside, and assisting the medical team with any task that is needed to stabilize the critical patients. According to Jessica, "Our role in direct patient care allows us to prevent drug-related problems, effectively collaborate with other healthcare providers, and positively influence outcomes for patients under our care."

Amy Choate, BS, RPh, works as the Oncology and Investigational Drug Studies Pharmacist at NWTHS. With her 28 years of practice experience, 14 of which have been focused on oncology, Amy works closely with oncologists to coordinate patient care, ensuring that complex chemotherapy regimens are followed and medications to manage side effects are optimized. Amy also serves as a resource for drug information for physicians and nurses alike in the rapidly changing oncology arena.

Specialized roles *not* directly involved in patient care have become necessary within the hospital setting as well. Clinical program development, technology management, antimicrobial stewardship, inventory management and pharmacoeconomics are all unique positions that require specialized skills and contribute to a well-rounded pharmacy team.

Chad Simpson, RPh, MBA, serves as the Pharmacy Operations Manager / Medication Safety Pharmacist at BSA Health System. In his role, Chad works with pharmacists and pharmacy technicians to deliver safe pharmaceutical care to patients by ensuring compliance with medication safety standards set by regulatory agencies and patient safety organizations. He analyzes processes throughout the medication continuum, seeking opportunities for improvement, and he has led the implementation of various technologies to enhance the safety of inherently high-risk medication processes. In describing his role, Chad states, "As leaders and medication safety pharmacists, we often deliver care to our patients *indirectly* by supporting our teams and ensuring they have the proper

education and resources to provide safe care to our patients."

Robin Christian, RPhT, works in a specialized role as the Pharmacy Technician Lead at Physicians Surgical Hospital Panhandle Campus. Being a smaller hospital, Robin is called upon to perform many duties beyond the typical scope of a pharmacy technician. She manages the medication formulary and inventory, is responsible for the pharmacy portion of regulatory surveys, oversees technology, and serves on the hospital's leadership team. She teaches about medication issues during annual nursing competencies, and with the help of technology, she ensures security of controlled substances and screens for potential diversion. Complying with requirements for pharmacist oversight, Robin is able to work relatively independently to meet all of the medication needs for the surgical center – and then some!

Advances in technology, contributing to enhanced patient safety and supporting growth of clinical services, have made a tremendous impact on hospital pharmacy practice. Electronic health records, making a patient's medical information readily available throughout their continuum of care, have allowed significant advancements in the healthcare industry. Quality of care has been enhanced through computerized prescriber order entry, which provides safety alerts to prescribers and bypasses the concern for illegible handwriting. Barcode scanning of medications, smart infusion devices and dispensing robots have all contributed to safety and efficiency in hospital pharmacy practice, shifting pharmacists' focus to provision of clinical services. The downside of reliance on technology, however, became apparent in September of 2020 when a cyber-attack on NWTHS (and other Universal Health Services facilities) disabled electronic systems, requiring reversion to pre-computer (i.e., paper) processes.

Opening the Texas Tech University Health Sciences Center School of Pharmacy was a game-changer for pharmacy practice in our region. In addition to attracting highly skilled specialized practitioners to Amarillo, the School has provided an outstanding workforce of well-trained, enthusiastic pharmacists. Once, hiring pharmacists to grow programs or fill vacated positions was a challenge; now, I am able to identify top performing students during their experiential rotations and recruit the best and the brightest – even before they've graduated or successfully completed their Board exams.

As the healthcare climate has evolved, so has the regulatory framework supporting and guiding it. As the healthcare system pharmacist representative on the Texas State Board of Pharmacy, I have been involved in initiatives to improve access to care through telehealth practice models and dispensing kiosks. These efforts are designed to ensure that pharmacy services are readily available to patients, a focus of its mission to promote, preserve and protect public health, safety and welfare. Regulatory requirements for "hospital at home" models are being defined, anticipating a growing concern for exceeding hospital capacity as we have experienced with the pandemic.

I would be remiss if I did not mention the tremendous impact that the COVID-19 pandemic has had on hospital pharmacy practice. Ensuring availability of new treatment modalities for patients became a priority, and when the COVID-19 vaccine was approved for use, our goal became immunizing health care providers as quickly as supply was available. Ever-changing therapeutic recommendations required continual review of literature, much of which was conflicting, as little data existed and urgency precluded the development of well-conducted clinical trials. Management of medication shortages became even more challenging than usual, not only for those medications used to treat and support COVID-19 patients, but for many other medications as the world faced a disruption in supply chains. For instance, commonly used electrolyte solutions such as potassium chloride and sodium phosphate have been in short supply across the nation. At NWTH, pharmacists and medical staff members collaborate to work around these sometimes-critical shortages. Meeting staffing demands proved to be challenging too, with workload dramatically increased and many pharmacists and pharmacy technicians facing personal illness and loss themselves.

Certainly, working in a hospital pharmacy during the pandemic has been the most interesting and challenging experience in my career. The reward, however, has been remarkable too; being part of a team that has provided quality healthcare to our city – our region – during its greatest time of need has been truly fulfilling. The local pharmacy community – the entire healthcare community, in fact – has collaborated to ensure that needs were met. The many advancements that hospital pharmacy has experienced in the past several decades really prepared us for this challenge, and speaking for my pharmacy colleagues, what an honor it has been to serve alongside other dedicated members of the healthcare team!

Lori Henke, PharmD, RPh is the Director of Pharmacy at Northwest Texas Healthcare System. She received her Bachelor of Science Degree from Southwestern Oklahoma State University and a Doctor of Pharmacy Degree from the University of Texas. She has dedicated her career to hospital pharmacy practice with a focus on patient safety, and she currently serves as the Vice-President for the Texas State Board of Pharmacy.

Building a Research Hub in the Panhandle:

The Evolution of the Department of Pharmaceutical Sciences

by Tom Abbruscato, PhD and Desmond Dunn

Some have called the Department of Pharmaceutical Sciences at TTUHSC's Jerry H. Hodge School of Pharmacy in Amarillo the Panhandle's best-kept secret, but to those who know the research happening there, it is anything but secret. Basic science research, in general, has always been a bit of a mystery to the public. It's a world in which basic discoveries, chart-filled publications, and funding from the Nation Institutes of Health (NIH) and Cancer Prevention Research Institute of Texas (CPRIT) are some of the goals that take years of dedication and work to achieve.

H-Index, Impact Factor, R01, R21, R03, R41 and other terms the layperson would not think about twice, are some of the measures by which researchers are judged. And by those standards, the Department of Pharmaceutical Sciences is doing pretty well. The Jerry H. Hodge School of Pharmacy currently has research grant funding totaling about $6M as well as extensive core equipment to support imaging, drug analysis and microscopy, and over 30 Ph.D. and M.S. graduate students enrolled in the Graduate Program in Pharmaceutical Sciences to support this growing research engine. Since the School of Pharmacy opened its doors in 1996, Amarillo has evolved into a pharmaceutical research HUB of the Panhandle.

Graduate Program

To support a growing research program, the School of Pharmacy understood that a Graduate Program in Pharmaceutical Sciences is an essential part of the wheel. In 1999, the Texas Higher Education Coordinating Board approved the first Ph.D. program in Amarillo that would train Ph.D. and M.S. students in Pharmaceutical Sciences. In 2018, the Graduate Program in Pharmaceutical Sciences celebrated awarding its 100th graduate degree to Dr. Laxmi Iyer, from Dr. Thekkumkara's Lab. Graduate students come from the world over to attend but many come from and are part of the Panhandle Community.

One of the first students to complete his entire Ph.D. at the School of Pharmacy was Paul Lockman in 2003. Dr. Lockman earned his BSN from WTAMU in 1994 and spent a decade at Northwest Hospital, BSA, and the Panhandle Poison Center before starting his Ph.D. in Pharmaceutical Sciences in 1999. After graduation, Dr. Lockman joined the Department as a research instructor and faculty, building his research program over the next decade, investigating the brain tumor microenvironment and testing novel treatments for brain metastasis. In 2013, Dr. Lockman left the Department to accept a new research position as the Douglas Grover Endowed Chair of Basic Pharmaceutical Sciences at WVU's School of Pharmacy. His research and leadership continues to this day.

Local Panhandle students continue to benefit from this unique opportunity. Dr. Heidi Villalba, a first generation college student, born and raised in Dimmit, earned her BS and MS degrees in Biology from West Texas A&M, and graduated with her Ph.D. in Pharmaceutical Sciences in 2018. Dr. Villalba completed her Ph.D. and postdoctoral fellowship in Dr. Abbruscato's Stroke Lab supported by the National Institute for Drug Abuse to study the cerebrovascular toxicity of vaping nicotine. With her research experience and graduate education from the School of Pharmacy, Dr. Villalba was recently recruited by the TTU School of Veterinary Medicine as a founding faculty to support its teaching mission and continue to grow her independent research program, right here in the Panhandle. Dr. Jennifer Paulson, another local (Pampa) student, completed both her pharmacy degree and Ph.D. in Dr. Abbruscato's Lab and now practices pharmacy in Pampa.

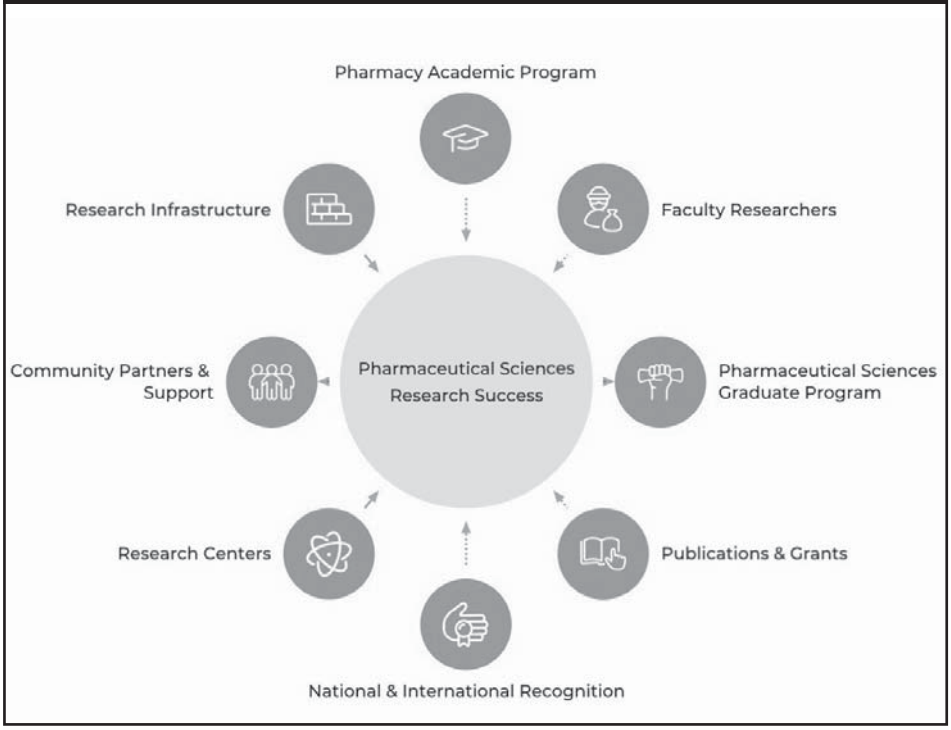
The research accomplishments of the Department of Pharmaceutical Sciences would not be possible without the innovative training and research focus of the graduate students in a program, where the faculty and students share a common vision to become outstanding pharmaceutical and biomedical scientist, with the end goal to benefit the community at large. A major mission for the graduate program remains to train the next generation of biomedical and pharmaceutical scientists. This golden opportunity also attracts world-class scientist to build their research careers in the Panhandle Region.

Starting a Niche Research Area: Blood-Brain Barrier

In the early years of the Department of Pharmaceutical Sciences, a research focus area developed related to investigating the role of the blood-brain barrier (BBB) in brain drug delivery and the crucial impact of the brain vasculature health to the progression of neurodegenerative disease-like brain stroke. In 2000, a BBB Research Center was formed by several founding research faculty in the Department (Drs. Smith, Abbruscato, Allen, Bickel, Karamyan, Thekkumkara, and Weis). The original goal was to encourage collaborative research related to discovering and understanding new drug targets that center on brain transport pathways to treat neurologic diseases. In a short amount of time these research areas took off with respect to the pharmacy school's research profile and competitiveness for federal research support.

In 2003, Dr. Smith and the BBB research center hosted the 4th International Cerebrovascular Biology Meeting in Amarillo with over 130 international attendees. The international brain barrier research community was completely focused on Amarillo and a cadre of like-

Building a Pharmaceutical Sciences Research Hub in Amarillo:
How to succeed in basic science on the high plains



minded scientists that came together with a goal to discover innovative ways to treat a variety of brain diseases. In a short amount of time, the Department of Pharmaceutical Sciences and Amarillo had gained international attention for innovative brain research. In 2003-2004, 3 faculty (Drs. Abbruscato, Bickel, Smith) received the first set of NIH R01 funding as principle investigators (PIs) for the first set of BBB-focused research projects in the Department of Pharmaceutical Sciences. This laid the foundation for building the future research culture and infrastructure of the SOP with respect to equipment, facilities and training of the next generation of scientist.

Expanding the Department's Research Breadth to Cancer

After creating a sizeable research program in cerebrovascular biology, the department and school began to build its research expertise towards innovative cancer-related research. The school recruited Dr. Ming-Hai Wang as the Amarillo Area Foundation Chair of Cancer Biology in 2004, an NIH funded scientist from University of Colorado. Cancer research was further expanded with the recruitment of several NIH funded cancer researchers (Drs. Liu, Srivenugopal, Zhang, Lu and Mikelis) over the next decade. In 2005, a Cancer Biology Research Center was formed with the mission to advance understanding, prevention, diagnosis, and treatment of cancer by generating new knowledge in cancer biology and therapy. Just one year later (2006), the NIH and Department of Defense funded the novel cancer projects of Drs. Smith and Lockman's Labs to more precisely treat brain metastases of breast cancer. This research momentum and investment was proven wise when, in 2007, Texans also voted to create the Cancer Prevention & Research Institute (CPRIT) to invest billions of dollars in the state's unprecedented fight against cancer.

In 2011, The School of Pharmacy and the Department of Pharmaceutical Sciences took another step into the research limelight by hosting a Cancer Symposium in Amarillo with Noble Laureate, National Academy of Sciences Member, and Chief Scientific Officer of CPRIT, Dr. Alfred G. Gilman, M.D., Ph.D. as the keynote speaker. The department's research efforts continued to focus on cancer and cures for cancer, which really gained interest from CPRIT. Over the next decade, CPRIT invested > $4 million in SOP research infrastructure supporting advancing research imaging and individual research projects of faculty. Just last year, Dr. Bickel and the Department of Pharmaceutical Sciences were awarded a $2.8 million core imaging support grant from CPRIT to support a core facility for whole-animal imaging to super resolution microscopy. This continues to support innovative cancer and non-cancer research in Amarillo.

Academic Drug Discovery in the Department of Pharmaceutical Sciences

Being a pharmaceutical sciences department, most all of our research focuses on some component of drug action. We were well positioned in 2011 to develop this aspect further by growing multidisciplinary expertise in medicinal chemistry, pharmacology, drug delivery, formulation and repurposing. In 2012, the Department of Pharmaceutical Sciences made strategic investments in hiring research faculty with expertise in medicinal chemistry (Drs. Trippier and German), expanding our chemical synthesis capacity. With more than $2 million invested by the SOP and TTUSHC, the department was able increase its research capacity with improvements to lab air handling systems to now support six additional chemical fume hoods and new analytical instruments including an NMR and LC-MS/MS for chemical analysis. And these research investments paid off, resulting in state-of-art chemical synthesis/analysis facilities and active, NIH supported drug discovery programs (Drs. Abbruscato, Cucullo, German, and Karamyan, Mikelis, and Trippier). Bringing in excess of $10 million in NIH supported research funds to support Amarillo research labs, these projects focus on novel drug discovery and drug repurposing projects to identify new treatments for both hard to treat cancers and brain stroke.

Cerebrovascular Impact of E-Cigarettes (E-Cig) Exposure on Youth

2014 was the first year that E-cig use surpassed tobacco products by young adults. This was a growing concern worldwide, and the Panhandle was not immune. Two Amarillo researchers (Drs. Abbruscato and Cucullo) had previously been funded independently

| *continued on page 24*

Happy Holidays

from the Potter-Randall County Medical Society Active Members

Anthony Agostini, DO
Syed Ahmed, MD
Brendan C. Albracht, DO
Douglas A. Albracht, DO
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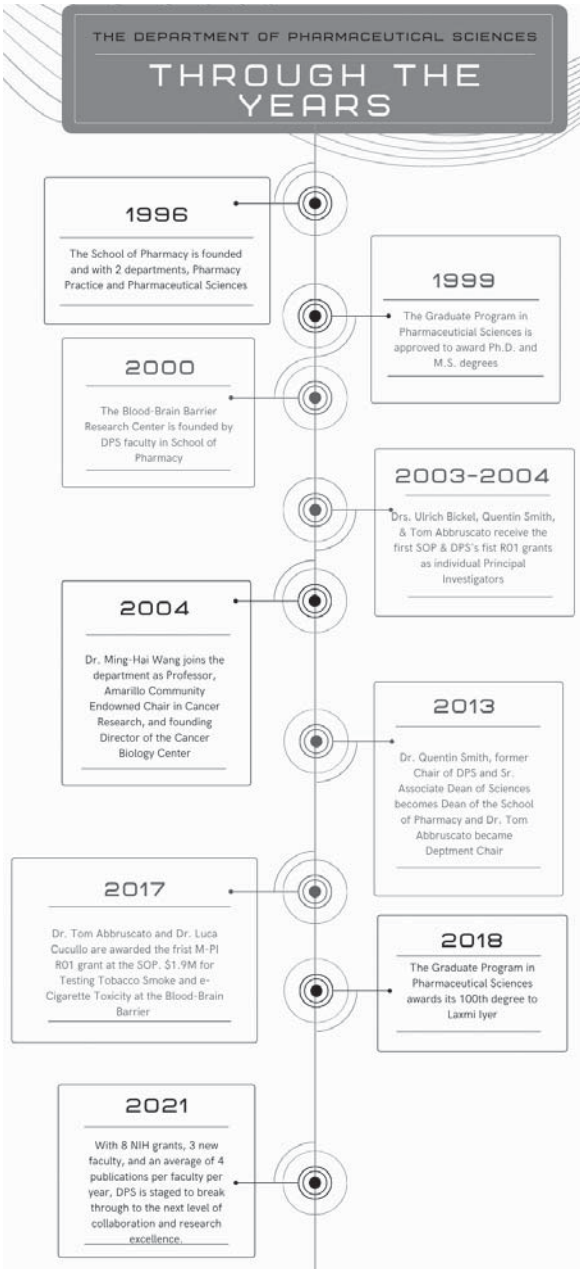
Lawrence P. Zarian, MD

by the NIH to study the cerebrovascular impact of tobacco smoking on brain toxicity (Cucullo) and stroke outcome (Abbruscato), prior to the widespread use of E-cigs. Being colleagues in the same department, these researchers decided to combine efforts to investigate the cerebrovascular impact of nicotine, delivered by E-cigs, on cerebrovascular toxicity and stroke. They combined their expertise using cell- and animal- based models of nicotine exposure to investigate the health effects of vaping nicotine to receive the first multiple PI NIH research grant. Currently, both Drs. Cucullo and Abbruscato's Labs are funded by the National Institute of Drug Abuse and National Institute of Neurological Disorders and Stroke to investigate the brain effects of vaping compared to use of traditional tobacco products. The FDA also supports their nicotine research to identify biomarkers of brain injury due to nicotine exposure via E-cigs. Their work will help inform the FDA and public on potential health effects of nicotine and additives in E-cigs on brain development and stroke risk.

Amarillo Collaborative Stem Cell Research for Dry Eye Disease

Dr. Das has was recruited to the pharmacy school in 2016 from The Ohio State University and since then has developed an active research program in the Department of Pharmaceutical Sciences investigating the effectiveness and mechanisms of stem cell-based therapies to treat various human disorders. His research program is truly translational and directly associated with human diseases that affect our Panhandle community. An example of this is that he has recently received FDA approval for a human corneal-derived stem cell product in collaboration with Dr. Sloan Rush (Panhandle Eye Group, Amarillo, TX). This cutting-edge work is currently supported by an R41/R42: Small Business Technology Transfer Grant funded by the NIH. Their pilot work was recently published in Clinical Ophthalmology and shows promising results in alleviating symptoms and improving quality of life in the setting of dry eye disease, which can be a challenge in the Panhandle.



Future Opportunities

And there is no sign of stopping for the Department. The newest members of the School are Drs. McMahon, Wilkerson, and Hiranita (all recruited from University of Florida), with new faculty appointments in the Department of Pharmaceutical Sciences. Dr. McMahon will also serve as TTUHSC's Senior Vice President for Research and Innovation. This successful, NIH funded research team will add to Amarillo's research focus on brain drug discovery with the goal of developing novel treatments for pain and drug abuse. Future department expansion will include recruiting new research faculty with expertise in drug discovery for the nervous system, including focus on neurodegenerative diseases, stroke, pain or brain cancer. We have already combined academic and research collaborations with our TTU School of Veterinary Medicine colleagues in Amarillo. The future is bright, and the Department will continue to develop many aspects of a successful research hub, including recruitment and development of innovative, collaborative research faculty, state-of-the-art facilities, specialized graduate training, and focused research centers of excellence. We plan to nurture all these components well into the future.

Tom Abbruscato, Ph.D. *is Chair of Pharmaceutical Sciences, University Distinguished Professor, and Senior Associate Dean of the Graduate Program in Pharmaceutical Sciences. He received his Ph.D. in Pharmacology and Toxicology from the University of Arizona, College of Medicine in 1997. He joined the Jerry Hodge School of Pharmacy in 2000 and has served as Chair of the Department of Pharmaceutical Sciences starting in 2009. His research program is currently funded by the NIH (NIDA and NINDS) and FDA and his research has been supported by the NIH starting in 1997. He also has recently served a 2-year term as the Chair of the NIH Study Section on Drug Discovery for the Nervous System. His hobbies include spending time with his family traveling and camping and distance running.*

Desmon Dunn *has been the Business Manager for the Department of Pharmaceutical Sciences at TTUHSC Jerry H. Hodge School of Pharmacy for 11 years. Born in northern Montana, he grew in Amarillo and graduated from Texas Tech University in 2008 with his B.A. in Philosophy and is currently finishing a M.B.A. from University of the People. He sits on the board of the Panhandle Cancer Cure Foundation, and enjoys reading, hiking, and spending time with his wife and dogs.*

A Story of the Importance of Research: One West Texas Laboratory

by Helen Thorsheim, PhD and Quentin Smith, PhD

Many people have friends, relatives, or acquaintances who have had their lives disrupted by the onset of serious central nervous system diseases. These include neurodegenerative diseases (Parkinson's disease, Alzheimer's disease), stroke, epilepsy, chronic pain, depression, brain tumors, and many others. The great majority are long term diseases, and for the vast majority there are no cures. Some can be controlled by drug therapy which returns life toward normality (e.g., pain, epilepsy, depression). For others, treatments are totally inadequate (e.g., Alzheimer's disease, brain tumors). For virtually all, there is a critical need for greater understanding of the basic mechanisms of CNS disease pathogenesis and for better drug targets to allow more successful treatment or prevention.

Quentin Smith tells of dual events within 4-5 months of each other in late 1975 and early 1976 that took away two of the people with whom he was closest in life: "Overnight, this changed my life trajectory and pushed me strongly toward research. I visited pharmacy and medical schools near where I lived, and they told me of the need for a greater number of people to fight these diseases. Within 8 months, I was in a doctorate program, learning with medical and pharmacy students the basic concepts of how the brain works (neuroanatomy/ medical physiology) and how drugs were developed for brain diseases (Principles of Drug Action). In the years since those initial steps, pharmaceutical research has made major advances in refining and enhancing the speed by which promising drug agents were identified and developed, with computer-controlled, robotic mass screening and 3D computer models of receptor binding sites. Predictions going forward during the 1990s and early 2000s were filled with hope of an ever-growing pipeline of highly potent and specific drug agents. It was the dawn of a new golden age that would transform therapy as we knew it."

Many of the first agents coming forward in the 1970s and 1980s performed extremely poorly in human testing. Treatment of stroke is a good example. A large number of impressive leads went down showing little or no activity in human stroke cases. Similarly, our track record has been equally poor against dementia and against brain tumors and CNS metastases. Many drug companies closed their central nervous system drug development projects. In the >40 years since 1980, the pace of advancement has been far slower than initially expected. This article will describe work from our West Texas laboratory and its contribution to understanding "the problem behind the problem of central nervous system drug development."

In addition to the problems of drug development in any organ, for CNS there is the additional problem of getting drugs into brain, caused by the blood brain barrier (BBB). The BBB is very old evolutionarily, present in virtually all organisms with a nervous system >1000 neurons. It provides insulation to lower the background noise in the brain so that cells of the brain can function efficiently. Anatomically, the blood-brain barrier (BBB) is located at the surface of the blood vessels that travel throughout brain. Unlike those of other organs, the cells that constitute the lining of the blood cells are tightly woven or sealed together, providing few if any gaps to allow compounds to cross,. Hence, the brain vessels block many compounds from entering brain, much like a wall between two countries.

Brain vessels also have selective "gates" or "transporters" that allow essential nutrients to pass in and out for brain metabolism. Drugs are affected by the same mechanisms as the BBB, and drug delivery and equilibration rates in brain are on average 10-100-times lower than in other tissues. Select groups of agents, however, can cross the BBB very well. For example, diazepam (Valium) goes into brain as fast as it can be delivered. Unfortunately, as we've learned in the past 30 years, there are whole large classes of agents that are impeded from entering brain because of their low permeability or because active pumps at the BBB transport the agents out of brain.

The problem of this barrier is illustrated in almost all CNS diseases we are trying to fight, with the majority of new agents being excluded from the brain so they do not reach effective levels. We shall illustrate the problem in one disease, brain tumor, which has affected three or more members in our families (1). Primary brain tumors are not common but are generally lethal when they occur. The problem is multiplied by the frequency of metastatic cancer, where many tumors like lung, breast and skin cancer migrate to and grow in the brain. People do not generally die directly from cancer of the breast. They die from the metastases that invade other organs like the brain. Brain metastases are particularly deadly because almost all drugs used to treat cancer work very poorly against brain metastases. There has been a controversy for 50 years as to the reasons behind this problem and what can be done to overcome it (1). Is it that the drugs don't get into the tumors, or that they do get in but, once there, don't work well for other reasons?

| *continued on page 26*

Our research shows that the BBB can be highly disrupted in a number of tumors, but very importantly, that the effect is extremely heterogeneous. As illustrated in our lab for the first time, drug delivery to brain metastases in breast cancer, though increased, is still greatly lower than the levels that are achieved in systemic tumors (2,3). For example, for one drug, paclitaxel, although drug levels are on average 10 times higher in brain tumors compared to brain, these levels are still ~20 times lower than levels found in matching tumors in other organs of the body—too low to kill the growing cancer cells. Importantly, although there are some areas within brain tumors where the barrier is totally broken down (allowing effective tissue drug levels), generally those select areas are a small percentage of the tumor. As a result, the average drug concentration throughout the tumor is one-to-two orders of magnitude less than in the high-uptake areas. In almost every tumor we investigated, there are areas where drug delivery was not elevated at all (1,4). Matching *in vivo* indices of drug activity and parallel drug exposure studies clearly showed that, though the barrier was severely damaged, it was still inhibiting drug equilibration to a remarkable degree. We have tested all the major clinical agents for this type of cancer, with similar findings for all. In the end, we estimated that over 80% of the problem in drug efficacy is because of barrier restriction to drug uptake- a very clear answer to this 50-year-old problem.

Interestingly, we also found a number of intrinsic brain changes (i.e. not due to the BBB) that contribute to resistance to chemotherapeutic drugs; so, the concept that tumors are somehow different from brain was also partially correct. We attribute 20% of the lack of efficacy to those changes. This research resulted in several high-impact publications (one Impact Factor 53, two Impact 12.7, and three Impact Factor 4.3) with over 1500 total citations of these papers by Oct 31, 2021. Our manuscript on lapatinib received the American Association of Pharmaceutical Scientists "most meritorious manuscript of the year" award in 2014 (3). The impact of this work is discussed in a Clinical Cancer Research Commentary submitted by George Sledge, which can be accessed at the same reference site as the original citation:

"*Brain metastasis may be the most devastating, and is certainly the most feared, consequence of breast cancer. It not only robs the patient of her life, it has the potential to rob her of her self, of her essence as a human being. It is also poorly studied. In the clinic, this dearth of research has been a function of the difficulty of obtaining tissue in those who suffer from it, and the lack of dedicated trials. In the laboratory, researchers have lacked model systems that allow them to dissect the mechanisms and effects of brain metastasis. This situation is now changing, as shown in the report by Lockman and colleagues in the current issue of Clinical Cancer Research*" (4). Dr. Sledge's commentary can be read in full for greater appreciation of the clinical impact and importance of our studies. In addition, we have showed in a companion human study with collaborators from three major cancer treatment centers (Memorial Sloan Kettering, Cleveland Clinic and NCI/NIH) that anticancer drug uptake in brain metastases of women with breast cancer is similar to results found in our animal models. Drug access to brain metastases in these women showed similar variability and deficit in drug delivery, validating our preclinical work (5).

Lastly, in our most recent study, we have addressed the long-debated conundrum that younger women with breast cancer develop more aggressive, rapidly growing brain metastases than do older women. In an additional Impact Factor 12.7 publication, we found that the brain environment and its BBB had a role in determining this difference in all the models of breast cancer brain metastases that we tested, but not when the same cell lines metastasized to other organs (e.g., to liver, lung, kidney or breast). In older women, the brain environment seems to be more protective than that in younger patients; this may be an important factor in the observed greater aggressiveness of brain metastases in younger women. Our paper provided hypotheses to support some preliminary biological mechanisms by which the effect may be mediated (6).

Our work has stimulated newer studies by pharmaceutical companies with compounds designed with better brain accessibility, which are showing greater promise for treatment of this terrible disease. We believe that our research has been a major stimulus to the field – where now drug companies are developing drugs with greater penetration and therefore greater efficacy against these cancers. We have also published other work on different mechanisms to improve drug delivery to brain metastases, using a variety of strategies (including receptor and transporter-based technologies) that show significantly enhanced anti-tumor effects. This, and other scholarly work in the School of Pharmacy, show that important research into the development of new ideas and therapies can go forward at Texas Tech and that this work can be stimulating and highly satisfying. It's been an honor for us to work with some of the finest researchers in our institution and across the country.

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Quentin Smith is Dean of the School of Pharmacy as well as University Distinguished and Murray Professor. After receiving his Ph.D. in Pharmacology, he worked for 17 years at the National Institute on Aging prior to coming to Texas Tech in 1997 to help build the School of Pharmacy.

Helen Thorsheim is a Research Associate in the Department of Pharmaceutical Sciences. After receiving her Ph.D. in Physical Chemistry, she did postdoctoral work at the Naval Research Labs in Washington DC on chemical vapor deposition of diamond for defense applications and worked at FDA for 10 years on food additive regulations. Since 2006 she has worked in Dr. Quentin Smith's laboratory, developing HPLC and LC-MS/MS analyses of drug levels in brain and brain tumors and mentoring graduate students.

The State of Community Pharmacy: Perspective from an Independent Community Pharmacist

by Jason Saucedo

Community pharmacy, sometimes called retail pharmacy, includes traditional chains (e.g., CVS and Walgreens), supermarkets (e.g., United and Walmart), mass merchants (e.g., Sam's Club and Costco) and independents (e.g., Good Neighbor and Health Mart) (1). With over an estimated 1.96 billion drugs given or prescribed between physician office visits and hospital emergency departments annually, it is no surprise that there are a whopping 61,000 community pharmacies across the U.S. (1)(2). Although this number has remained steady over the past several years, the number of community pharmacist positions is predicted to decline by 18,200 from 2020 through 2030 (3). With the community pharmacist often being deemed health care's most accessible professional – especially in rural areas such as West Texas – this is an alarming prediction. While numerous existing and future challenges exists, there have been recent triumphs that keep the community pharmacist optimistic they may continue to stay in business and to positively impact their communities.

CHALLENGES

A community pharmacy, like any other business, needs to make a profit in order to continue its services. One main challenge in the industry is below-cost reimbursement for medications dispensed. This comes as a surprise to the public as few other types of businesses, if any, often sell their goods at or below cost. With approximately 90% of medication being paid for by third-party payers (e.g., Medicare, Medicaid, and Commercial insurance), this leaves on average about 10% of scripts a pharmacy may manage pricing on (1). Third party payments are often managed and controlled by Pharmacy Benefit Managers (PBMs) on behalf of the payers. Because of corporate mergers and acquisitions, just three PBMs (Express Scripts, CVS Caremark, OptumRx) now control 77% of all third-party payments (4). What makes it more complicated is the fact that these PBMs (including the three mentioned) also operate pharmacies of their own, whether it be community or mail order pharmacies.

It is important to understand how PBMs work. They basically serve as middlemen between the payers (insurers and governmental entities), the pharmaceutical companies, and pharmacies. PBMs were initially devised to help insurers with claims processing and other administrative matters such as record keeping. Over time the roles of PMBs have grown exponentially: they devise formularies, establish tiers of payment (i.e., how much co-pay the patient is responsible for) and negotiate prices with the pharmaceutical companies and pharmacies alike. Like hospital and ER charges, the financial arrangements are complex and obscure. It has been very difficult even for governmental entities such as CMS to get to the bottom of these byzantine arrangements.

One way PBMs make money is by reimbursing pharmacies one total, then charging the plan sponsor (e.g., the state of Texas, in the case of Medicaid) a higher price for the same drug, and then taking the difference. This price difference, which is often called the "spread", was discovered to be $224 million dollars one year for the Ohio Medicaid program (5). What was even more alarming in Ohio's investigation was the realization that one of these PBMs was paying its competitors less than it paid its own pharmacies. In one case, it would have had to pay Walmart pharmacies 46% more for generic drugs to equal the rate it was paying its own pharmacies (5).

Another practice of PBMs that proves a challenge for community pharmacies, especially independents, is the administration of Direct and Indirect Renumeration Fees (DIR Fees), sometimes referred to as "clawbacks". DIR fees are "additional compensation received after the point of sale that changes the final costs of the drug for the payer or the price paid to the pharmacy for the drug" (6). These DIR fees mainly apply to Medicare patients; however, Medicare makes up about 37% of retail pharmacy claims (1). Months after a medication is dispensed, the pharmacy can be charged the DIR fees. (This similar to the way hospitals can be penalized after the fact if their readmission rates are too high or their five-star ratings are too low). For example, if a certain number of patients do not refill their prescriptions on time, the pharmacist can be penalized post facto. (This is one reason why your pharmacist tries to promote compliance with blister packaging, weekly pill boxes or phone reminders to patients.)

A challenging aspect of DIR fees for community pharmacy is difficulty in accurately predicting what these future charges are going to be. Being able to forecast financial information, such

In Memoriam

John Alpar,
MD, Ophthalmologist

died July 13, 2021
at the age of 95.
He was a member of
Potter-Randall County
Medical Society for 61 years.

as cash flow, is a critical aspect of every business, and not being able to do so can ultimately put pharmacies in a financial bind. Furthermore, because of the timing of their assessment, DIR fees may cause patients to enter the coverage gap ("the donut-hole") quicker. This is "...because the price ***actually paid*** by the Part D plan sponsor after the application of the later-in-time DIR Fee is lower than the amount initially paid out by the Part D plan sponsor (or its PBM) at the point-of-sale and applied to the enrollees' coverage limits" (7). Lack of transparency and concern about the effects of DIR on the health care system and patients have even led the American Society of Clinical Oncology to release a white paper on the issue (7).

In addition to the challenges mentioned above, a potential and likely shift of pharmacy services from traditional brick and mortar shops to online pharmacies is a concern for community pharmacy. With the entry of Amazon pharmacy and the growth of technology enabling other e-commerce giants, it is only a matter of time before the healthcare system is seriously affected. A major concern for community pharmacy with this shift is patient safety. It is well known that medication stability can be affected by temperature. With online ordering, there may not be controls in place to protect packages in route from extreme and prolonged temperature variations. There is also a concern as to the quality of patient counseling. In community pharmacies, counseling is highly regulated, and patient are counseled before they are allowed to leave. With online ordering, the patient may not get counseling or the same quality of counseling. As with any product or service, online ordering enables and encourages shopping at multiple places. Although beneficial in terms of increased competition for pricing, this makes it difficult for the pharmacist to know all the medications the patient is actually taking, thus making drug utilization reviews (e.g., checking for drug-to-drug interactions) almost impossible.

TRIUMPHS

PBMs for years claimed that the Employee Retirement Income Security Act (ERISA) prevented any state regulation of PBMs. This changed when the Supreme Court of the United States gave their ruling on *Rutledge v. Pharmaceutical Care Management Association (PCMA)* on December 10, 2020. In attempt to address the issue of below-cost reimbursement, Arkansas' Act 900 was passed. This act disallowed PBMs from paying pharmacies below cost. In this case the supreme court ruled that the Arkansas' Act 900 is not pre-empted by ERISA, thus allowing Arkansas to regulate PBMs in this manner (8). This opened the door for states to enact their own legislation to help regulate PBMs and increase transparency in PBM practices.

In May of 2021, House Bill 1763 became law in Texas. This law prohibits PBM clawbacks (DIR fees), allows local pharmacies to mail and deliver prescriptions if requested by the patient, prohibits PBMs from paying their own retail or mail-order pharmacies more than they pay other pharmacies in a network, and prevents PBMs from requiring accreditations or certifications above those required by state and federal law in order to dispense specialty drugs (9). Although this law addresses clawbacks, it will not stop Medicare DIR fees until reform on this matter is done at the national level.

Additionally in June of 2021, House bill 1919 became law in Texas and took effect September 1, 2021. This law allows patient choice of pharmacy by stopping PBMs from steering patients to their own pharmacies. It also prohibits PBMs from requiring or inducing patients with reduced cost-sharing to use their affiliated pharmacy and requires patient consent to transfer a prescription (10). Before this law, pharmacy PBM affiliated pharmacies would transfer prescriptions or obtain new scripts from physicians without patient knowledge.

During the pandemic, it was realized that community pharmacists can prove a great resource in promoting and ensuring public health. Under the PREP (The Public Readiness and Emergency Preparedness) Act, which is active during the current COVID-19 pandemic, pharmacists can order and administer childhood vaccines and immunizations to patients 3-18 years of age including COVID-19 vaccines. Pharmacists are additionally authorized under PREP to order and administer COVID-19 tests, thus positioning community pharmacists to address misinformation.

THE FUTURE

Passing of legislation helping to regulate PBMs will prove helpful to both community pharmacist and patients. Despite recent legislation, it will be interesting to see if and how the State will enforce and monitor these laws. Currently, community pharmacies in Texas have yet to see enforcement of many regulations. Community pharmacists have demonstrated their commitment to public health during this pandemic and hope that their expanded scope of authority will persist after expiration of the PREP Act. Regarding a major potential shift to online pharmacy, community pharmacists are hopeful this display of commitment has increased trust and loyalty from patients and prescribers helping to retain patients in their practice. Challenges will always arise, but this will never deter community pharmacy dedication to the communities they serve.

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| *continued on page 30*

In Memoriam

John Milton,
MD, Internist

died August 27, 2021
at the age of 85.
He was a member of
Potter-Randall County
Medical Society for 53 years.

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Pharmacist Jason Saucedo was born and raised in Amarillo and completed undergraduate studies at Amarillo College and West Texas A&M. He graduated from Texas Tech Health Sciences Center School of Pharmacy in 2016 and became the new owner and pharmacist in charge at Roger's Pharmacy in Dumas,TX in 2018.

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Pharmacists Improve Patient Safety: Promote & Involve Them in Your Healthcare

by Charles F. Seifert, PharmD, FCCP

Next year in July, I will celebrate my 40th year as a licensed pharmacist. I have been a clinical pharmacist rounding with teams of physicians for almost as long. A running joke among my physician colleagues is, "as long as they continue to teach you about drugs in medical school the way they do, I'll always have a job". Currently I round with a group of very talented attending physicians, medical residents and medical students at University Medical Center in Lubbock, TX. We also have pharmacy students and pharmacy residents on our team. We work daily with a variety of other healthcare professionals including nurses, social workers, physical therapists, occupational therapists, speech-language pathologists, and others. We work as a team to take care of approximately 8 to 14 inpatients a day. Medical rounds usually start at 9:30 every morning and last approximately 2 to 2.5 hours. The 3rd-year medical students and 4th-year pharmacy students are like magnets attracted to each other. Each professional realizes that the other has something to offer.

Our role on the medical team is to make sure patients are on the best drug for their condition at the right dose and for the appropriate duration. Recently a patient with a severe blood infection from her urinary tract presented to the hospital and was not improving. She had been started on antibiotics with a high degree of resistance. We recommended that the antibiotics be switched to a more appropriate combination for her condition, and she improved dramatically the next day. We routinely recommend dosage alterations to improve blood pressure control in patients with hypertension. We monitor the effects of drugs and adjust dosages to reflect appropriate blood concentrations. It is a very rewarding job! Unfortunately, not all of the medical teams in our hospital have a pharmacist on their teams or not all the time. As seen below, there is a real need for more pharmacy involvement in the care of patients.

According to the Centers for Disease Control, 82% of American adults take at least one medication and 29% take five or more (1). Adverse drug reactions account for approximately 1.3 million emergency department visits and 350,000 hospitalizations each year. An estimated $3.5 billion is spent on the excess medical costs of adverse drug reactions annually. More than 40% of costs related to out-of-hospital adverse drug reactions might be preventable. The latest figures estimate that between 210,000 and 440,000 deaths occur each year due to preventable medical errors, of which adverse drug reactions are a portion (2). The most recent evidence ranks avoidable medical errors as the 3rd leading cause of death in the U.S. The latest estimates from the Center for Medicare & Medicaid Services are that spending on prescription drugs in the U.S. for 2019 was $369.7 billion, more than nine times the $40.3 billion spent in 1990 (3). Retail prescription drugs accounted for only 10% of the $3.8 trillion spent in 2019 on health care. Unintentional medication misuse can lead to patient harm and additional health care costs.

In the hospital it is estimated that over 100 steps are involved from the time a prescriber decides on a drug until it is administered correctly to the patient, with an error waiting at every step along the way (4). There are multiple checks and balances to ensure a patient's safety, but if those checks are overlooked or missed the patient is at a higher risk of a preventable adverse drug event. The Wall Street Journal in 2016 recommended five steps to make hospitals less dangerous including: adopting structured handoffs, bringing in the pharmacists, getting serious about infection, fighting diagnostic error, and making electronic health records interoperable (5). All of these recommendations seem like great ideas, but the one that caught my attention is to bring in the pharmacists. What Dr. Lieber, the author of the article, was saying is that pharmacists should be placed strategically in every patient care area, rounding with physicians as part of a medical team. In a 1999 study in the *Journal of the American Medical Association*, putting pharmacists on medical teams with physicians on a general medicine unit decreased preventable adverse drug effects by 78% (6). Additional studies have repeatedly confirmed that pharmacists placed in key areas have reduced preventable adverse drug reactions by almost 50%. Bond & Raehl, in their hallmark set of articles published in the mid- to early 2000s, showed clearly that, as clinical pharmacists in hospitals increased, mortality and cost of care decreased dramatically (7,8). As clinical pharmacist staffing increased from 0.5 full-time equivalents (FTE)/100 occupied beds to 4.25 FTE/100 occupied beds, the mortality was reduced from 115 deaths/1000 admissions to 45 deaths/1000 admissions. Several other studies have showed that clinical pharmacists placed in key positions in hospitals, clinics, and long-term care facilities improve care and reduce cost. Every study showed that pharmacists improved care with an average return on investment of $7.98 for every $1.00 spent (9).

We have also evaluated several models of care in which pharmacists are involved. I will share three of our studies that demonstrate that pharmacists involved in patients' care through multiple interventions improve care and reduce cost to the health care system. In cooperation with my colleague, Dr. Brian Irons, we evaluated the management of complicated hypertension patients who

were referred to us by one of our cardiologists (10). These patients were more difficult to manage and were on more antihypertensive drugs than a similar group of patients managed by the cardiologists. Within approximately seven months, significantly more of the patients managed by our group were at the desired blood pressure goals than those managed by the cardiologists. It was not rocket science. We saw the patients more frequently than the cardiologists in that same time period (approximately 11 visits per year compared to the cardiologists whose patients had only 3.5 visits per year). Not only was the blood pressure better controlled by the pharmacist group, we were more accessible and could see the patients more often.

Another project we implemented was to guide physicians to the appropriate treatment plans through the use of the computer. We discovered that physicians were not appropriately treating a very serious condition known as *Closteroides difficile* (*C. diff*) colitis (11). It has a very high mortality if not treated correctly. We worked very closely with the laboratory to only report positive results in patients with watery diarrhea (12). If the samples were positive, the computer system automatically launched a standardized protocol that the physicians should follow, while giving them the option not to follow the protocol. If they did not follow the protocol, they had to state the reason. In those patients where the protocol was followed, the mortality was significantly reduced from 11% to 4% (12). The care of patients with *C. difficile* colitis and diarrhea was streamlined to improve care and reduce mortality.

The last project I'd like to discuss was a large project that involved pharmacists in an effort to reduce admissions and emergency room visits to the hospital by improving outpatient navigation (13). The project involved administrators, physicians, nurses, pharmacists, and community health workers. The community health workers were further trained as patient navigators for patients who frequently visited the emergency department or hospital. The patient navigators were required to visit the homes of the patients at least once, and all patients had a therapeutic review by the pharmacy team. Pharmacy residents went to the homes of patients who the patient navigators deemed needed help with their medications. More complicated patients were reviewed every month by the entire team. Both emergency room visits and hospital admissions were significantly reduced in these patients, compared to before patient navigation had begun. The estimated cost avoidance to the hospital for the full three years of the program was $3,799,719.

You can see through my own experience of almost 40 years that pharmacists placed in key areas definitely improve patient care and reduce costs. Unfortunately, not all of these areas have advanced trained pharmacists. For your care to be optimal, pharmacists must be a critical component in the evaluation and treatment of your condition. This is even more important in high-risk areas

| *continued on page 34*

like hospitals and nursing homes. Even for routine care in the clinic, pharmacists are important to protect your health and safety. Don't blindly take drugs without your pharmacist's evaluation and input. Don't hesitate to question what your physician is prescribing and why. Is it the best drug? Is it the right drug? Is it the right dosage or dosage form? Are there any interactions with other drugs or food? In the year 2021, while the COVID pandemic is still going on, don't forget that medical errors are still responsible for a large number of deaths in the United States. The pharmacist plays a critical role in reducing that number. You should promote advanced trained pharmacists in key areas and demand that they be routinely involved in your own care.

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In Memoriam

Andrew Stenhouse,
MD, Internist

died September 15, 2021
at the age of 87.
He was a member of
Potter-Randall County
Medical Society for 47 years.

CHARLES F. SEIFERT, PHARM.D., FCCP: *Dr. Seifert was born and raised on a ranch outside of Hettinger, ND. He received his Bachelor of Science in Pharmacy from North Dakota State University in 1982 and his Doctor of Pharmacy from The University of Texas at Austin and The University of Texas Health Science Center at San Antonio in 1984. He completed an ASHP accredited clinical pharmacy residency at The University of Missouri at Kansas City in 1985. He has been a faculty member at the University of Oklahoma and the Director of Clinical Pharmacy Services at a regional hospital in Rapid City, SD. Currently he is Professor of Pharmacy Practice and the Founding Regional Dean for Lubbock Programs in the Jerry H. Hodge School of Pharmacy at Texas Tech University Health Sciences Center.*

Dr. Seifert was one of the first Board Certified Pharmacotherapy Specialists in the nation and is a Fellow of the American College of Clinical Pharmacy. He has over 140 published journal articles, book chapters, abstracts, and newspaper and magazine articles.. His clinical interests include adult internal medicine, gastroenterology, nutrition, clinical toxicology, anticoagulation, and cardiopulmonary therapeutics. His current research interests include nursing education and accuracy in the delivery of medications through enteral feeding catheters, interprofessional collaborative practice, healthcare system utilization, patient navigation, opioid overdose risk and naloxone dispensing practices. Dr. Seifert has received numerous awards for his teaching, practice, service, and research; most recently the 2021 TTUHSC President's Excellence in Interprofessional Teamwork Award.. He met his wife Cheryl at church in San Antonio and has been blessed with four beautiful children and two grandchildren. He is an accomplished vocalist and is very active in the Celebration Choir at Christ the King Cathedral. He enjoys watching his youngest compete as a hunter/jumper in AQHA, writing contemporary Christian music, Big XII sports and is a die-hard Minnesota Vikings football fan.

Spotlight on New Members

The following were approved for membership on January 19, 2021:

REGULAR MEMBERSHIP:

BEGGS, DANIEL A., M.D
GASTROENTEROLOGY (GE)
6700 W. 9th, Amarillo TX 79106 (Rejoined). Graduated from University of Kansas School of Medicine, Kansas City KS 1992. Internship and Residency at University of Kansas, Kansas City KS 1993-1997.

KHAZNADAR, MOHAMEDAOUF, M.D.
INTERNAL MEDICINE (IM)
1901 MediPark, #124, Amarillo TX 79106 (Rejoined). Graduated from University of Aleppo, Syria Arab Republic 1980. Residency at Texas Tech University Health Science Center, Amarillo TX 1993-1996.

KOLZE, CHRISTOPHER, M.D.
GENERAL SURGERY (GS)
6 Medical Drive, Amarillo TX 79106. Graduated from Texas Tech University Health Science Center, Lubbock TX 2012. Internship and Residency at University of Tennessee Medical Center, Knoxville TN.

RAWAL, PARESH, M.D.
INTERVENTIONAL CARDIOLOGY (IC)
1901 Port Lane, Amarillo TX 79106. Graduated from M. P. Shah Medical College, Saurashtra University, Jamnagar, Gujarat, India 1989. Residency and Fellowship at Loyola University Medical Center, Maywood IL 1990 Internal Medicine - and Cardiovascular Diseases 1994-1997.

WHEAT, ERICA GRIFFIN, M.D.
GENERAL SURGERY (GS)
6 Medical Drive, Amarillo TX 79106. Graduated from Texas Tech University Health Science Center, Lubbock TX 2014. Residency and Fellowship at University of Texas Southwestern, Dallas TX 2014-2019.

LIFE MEMBERSHIP:

LARY, MICHAEL, M.D.
GENERAL SURGERY (GS)

The following were approved for membership on March 23, 2021:

FIRST YEAR MEMBERSHIP:

CASSUTO, JAMES, M.D.
DIAGNOSTIC RADIOLOGY/NUCLEAR RADIOLOGY (DR/NR)
1901 MediPark, #2050, Amarillo, TX 79106. Graduated from New York Medical College, Valhalla, NY 2015. Internship at Atlantic Health System, Morristown, NJ 2015-2016. Residency at Jackson Memorial Hospital, Miami, FL 2016-2020 (Radiology and Nuclear Medicine).

LENNARD, LUKE A., M.D.
RADIOLOGY (R)
1901 Medi Park, #2050, Amarillo, TX 79106. Graduated from Texas Tech University Health Science Center, Lubbock, TX 2014. Internship at Medical College of Georgia, 2014-2015. Residency at Virginia Commonwealth University, Richmond, VA 2015-2019. Fellowship at University of Alabama at Birmingham, Birmingham, AL 2019-2020 (Abdominal Imaging).

REGULAR MEMBERSHIP:

DIEGUEZ, JAVIER, M.D.
PULMONOLOGY (PUD)
6700 W. 9th, Amarillo, TX 79106. (Rejoined). Graduated from St. George's University School of Medicine, St. George's, Grenada 2007. Internship, Residency and Fellowship at St. Michael's Medical Center, Newark, NJ 2007-2013.

LOPEZ, NICOLE, M.D.
FAMILY MEDICINE (FM)
1400 S. Coulter, Amarillo, TX 79106. Graduated from Texas Tech Health Science Center, Lubbock, TX 1999. Residency at Texas Tech University Health Science Center, Amarillo, TX 1999-2002.

PRUITT, SPENCER, M.D.
PEDIATRICS/PEDIATRIC CRITICAL CARE (PD/CCP)
400 S. Coulter, Amarillo, TX 79106. Graduated from McGovern Medical School at University of Texas Health Science Center, Houston, TX 2010. Internship and Residency at Our Lady of the Lake Medical College, Baton Rouge, LA 2010-2014. Fellowship at Baylor College of Medicine, Texas Children's Hospital, Houston, TX 2014-2017 (Pediatric Critical Care).

SIGLER, MARK B., M.D.
PULMONOLOGY (PUD)
1400 Coulter, Amarillo, TX 79106. Graduated from Creighton University School of Medicine, Omaha, NE 2009. Internship at University of Oklahoma, Tulsa, OK 2009-2010 (Emergency Medicine). Residency at Scott & White, Temple, TX 2010-2013 (Internal Medicine). Fellowship at Texas Tech University Health Science Center, Lubbock, TX 2013-2016 (Pulmonology/Critical Care).

RETIRED:

CAZZOLA, HARRY, M.D.
OBSTETRICS/GYNECOLOGY/FAMILY MEDICINE (OBG/FM)
1 Tascocita Circle, Amarillo, TX 79124.

KIBBEY, RICHARD, M.D.
UROLOGY (U)
2 Edgewater, Amarillo, TX 79106

The following were approved for membership on May 18, 2021:

FIRST YEAR MEMBERSHIP:

LEE, JAY, D.O.
ANESTHESIOLOGY/PAIN MANAGEMENT (APM)
6826 Plum Creek Drive, Amarillo TX 79124 Graduated from University of North Texas Health Science Center, Texas College of Osteopathic Medicine, Fort Worth TX 2016. Internship at Waterbury Hospital, Waterbury CT 2016-2017 (Internal Medicine). Residency at Beth Israel Deaconess Medical Center, Boston MA 2017-2020 (Anesthesiology). Fellowship at University of Rochester Medical Center, Rochester NY 2020-2021 (Pain Medicine).

YHIP, JAMES P., M.D.
CARDIOLOGY/INTERVENTIONAL CARDIOLOGY (CD/IC)
1901 Port Lane, Amarillo TX 79106. Graduated from Loma Linda University School of Medicine, Loma Linda CA 1991. Internship (Rotating) at Santa Clara Valley Medical Center, San Jose CA 1991-1992. Residency at MD Anderson Cancer Center, Houston TX 1992- 1993. Residency at Cedars-Sinai Medical Center, Los Angeles CA 1993-1996. Fellowship at University of Texas Hermann Hospital, Houston TX 1996-1999. Fellowship at Arizona Heart Institute/Good Samaritan Hospital, Phoenix AZ 1999-2000.

REGULAR MEMBERSHIP:

ELLINGTON, SUSAN ELIZABETH, M.D.
PEDIATRICS (PD)
7659 Hillside Road, Suite 300, Amarillo TX 79119. (Rejoined) Graduated from University of Texas Health Science Center, Long School of Medicine, San Antonio TX 1992. Internship and Residency at Children's Hospital, Dallas TX 1992-1995. Fellowship at Texas Scottish Rite Hospital, Dallas TX 1998-1999.

RETIRED MEMBERSHIP:

PATTON, STEVEN, M.D.
ANESTHESIOLOGY (AN)

The following were approved for membership on July 20,2021:

TRANSFER MEMBERSHIP:

SCHNIEDERJAN, JOSEPH P.
(RADIOLOGY) (R)
Transfer from Harris County Medical Society. 1501 Coulter, Diagnostic Imaging, Amarillo, Texas 79106. Graduated from University of Texas Health Science Center, San Antonio, Texas 2004. Internship at University of Texas Health Science Center, Houston, Texas 2004-2005 (Transitional Year). Residency at Baylor College of Medicine, Houston, Texas 2005-2009.

LIFE MEMBERSHIP:

GIRON, MILTON
(NEPHROLOGY) (NEP)

McKINLEY, JOHN P.
(GENERAL SURGERY) (GS)

The following were approved for membership on September 21, 2021:

FIRST YEAR:

O'DELL, MONTANA JOE, M.D.
FAMILY MEDICINE (FM)
215 Coulter, Suite 100, Amarillo TX 79106. Graduated from Texas Tech University Paul L. Foster School of Medicine, El Paso TX 2018.

TRANSFER:

OSTEEN, JAMES, M.D.
HOSPITALIST (HO)
1000 S. Coulter, #100, Amarillo TX 79106. Transfer from Dallas County Medical Society. Graduated from Texas Tech University Health Science Center, Lubbock TX 2015. Residency at Baylor University Medical Center, Dallas TX 2015-2018 (Three Year Program, Hematology and Oncology).

REGULAR MEMBERSHIP:

HANRAHAN, JEFFERY, M.D.
PEDIATRICS, HEMATOLOGY/ONCOLOGY (PHO)
BSA/Harrington Cancer Center, 1751 Wallace Blvd., Amarillo TX 79106. Graduated from St. George's University School of Medicine, St. George's, Grenada 1998. Residency at University of New Mexico, Albuquerque NM 2001-2004.

SESSIONS, CRAIG, M.D.
SURGERY, ORTHOPEDIC/SURGERY (ORS)
3501 Soncy, #404, Amarillo TX 79119. Graduated from Texas Tech University Health Science Center, Lubbock TX 1994. Residency at Texas Tech University Health Science Center, Lubbock TX 1994-1999.

LIFE MEMBERSHIP:

BYRD, BILL, M.D. - NUCLEAR MEDICINE (NM)

Happy Holidays

from the Potter-Randall County Medical Society Resident Members

Ikha Al-Azzawi, MD
Abdulelah Almutairi, MD
Shyla Arismendez, MD
Steven Cummings, MD
Daniyah Elagi, MD
Martha Gonzalez, DO
Jacob Hall, MD
Joe Lin, DO
Koley"Chance" Pack, MD
Matthew Thigpen, MD
Kerolos Abdelmalek, MD
Khaled Alhbshi, MD
Hamsa Aljumaili, MD
Muhammad Amin, MD
William Baladron Guerra, MD
Dhara Dave, MD
"Jade" Dharmarpandi, MD
Muhammad Khan, MD
Tarek Mansi, MD
Nandar Mon, MD
Tarek Shihab, MD
Moutasim Souliman, MD
Hina Yousuf, MD
Dalya Azel, DO
Deepika Kaushal, DO
Jonathan Werner, MD

Justin Williams, MD
Christina Young, MD
Lynn "Kevin" Benson, MD
Oluwatosin"Tosin" Bewaji, MD
Matthew Goldfinger, DO
Schyler Zane Grodman, MD
Mithra Lakshmi Narasimhan, MD
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Safanah Alshinqity, MD
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Carly Hubbard, DO
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Joshua Sorenson, MD
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Eman Alhussain, MD
Ola Al-Jobory, MD
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Nayeli Cabrera, DO
Pedro Calles, DO
Ryan Corjay, DO
Andy Huang D,O,
Allison Ogle, DO
Rachel Walker, DO
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Adrian Mola De La Rosa, MD

Shree Dharmarpandi, MD
Mousab Diab, MD
Noor Dweik, MD
Michael W. Ebrahim, MD
MD Rockyb Hasan, MD
Falah Abu Hassan, MD
Basheer Mohammed, MD
Amaka Odimegwu, MD
Anjali Roy, MD
Sadia Tanami, MD
Sinan Yaqoob, MD
Alexis Borden, DO
Kristin LeBrasseur, DO
Bless Onaiwu, MD
Jessica Farlee, MD
Ashton Hierholzer, MD
Julia Magness, DO

Happy Holidays

from the Potter-Randall County Medical Society Retired Members

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Dr. John J. Alpar
Dr. & Mrs. Masoud Alzeerah
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Dr. & Mrs. William East
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Stem Cell Research at the Texas Tech School of Pharmacy

by Hiranmoy Das, PhD

For years now, stem cell research has been on the cutting edge of regenerative medicine. One of the labs contributing to the development of stem cell applications is that of Hiranmoy Das, PhD, FAHA, a professor at the Jerry H. Hodge School of Pharmacy and a member of *National Academy of Inventors (USA).* Dr. Das's lab focuses on research using various types of non-embryonic stem cells, including corneal epithelial stem cells (CESCs). These cells are taken from a region of the eye called the limbus, which surrounds the cornea, the clear tissue that covers the pupil and iris. The limbus serves as a reservoir for CESCs and provides replacement of cells to the cornea when needed.

Dr. Das's research using these cells has moved into clinical trials in collaboration with Sloan W. Rush, M.D. at the Panhandle Eye Group in Amarillo, TX, and with Jennifer Chain, Ph.D. at the Oklahoma Blood Institute in Oklahoma City, OK. The trial focuses on the treatment of dry eye disease (DED), which is estimated to affect half of the population and has an annual financial burden of as much as $50 billion in the United States. While current treatments for DED exist, they are not consistently effective. Recent studies from Das's group isolated CESCs and used their secretory products, including growth and anti-inflammatory factors, to make a solution that can be utilized like eye drops. Patients suffering from DED, as identified by Standardized Patient Evaluation of Eye Dryness (SPEED™) and Ocular Surface Disease Index (OSDI©), used the treatments four times a day every day for twelve weeks. Das's team reported an average improvement of 23% in DED patients as reported by SPEED™ and 17.1% when assessed by OSDI© standards (as compared to the patients' initial baseline symptoms). The team currently plans to confirm these encouraging results with further trials and hopes to translate this initial success to other diseases, such as a genetic condition called Fuchs' dystrophy that causes the deterioration of corneal cells on the surface of the eye.

A recently developing area of research in Das's lab in Amarillo is related to the COVID-19 pandemic. One of COVID-19's key characteristics is the "cytokine storm," which refers to a dramatic increase in pro-inflammatory factors in the cardiovascular system. This reaction to the virus can have long-lasting side effects, dubbed "long COVID," symptoms of which can include chronic fatigue and shortness of breath. Research carried out in Das's lab involves the establishment of a cell line that replicates the activity of COVID-19 in the cells of the human body. For the development of this project Dr. Das is collaborating with the *Center of Excellence for Covid Research* TTUHSC-SOM group including Drs. Naguib, Wright, Vasylyeva, Bhaskaran, Dai, and Dharmapandi. This process can give valuable insight into some of the mechanisms of the disease and may allow for future development of possible COVID treatments.

The other regenerative treatment approach that may apply to long COVID involves other types of stem cells: dental pulp-derived stem cells (DPSCs), which are isolated from wisdom teeth, and hematopoietic stem cells (HSCs), which are taken from umbilical cord blood. These cells support the regeneration of tissues while suppressing cellular inflammatory responses, and could provide much-needed support in the treatment of COVID-19. While vaccination against COVID has proven effective in preventing and mitigating acute infection, treatments for long COVID remain elusive. This is another area where stem cell treatments may prove beneficial.

In the long term, the lab hopes to provide a clinical overview of COVID and to see if their stem cells can contribute to treatments for the condition. Another long-term goal is to analyze plasma samples taken from human patients, to study the chronic inflammatory response to COVID and to see if it can be mitigated using stem cells.

An established specialty in the Das lab is the application of stem cell treatments for bone and joint diseases, specifically for osteoporosis and rheumatoid arthritis (RA). Osteoporosis is the result of an imbalance of activity of two cell types: osteoblasts, which originate from bone-derived stem cells (also called mesenchymal stem cells), and osteoclasts, which originate from myeloid cells and which break down bone. In healthy bones, these cells work in tandem to regenerate bone and maintain skeletal integrity, but in osteoporosis, osteoclast activity outpaces osteoblast activity, causing decreased bone density and an increased likelihood of fractures. Early *in vitro* results from Das's lab show that dental pulp derived stem cells (DPSCs) isolated from third molar teeth have the potential to differentiate towards cells that share characteristics with osteoblasts. Additionally, DPSCs seem to inhibit the formation of osteoclast cells from undifferentiated monocytes, though more studies need to be conducted to confirm these results.

RA is an extremely common autoimmune condition that, if untreated, can severely and permanently damage joints in the body. It is caused by hyperactive immune cells that target the patient's joints by producing inflammatory factors that tag joint tissues for destruction. The cells then break down joint tissues (cartilages and bones), which can lead to decreased mobility and pain in the affected joints. Research conducted by Das's lab shows that DPSCs suppress cell

processes that lead to the production of inflammatory factors. DPSCs also secrete growth factors that contribute to the health of local cells, which could be key to preventing the chronic joint damage seen in severe RA.

Another project involves a transcription factor called Kruppel-like factor 2 (KLF2), which prevents the differentiation of monocytes into osteoclasts. This differentiation is linked with autophagy, a repair process in cells that breaks down damaged organelles. Das's lab has shown that KLF2 regulates autophagy and that DPSCs can increase KLF2 expression. This DPSC-mediated increase in KLF2 expression prevents osteoclastic differentiation and is likely to decrease the severity of osteoporosis and rheumatoid arthritis.

The Das lab also focuses on central nervous system research. Many diseases and conditions that affect the brain (such as stroke, Alzheimer's disease, and Parkinson's disease) involve high levels of inflammation in the brain. The brain has its own immune environment, separate from the rest of the body, which leads to a type of inflammation called neuroinflammation. Regulating neuroinflammation is extremely important, as high inflammatory activity can have adverse effects on all the cell types in the brain. DPSCs have a well-reputed ability to combat inflammation, but they also secrete specific factors that support the growth of neurons and other cell types in the brain. Das's lab focuses primarily on the interactions between DPSCs and astrocytes, brain cells that primarily act to protect and support neurons. They have collected encouraging *in vitro* data showing that DPSCs have a protective effect on astrocytes that are undergoing intense cellular stress similar to that seen in brain trauma and neurodegenerative diseases. The lab plans to perform a study using mice to see if these effects on astrocytes are also seen *in vivo*.

Finally, Das's lab has been working on potential therapies for the treatment of inflammatory bowel diseases (IBD). The two primary manifestations of IBD are Crohn's disease and ulcerative colitis (UC). Crohn's disease consists of uncontrolled inflammation that runs in patches through the small and large intestines, while UC is characterized by continuous inflammation confined to the large intestine. Both conditions cause abdominal discomfort and irregular bowel movements that can make managing day-to-day tasks difficult for those affected. Worse, if untreated, these diseases can cause tissue damage in the lining of the intestine with adverse long-term consequences. While there are treatments to alleviate the symptoms of these diseases, there is no known cure for them. Das's lab hopes to change that with the introduction of DPSCs to treat IBD. As discussed above, DPSCs have potent anti-inflammatory capabilities and can also promote tissue repair. Early experimental results have shown reductions in the activity of inflammatory signaling pathways. One animal trial using the treatment has been completed, the results of which are still under analysis. A breakthrough on this front would be monumental, as it would be a major step towards a cure for a disease that has thus far been difficult to treat effectively in many patients.

As regenerative medicine becomes more of a focus in pre-clinical and clinical research, stem cell research is rapidly expanding. While research has progressed, some studies involving stem cells have run into difficulties, as clinical trials have often lacked the efficacy seen in earlier stages of testing. It's important to remember, however, that stem cell research is still a young and developing field that will likely improve with optimization, and Das's teams are making important contributions to developments in the field.

Hiranmoy Das, MSc, PhD, a fellow of American Heart Association, and a member of National Academy of Inventors, USA, currently a professor in SOP, TTUHSC. Dr. Das is a world-famous scientist in the field of transcription biology and stem cell research. He has published his research articles in numerous high impact Journals, multiple book chapters, edited two books and published five patents. He is a founding member of 3 startup companies and commercializing his university-based research. Dr. Das currently has multiple NIH grants, and serving in one of the NIH Study Sections as a chartered member.

Medication Cleanout: 13 Years and Running

by Jeanie Jaramillo-Stametz, PharmD, MS

A fourteen-year-old male had a bad day at school, where he was bullied by classmates. After coming home, he went to the family medicine cabinet and ingested the remaining contents of a vial of his grandmother's heart medication, amlodipine. She had passed away two years prior after coming to live with the family to receive hospice care. Unfortunately, her medications had never been removed from the home. His mother found him unconscious in his room after coming home from work several hours later. She called 9-1-1; her son was taken to the emergency room where he received treatment, but, ultimately, he did not recover and lost his life. In the interest of patient confidentiality, this is a fictitious scenario, but poison centers and hospitals manage cases like this across the U.S. on a daily basis. Similar cases have occurred right here in the Panhandle of Texas.

As the director of the Texas Panhandle Poison Center (TPPC) of the Jerry H. Hodge School of Pharmacy in Amarillo, I review charts regularly on the management of cases of unintentional poisoning of young children who access medications around the home. I also see exposures that occur due to medication misuse, abuse, and suicidal gestures. In 2008, our TPPC educator and I sat down to discuss what our poison center could do to reduce these preventable medication-related poisonings. We each did some research and found that medication take-back programs were being conducted in Wisconsin and Maine. After speaking with representatives from these initiatives, we pursued development of a program here in the Panhandle. One of our challenges was a restriction in the Controlled Substances Act that prohibited anyone, other than law enforcement, from having in their possession a controlled substance that was prescribed for someone else. There were also environmental concerns that had to be considered, as well as compliance with Texas State Board of Pharmacy rules and the Texas Commission on Environmental Quality. We developed a plan to address the myriad of regulatory hurdles, then gained support from administration and finally began working on the program.

In March of 2009, the first Medication Cleanout event of TTUHSC was conducted at two locations in Amarillo. It was a resounding success. Since that time, events have been conducted twice a year, and the program has been expanded to Abilene and Lubbock as well. Although events were initially held in smaller communities too, like Pampa and Canyon, limited resources have prevented continuation in these areas. From inception to date, 74 events have been completed. Over 21,000 participants have come through the drive-through lines and dropped off medications for appropriate disposal. This has resulted in the collection of more than 58,000 pounds of non-controlled substances (including prescription and over-the-counter medications), 3,600 pounds of controlled substances, and 5,800 pounds of medical sharps. Our Medication Cleanout events fulfill a critical need for Panhandle residents. In fact, curbside surveys indicate that a majority of participants believe that protecting the environment is the most important reason to bring medications for disposal and that, had the events not been available, participants would simply have "kept" their medications.

One of the most impressive collections received from a single household was that from "car 188" from an event in Amarillo (see images 1 and 2). These medications were screened to ensure they were not from a business, such as a pharmacy or nursing home. From this single household, almost 50,000 units (pills, patches, milliliters, etc.) were collected. Using wholesale acquisition costs at that time, the estimated value was more than $65,000. A significant proportion of the these were controlled substances. Had these items been diverted, they would have had an estimated street value of ~$385,000 (See Tables 1 and 2 for a detailed breakdown).

Image 1:

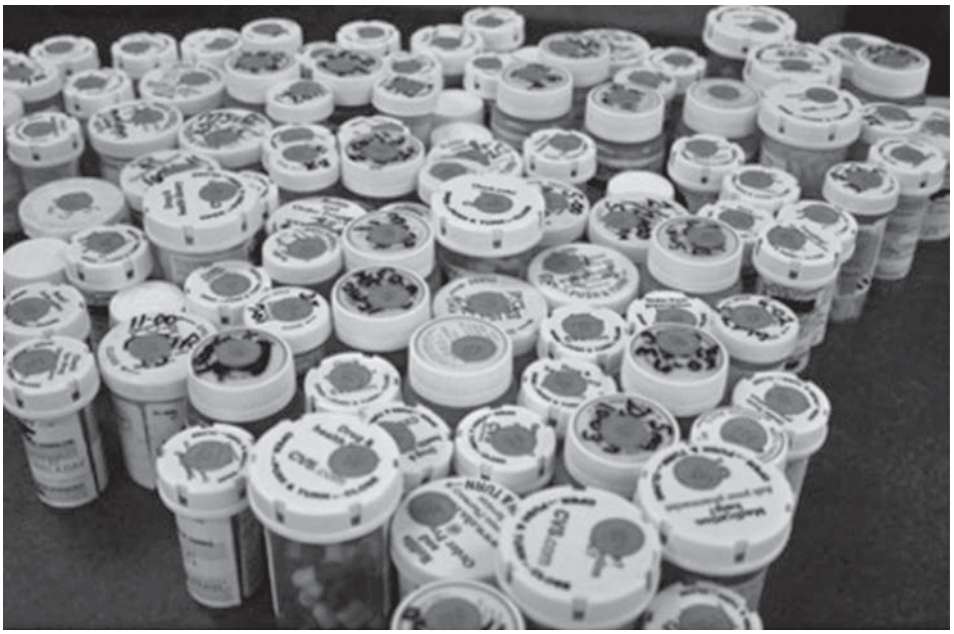

Image 2:

Although most of the general public is aware that they should not flush medications down the drain or throw them in the household trash, many are not aware of how they should dispose of their medications. Therefore, they simply allow them to accumulate in their homes. This is a dangerous practice, and this is exactly the population the Medication Cleanout program is designed to reach.

Another well-known issue that is evident through Medication Cleanout collections is medication non-adherence. Non-adherence is defined as failure "to adhere to a prescribed dose and interval" of a medication regimen (1). It's estimated that non-adherence rate is around 50% for most medications, increasing to nearly 80% when the medication is used to treat a condition without overt symptoms (like high cholesterol) (1). And males are 1.3 times more likely to be non-adherent than females (2). At medication collections events, it is not unusual to see 10 to 20 bottles of the same medication for the same person – all unopened. These are usually from mail-order pharmacies and are for chronic conditions. This may result from the use of auto-refill features in which a new supply is shipped to the patient when the computer calculates they should be almost out. Such systems generally do not require contact with patients to determine if they have a remaining supply, if they are still using the medication, or even if they are still alive. This appears to have played a role in the "car 188" example above. Such cases also contribute to medication waste and unnecessary use of healthcare dollars.

Since our poison center is part of an academic institution, it has been important to include teaching and research as components of the Medication Cleanout program, in addition to the community service aspect. Students have been recruited as volunteers throughout the program with a concerted effort to include not only pharmacy students, but nursing, medicine, and other allied health students as well. Volunteers see first-hand the incredible volume of medications that remain unused and the age of the medications, many of which expired prior to the birth of our students! Research efforts have focused primarily on documenting the collection of controlled substances including opioids. Medication Cleanout staff led a multi-state initiative investigating the collection of controlled substances across six states from 2011 to 2015, the results of which were published in the *Journal of Substance Use* (3). Over 280,000 units were collected and logged, revealing that morphine prescriptions had the greatest average units dispensed at 85 per prescription. Hydrocodone had the greatest number of prescriptions and pregabalin had the highest amount of waste (74.8% of prescribed quantity). On average, more than half of all controlled substance prescriptions remained unused. Since that time, the U.S. Drug Enforcement Administration (DEA) has re-scheduled hydrocodone as a C-II, making requirements for prescribing and dispensing more stringent. Subsequently, the Medication Cleanout program has seen a marked drop in hydrocodone col-

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Controlled Substances

Product:	Strength:	Quantity:	Est. Value:
diazepam	5	2385	$140.12
hydrocodone/apap	10/325	500	$349.50
hydrocodone/apap	5/500	22	$3.11
Lyrica	75	84	$235.68
morphine	30	6699	$3,678.58
morphine	15	3338	$966.90
MS Contin	30	3	$9.36
MS Contin	15	6	$9.85
oxycodone/apap	5/500	802	$322.81
temazepam	30	180	$90.09
carisoprodol	350	50	$50.00
TOTAL		14069	$5,855.99

Table 1:

lections, but conversely, has seen a marked increase in tramadol and acetaminophen/codeine collections.

Upon implementation, it was thought that the Medication Cleanout program would be a temporary measure, of perhaps a few years, to fill the gap until convenient medication disposal options became available. Thirteen years later, there are now drug disposal kiosks at some pharmacies and law enforcement agencies, but these are not nearly widespread enough to meet demand, and they are not well-known. The DEA has also now developed a national database locator tool to help members of the public locate a disposal site near them (https://takebackday.dea.gov; Collection Site Locator link). While this tool includes registered collectors for medication disposal, it does not include sites located at law enforcement agencies. In Texas, the State Board of Pharmacy has added a requirement to the Texas Administrative Code that anyone dispensing C-II medications must provide written notice regarding the safe disposal of that substance, to include physical locations or an internet address for a searchable database of locations (4). This requirement is waived for those entities that have a drug disposal kiosk on-site or those that provide a mail-back envelope or chemical that renders the medication unusable or irretrievable.

Over the next five to ten years, we hope to see expanded availability of drug disposal kiosks at all pharmacies. But that alone will not be enough. We need to educate the public on the extreme importance of disposing of their unused or un-needed medications quickly and appropriately. The loss of even one life is one too many.

For more information on the Medication Cleanout program, readers may contact Jeanie Jaramillo-Stametz at the Jerry H. Hodge School of Pharmacy in Amarillo. Email: jeanie.jaramillo@ttuhsc.edu or call the Medication Cleanout line at (806) 414-9495.

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Dr. Jaramillo-Stametz graduated from the School of Pharmacy at Texas Tech University Health Sciences Center in 2001. She completed a residency in Drug Information and then began working as the managing director of the Texas Panhandle Poison Center, in a joint position as assistant professor at TTUHSC. She has served as director of the Medication Cleanout program since its inception in 2009. Her research interests include medication-related poisonings and drugs of abuse.

Non-Controlled Rx Substances

Product:	Quantity:	Est. Value:	Product:	Quantity:	Est. Value:
Antacids	446	$2,428.81	Hormones/antagonists	2568	$666.22
Antibiotics	405	$1,177.04	Miscellaneous	3527	$5,768.70
Anticholinergic drugs	168	$3,680.93	MVI: adult	91	$83.54
Anticoagulants	3977	$4,064.26	Cyclobenzaprine	356	$538.53
Antidepressants	570	$2,595.63	Methocarbamol	419	$714.67
Antifungal	245	$326.28	Other skeletal muscle relaxant	3868	$5,575.44
Antihistamine	6067	$6,456.57	Opioids (tramadol)	1279	$2,713.26
Antineoplastics	20	$423.16	Oral hypoglycemic: biguanide	79.5	$94.01
Antiparasitics	745.5	$1,078.09	Colchicine	14	$4.44
Asthma therapies	1736	$8,508.77	Ibuprofen	93	$5.13
Cardiovascular	6020.5	$11,096.50	Indomethacin	13	$30.36
Cydic Antidepressants	232	$248.06	Naproxen	248	$568.09
Diuretics	951	$203.76	Other B complex vitamins	134	$148.23
Electrolytes	64	$25.49	Buspirone	49	$97.54
Gastrointestinal	388	$118.99	Phenothiazine	115	$87.44
			TOTAL	34889	$59,527.91

Table 2:

Bootstrapping Our Way Out of the Pandemic Testing Crisis

by Todd Bell, MD and Eric MacLaughlin, PharmD

As the calendar year 2019 was dying, a "once in a generation" pandemic was born. By January 2020, it was clear that the outbreak of a novel beta coronavirus would affect the globe. Even with weeks to prepare, though, few recognized the magnitude of the impact. Beyond the predicted stress on the health care system, COVID-19 impacted global supplies and consumer products. Most Americans experienced the shock of walking down the paper-products aisle at the grocery store where empty shelves bore testimony to the global interconnectedness of supply chains and the human foible of "panic buying." Although less well recognized by the general public, supply chain issues also altered the availability of medical supplies. Public health messaging regarding masks was, with the good intention of preserving limited supplies for hospitals but unfortunate consequences, biased to highlight that we initially had no compelling data to support the use of masks by the general public. Subsequently, improvised masks, 3-D printed ventilator splices, homemade cotton swabs made of plastic sticks rolled in glue and synthetic cotton fuzz, and a plethora of grassroots research regarding the virus led some to deem COVID-19 the "do it yourself" pandemic.

By the end of March 2021, the Panhandle had begun to experience delays and backorders in viral transport media (VTM). Viruses are particles of significant fragility, relying on the host cell to be able to remain viable. Survivability outside of the cell is measured in hours. Desiccation is one of the most predictable and reliable means of destroying a virion. Polymerase Chain Reaction (PCR) is now a basic testing method to amplify the nucleic material from a pathogen of concern. A primer matching a known section of nucleic material in the pathogen of interest creates the initial binding site from which a florescent labeled nucleic acid segment can grow. If the pathogen's nucleic material is present, the nucleic material will eventually be amplified to the threshold at which the fluorescent labeling can be identified. Once a unique genetic sequence of the virus has been elucidated then, a diagnostic test can be developed. This test methodology, though, requires enough intact pathogenic nucleic material for the process to work. Sending "dry" samples of the virus to the lab increases the likelihood that the nucleic material which forms the blueprint of the test amplification will be damaged and the test will not work. Likewise, overgrowth of other nucleic material (e.g., bacterial contaminants) will potentially interfere with the assay by increasing the "background" noise with amplification of random snippets of genetic material. Finally, PCR test assays are designed and tested against specific sample types with specific transport media. Optimal test performance depends on adhering to the original "recipe" used in the development of a test assay.

After initial missteps in the development of a COVID-19 PCR assay, the CDC rolled out a reliable test for diagnostic testing in March 2020. Although the burden of disease activity centered on the Northeast and Northwest coasts, it was clear that any portion of the country could be affected. When a four-hour plane ride can move a citizen from one coast to another, anyone in the country with a cough or fever can be a potential COVID-19 patient. Soon shortages developed in PCR testing supplies, including VTM. VTM supplies were on backorder and shipments were delayed.

Since COVID-19 testing became first priority, many other diagnostic tests were deferred; so I began calling colleagues who might have unused VTM in their clinic or laboratory. Quickly exhausting those supplies, I called Dr. Eric MacLaughlin, Chair of the Department of Pharmacy Practice at TTUHSC School of Pharmacy, to see if any researchers in his department might have VTM. He agreed to survey the faculty. He soon called me back to say that he had not found any hidden troves of VTM, but that he had a faculty member who was comfortable producing the material. Dr. Uli Bickel had done his medical training in Germany before joining the faculty at the TTUHSC School of Pharmacy. Dr. Bickel volunteered that the actual recipe for VTM was relatively simple, requiring only basic ingredients and fastidious attention to contamination control. Drs. Bickel, MacLaughlin, Mikala Conatser (pharmacy practice

| *continued on page 44*

In Memoriam

James Luce,
MD, Oncologist

died January 21, 2021
at the age of 98.
He was a member of
Potter-Randall County
Medical Society for 31 years.

faculty specializing in sterile compounding), and two graduate students readily agreed to make a batch.

The introduction of a variable into a diagnostic strategy, though, is fraught with uncertainty. Would the solution be sterile? Would the solution have an optimal testing performance to correlate with the CDC-derived PCR assay? To ensure the viability of the "homebrew" VTM, we needed to test the VTM against negative samples and positive samples, as well as to perform sterility testing on each batch produced. The sterility testing was easily performed in the West Texas Influenza Center Laboratory at TTUHSC, Amarillo. The positive and negative tests would require some assistance. Although multiple laboratories in town perform PCR testing, the majority use "pre-packaged" kits. A commercial PCR platform is calibrated to perform a PCR test with a proprietary PCR ingredient kit. Only a few labs in our community have the expertise to customize their platform to match a novel diagnostic assay. Those labs that did have that capacity did not have access to positive and negative controls to calibrate their assay by which we could perform control testing on the VTM.

We then reached out to the Texas Tech University Bioterrorism Response Laboratory in Lubbock, TX. The Laboratory Response Network (LRN) system is designed to provide testing capacity to public health systems across Texas. An unsung hero of pandemic preparedness, the LRN system frequently fights budget challenges and public messaging to provide an invaluable resource to the citizens of Texas in times of crisis. Dr. Reinoso Webb at the LRN was kind enough to arrange positive and negative testing of clinical COVID samples to verify the lack of contamination or interference in assay processing.

By April 2020, as the global availability of VTM had plummeted, our colleagues in the School of Pharmacy were producing 20,000 vials of VTM per week. Powered by a rotating cast of volunteer faculty and staff, VTM was produced in bulk and aliquoted into individual testing vials. The SOP effort was led by Dr. MacLaughlin with the support of Dr. Bickel and the Dean of the School of Pharmacy, Dr. Quentin Smith.

Despite an initial focus on local testing requirements, we were soon receiving requests from across Texas and the region. Initial efforts to coordinate VTM delivery were stymied by clinical care and other conflicting priorities. Thankfully, Dr. Evelyn Sbar, a ubiquitous and essential part of the TTUHSC pandemic response, stepped into the breach. Leading a team of volunteers, clinical staff and faculty from the TTUHSC Department of Family Medicine, Dr. Sbar coordinated the delivery of TTUHSC VTM across the state of Texas. Initially, deliveries were made in person to local medical providers and laboratories. As word spread about the availability of our VTM, distribution was shifted to a "mail order" process. This was not, however, without difficulty. As we had not done a temperature stability study on our VTM process, the vials had to be shipped and stored cold. This required coordination with ordering medical providers to ensure a delivered tranche did not sit on a receiving dock overnight or over a weekend.

In late April, TTUHSC began supplying VTM across the state through the Texas Division of Emergency Management. Utilizing the previously established state supply network allowed us to streamline the distribution process and to focus on production. To increase production capacity, automated liq-

In Memoriam

John Baay,
MD, Thoracic Surgeon

died March 13, 2021
at the age of 88.
He was a member of
Potter-Randall County
Medical Society for 27 years.

uid handlers were purchased through a TDEM grant to allow automation of the filling process. The first batch of VTM delivered through the state supply network was shipped on an otherwise empty refrigerated tractor-trailer bound for San Antonio with likely its lightest, but most anticipated, cargo.

By the end of 2020 the commercial global supply chain for VTM had adapted to the burgeoned demand. Requirement for "homebrew" diminished. The last locally-produced VTM was shipped on January 11, 2021. Another pandemic "DIY" project was completed.

The TTUHSC VTM production project produced approximately 456,000 vials of VTM. Close to half a million people were able to be tested who otherwise may not have been. If the case positivity rate at the time of VTM production was 10% (as was the case during large parts of late 2020), it could be estimated that 46,000 cases of COVID-19 were identified due to the efforts of the TTUHSC team. To further extrapolate, each of those 46,000 cases would be anticipated to infect 3 other individuals. Early testing and identification could decrease the number of secondary infections by half. Perhaps, then, 69,000 secondary cases of COVID-19 and 690 deaths were prevented due to local VTM production efforts.

"Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it's the only thing that ever has." – Margaret Mead

With Appreciation to the TTUHSC COVID-19 VTM team and the many unlisted volunteers who made the work happen.

School of Pharmacy:
Eric MacLaughlin; Mikala Conatser; Uli Bickel; Maegan Whitworth; Jill Frost; Heather Houser; Dena Hair; Kim Akins; Desmond Dunn; Behnam Noorani; Siavash Shahbazi

School of Medicine:
Evelyn Sbar; Paula Winkleblack; Aaliyah Thompson

Dr. Todd Bell graduated from medical school at University of Arkansas for Medical Sciences in 2001, afterwards completing a combined Internal Medicine-Pediatrics residency at Duke University Medical Center. His professional interests include Dysautonomia and Hypermobility Syndromes, Public Health, and Student and Resident Education. He is an associate professor in the Departments of Pediatrics and Family Medicine at TTUHSC, and has served as the local Health Authority for Potter-Randall Counties since July 2021.

Eric J MacLaughlin, Pharm.D., FASHP, FCCP, BCPS is Professor and Chair, Department of Pharmacy Practice at the Texas Tech University Health Sciences Center (TTUHSC), Jerry H. Hodge School of Pharmacy. He is also a Clinical Professor in the Departments of Family Medicine and Internal Medicine at the TTUHSC School of Medicine. In addition to teaching, research, and scholarship, Dr. MacLaughlin practices in family medicine, providing team-based comprehensive medication management services for patients with hypertension, diabetes, and other chronic diseases.

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