

Leuprolide Acetate Injection Depot

(Leuprolide Acetate for Depot Suspension) 22.5 mg^*

	DETAILS
NDC ¹	69097-909-50
STRENGTH ¹	22.5 mg
ROUTE OF ADMINISTRATION	Intramuscular injection
SELLING UNIT	1 kit consisting of a LEUPROLIDE ACETATE INJECTION MIXJECT single-dose delivery system
SELLING UNITS PER SHIPPER CASE	80
STORAGE ¹	Store at controlled room temperature at 20°-25°C (68°-77°F); excursions permitted between 15°C and 30°C (59°C and 86°F) [see USP Controlled Room Temperature]
STORAGE AFTER RECONSTITUTION ¹	The suspension should be administered immediately after reconstitution
SHELF LIFE ²	36 months from date of manufacture

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WHOLESALER/DISTRIBUTOR ORDER ENTRY NUMBER			
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Please visit www.ciplaleuprolide.com or scan the QR code for full Prescribing Information.

1. LEUPROLIDE PRESCRIBING INFORMATION, CIPLA, 2018. 2. Data on file. CIP-REF-LEU-001. Warren, NJ: Cipla USA; 2022

Medical Information:

Report Adverse Events/Side Effects | Report Product Complaints | Submit Medical Inquiries:











INDICATIONS AND USAGE¹

LEUPROLIDE ACETATE INJECTION DEPOT (leuprolide acetate for depot suspension) 22.5 mg for 3-month administration (leuprolide acetate) is indicated for palliative treatment of advanced prostate cancer.

IMPORTANT SAFETY INFORMATION¹

Contraindications: Hypersensitivity: LEUPROLIDE ACETATE INJECTION DEPOT is contraindicated in individuals with known hypersensitivity to GnRH agonists or any of the excipients in LEUPROLIDE ACETATE INJECTION DEPOT. Anaphylactic reactions to GnRH agonists have been reported.

Warnings And Precautions:

- Tumor Flare: LEUPROLIDE ACETATE INJECTION DEPOT causes increases in serum levels of testosterone during the first weeks of treatment. Isolated cases of ureteral obstruction and spinal cord compression have been observed, which may contribute to paralysis with or without fatal complications. Transient worsening of symptoms may develop. Patients may experience a temporary increase in bone pain. Patients with metastatic vertebral lesions and/or with urinary tract obstruction should be closely observed.
- Hyperglycemia and Diabetes: Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Monitor blood glucose and/or glycosylated hemoglobin (HbA1c) periodically in patients receiving a GnRH.
- Cardiovascular Diseases: Increased risk of developing myocardial infarction, sudden cardiac death and stroke has been reported, and should be evaluated carefully along with cardiovascular risk factors. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed accordingly.

- Effect on QT/QTc Interval: Androgen deprivation therapy may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.
- Convulsions: Convulsions have been observed and should be managed accordingly.
- Laboratory Tests: Monitor serum levels of testosterone following injection of LEUPROLIDE ACETATE INJECTION DEPOT 22.5 mg for 3-month administration.
- Embryo-Fetal Toxicity: LEUPROLIDE ACETATE INJECTION DEPOT may cause fetal harm when administered to a pregnant woman. Advise pregnant patients and females of reproductive potential of the potential risk to the fetus.

Most common adverse events (incidences >10%) are hot flushes, upper respiratory infection, fatigue, diarrhea, pollakiuria, arthralgia, and injection site pain.

Use in specific populations:

Lactation: A decision should be made to discontinue breastfeeding or discontinue the LEUPROLIDE ACETATE INJECTION DEPOT.

Females and Males of Reproductive Potential: LEUPROLIDE ACETATE INJECTION DEPOT may impair fertility in males of reproductive potential.

Pediatric Use: The safety and effectiveness of LEUPROLIDE ACETATE INJECTION DEPOT in pediatric patients have not been established.

Geriatric Use: Hot flushes occurred with equal frequency in those \leq 65 years of age.

To report suspected adverse reactions, contact Cipla at 1-866-604-3268 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.







LUGPA 2024 Regional Meeting

Table of Contents

Welcome Letter	7
LUGPA 2024 Regional Meeting Agenda	9
Thank You to Our Meeting Sponsors and Exhibitors	15
Industry Symposiums	16
LUGPA 2024 Regional Meeting Faculty Biographies	19
Exhibit Floor Plan	22
Industry Roundtable Discussion Notes	23



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Atrium Health Wake Forest Baptist



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Sandra Paul Head of Planning, Alfred Health, Australia





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LUGPA 2024 Regional Meeting

Welcome





Dear Colleagues:

On behalf of the LUGPA Board of Directors, welcome to the 2024 Regional Meeting. We are so delighted to be meeting in Nashville Tennessee known as the "Music City" and home to many major healthcare centers and universities.

This year's theme "The Tough Get Tougher-Pathways to Increase Revenue and Drive Excellence" reflects how LUGPA practices can create strategies to address important administrative and clinical care issues such as building an effective team, payor contracting, pre-authorization, in-office dispensing and incorporating prostatic artery embolization and radioligand therapy into your practice. This interactive program will provide you with solutions and allow you to exchange information to improve patient care.

Kicking off the meeting, participants will hear from Matt Daniels, Director of Leadership and Organizational Development at HCA Healthcare, who will address the importance of engaging and developing your team. We will then hear from Dave Carpenter who will provide insight into maximizing payor contracts for your LUGPA practice. A panel moderated by Alan Winkler will provide solutions to challenges with the process of pre-authorization. Kirsten Anderson and E. Scot Davis will moderate the last morning session that will address the pros and cons of implementing prostatic artery embolization (PAE), PSMA/PET imaging and radioligand therapy into your practice.

In the afternoon, Dr. David Morris will lead a discussion on best practices for in-office pharmacy dispensing and we'll get to talk with select industry partners on meaningful ways to implement practical solutions into your practice. We will conclude our education session with an Open Mic session which will allow you to ask questions and share information. Finally, we will walk to the Assembly Food Hall to socialize, and enjoy food, cocktails and entertainment.

We would like to thank our Industry Supporters, for without their support, this meeting would not be possible.

Thank you for attending the 2024 Regional Meeting, for your membership and for your continued support. Please join us as we acknowledge our achievements as the only nonprofit trade association dedicated to the advancement and preservation of the independent practice of urology.

Sincerely,

Evan R. Goldfischer, MD

Evan R. Goldfischer, Mi President, LUGPA

90

Jeffrey Spier, MD Chair, LUGPA Program Committee



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LUGPA 2024 Regional Meeting

Overview



Friday April 12, 2024

*Please note that speakers and agenda topics are subject to change.

TIME	SESSION TITLE	LOCATION
5:00 p.m. – 7:00 p.m.	Meeting Registration/Information	Broadway Foyer
6:00 p.m. – 7:00 p.m.	Exhibit Hall	Broadway Ballroom 2 & 3
6:00 p.m. – 7:00 p.m.	Welcome Reception Sponsored by: Cardinal Health	Broadway Ballroom 2 & 3

Saturday April 13, 2024

TIME	SESSION TITLE	LOCATION
7:00 a.m. – 4:15 p.m.	Registration/Information	Broadway Foyer
7:30 a.m. – 8:30 a.m.	Industry Symposium Breakfast Getting Ahead of Advanced Prostate Cancer David Morris, MD Sponsored by: Johnson&Johnson	Broadway Ballroom 1
8:30 a.m. – 10:30 a.m.	Educational Session	Broadway Ballroom 1
10:15 a.m. – 11:00 a.m.	Break in the Exhibit Hall	Broadway Ballroom 2 & 3
11:00 a.m. – 12:30 p.m.	Educational Session	Broadway Ballroom 1
12:30 p.m. – 1:30 p.m.	Industry Symposium Lunch Exploring The Role of NUBEQA® (darolutamide) in mHSPC in Combination With Docetaxel and in nmCRPC Scott Sellinger, MD Sponsored by:	Broadway Ballroom 1
1:30 p.m. – 3:15 p.m.	Educational Session	Broadway Ballroom 1
3:15 p.m. – 3:45 p.m.	Break in the Exhibit Hall	Broadway Ballroom 2 & 3
3:45 p.m. – 4:30 p.m.	Educational Session/Conclusion	Broadway Ballroom 1
4:30 p.m. – 6:00 p.m.	Social Activity: Assembly Food Hall Sponsored by: Verity Pharmaceuticals	5055 Broadway Place Nashville, TN



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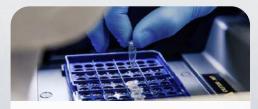
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LUGPA 2024 Regional Meeting

Program Agenda

Saturday April 13, 2024

*Topics and Speakers Subject to Change

TIME	CECCION TITLE	LOCATION
7:00 o m 4:15 o m	SESSION TITLE	LOCATION
7:00 a.m. – 4:15 p.m.	Meeting Registration/Information	Broadway Foyer
7:30 a.m. – 8:30 a.m.	Industry Symposium Breakfast Getting Ahead of Advanced Prostate Cancer David Morris, MD Sponsored by: Johnson&Johnson	Broadway Ballroom 1
8:30 a.m. – 8:35 a.m.	Welcome and Introductions Jeffrey Spier, MD	Broadway Ballroom 1
8:35 a.m. – 9:30 a.m.	Engaging & Developing Your Team Matt Daniels Director, Leadership and Organizational Development at HCA Healthcare	Broadway Ballroom 1
9:30 a.m. – 10:15 a.m.	Payor Contracting: When to Hold 'em, Fold 'em and up the Ante Dave Carpenter	Broadway Ballroom 1
10:15 a.m. – 11:00 a.m.	Break in Exhibit Hall (food and beverage will be served)	Broadway Ballroom 2 & 3
11:00 a.m. – 11:45 a.m.	The Everchanging Landscape in Pre-Authorization Requirements Alan Winkler, MHSA, FACMPE, Aleks Alchev, Josie Cox, Alysha Saenger, Hector Santana	Broadway Ballroom 1
11:45 a.m. – 12:30 p.m.	Hot Models and Trends in PAE/PSMA/PET/Radioligand Therapy Kirsten Anderson, CMPE, CPC, CASC, E. Scot Davis, MPA, MBA	Broadway Ballroom 1
12:30 p.m. – 1:30 p.m.	Industry Symposium Lunch Exploring The Role of NUBEQA® (darolutamide) in mHSPC in Combination With Docetaxel and in nmCRPC Scott Sellinger, MD Sponsored by:	Broadway Ballroom 1

Saturday April 13, 2024

TIME	SESSION TITLE	LOCATION
1:30 p.m. – 2:30 p.m.	Best Practices for IODs/Pharmacies David Morris, MD, Aleks Alchev, Erika Ferrozzo, John Lengauer	Broadway Ballroom 1
2:30 p.m. – 3:15 p.m.	Industry Roundtable Discussion	Broadway Ballroom 1
3:15 p.m. – 3:45 p.m.	Break in Exhibit Hall (food and beverage will be served)	Broadway Ballroom 2 & 3
3:45 p.m. – 4:15 p.m.	Open Mic Jeffrey Spier, MD, Kirsten Anderson, CMPE, CPC, CASC, Dave Carpenter, E. Scot Davis, MPA, MBA, David Morris, MD, Alan Winkler, MHSA, FACMPE	Broadway Ballroom 1
4:15 p.m. – 4:30 p.m.	Conclusion Jeffrey Spier, MD	Broadway Ballroom 1
4:30 p.m. – 6:00 p.m.	Social Activity: Assembly Food Hall Sponsored by: Verity Pharmaceuticals	5055 Broadway Place Nashville, TN



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WELCOME RECEPTION
FRIDAY, APRIL 12TH
6:00PM - 7:00PM
BROADWAY BALLROOM 2 & 3



Thank you



Social Event Sponsor
Saturday, April 13th
4:30pm - 6:00pm
Assembly Food Hall ∞ East Mezzanine





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Saturday, April 13, 2024

Johnson&Johnson

7:30 a.m. – 8:30 a.m. Broadway Ballroom 1

Getting Ahead of Advanced Prostate Cancer

David Morris, MD

Saturday, April 13, 2024



12:30 p.m. – 1:30 p.m. Broadway Ballroom 1

Exploring The Role of NUBEQA® (darolutamide) in mHSPC in Combination with Docetaxel and in nmCRPC

Scott Sellinger, MD



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LUGPA 2024 Regional Meeting

Faculty Biographies



Evan R. Goldfischer, MD, MBA, CPI, LUGPA President

Dr. Goldfischer received his BA from Tufts University and his MD from Cornell University Medical College. He completed his internship in general surgery and his residency in urology at the University of Chicago. He completed a fellowship in endourology under the direction of Arthur Smith at Long Island Jewish Medical Center. Dr. Goldfischer received his MBA from the University of Massachusetts and is a Certified Physician Executive. He served as the co-founding CEO of Premier Medical Group of the Hudson Valley, as well as founding Director of Research.

Dr. Goldfischer has written over 100 peerreviewed abstracts and publications and has lectured on six continents. In addition, he was elected to the LUGPA Board of Directors in 2014 currently serving as President. He is the Editor-in-Chief of Practice Management for Urology Groups: LUGPA's Guidebook Second Edition published in 2020 and is the author of Even Urologists Get Kidney Stones – A Guide to Prevention and Treatment, published in 2018.



Jeffrey Spier, MD, Chair, LUGPA Program Committee

Dr. Spier is CEO and President of Rio Grande Urology (RGU) founded in 2008 serving West Texas and Southern New Mexico. RGU has 26 providers with 5 offices and 2 radiation centers in El Paso, Texas and Las Cruces, New Mexico. Dr. Spier has overseen the tremendous growth of RGU, becoming the largest private practice physician group in the region. Rio Grande Urology continues to expand with the formation of the Rio Grande Cancer Specialists (RGCS) providing radiation therapy, theranostics, as well as the RGCS Advanced Prostate Cancer. This center of excellence includes clinical research with ongoing expansion and treatment into other genitourinary oncologic conditions. "RGU is committed to serving the urologic and oncologic needs of our patients, providing state of the art and compassionate care," said Dr. Spier.

Dr. Spier is board certified by the American Board of Urology and member of the American Urological Association and South Central Section of the AUA. He graduated from the University of Texas Medical Branch in Galveston, Texas where he also completed his Urology residency training. He currently serves on the Large Urology Group Practice Association (LUGPA) Board of Directors. He is past President of the El Paso County Medical Society, board member of the University of Texas at Galveston Alumni Board of Trustees and has served on the board of the Texas Urological Society.



Aleksandar Alchev

Aleksandar Alchev is a Cancer Program Manager at Minnesota Urology. He has over 10 years of experience in healthcare and is passionate about helping patients overcome administrative and clinical barriers and providing them with support when they need it most.

Aleks is responsible for managing and overseeing the Cancer Program, which is made up of a diverse team of 6 professionals with different skills and expertise. He oversees the In Office Dispensary, Prostate Cancer Navigation, Cancer Center Operations, and Men's Health Program.

Aleks is committed to providing the most comprehensive care possible to his patients. He continues to educate himself

on emerging therapies and trends, and he works with his team to develop and implement procedures and policies that are compliant with all applicable regulations.

Aleks is certified to practice Dentistry in Europe. He received his Master's in Business and Administration from Franklin University in Columbus, OH, and his Doctorate in Dentistry from Sts. Cyril and Methodius University in Skopje, Macedonia.

Aleks is based in the Twin Cities, where he lives with his family.



Kirsten Anderson
Chief Executive Officer, Oregon Urology
Institute and Oregon Surgery Center

Kirsten Anderson has a 20+ year record of achievement and demonstrated success leading physician practice and healthcare organizations including more than 15 years' experience specifically in Urology Medical Practices and Ambulatory Surgery Centers.

Kirsten received her Bachelors of Science Degree from Virginia Tech and her Masters Degree in Health Administration from the Medical University of South Carolina. She is certified as a Medical Practice Executive (CMPE) by MGMA, a Certified Professional Coder (CPC) through AAPC, and certified as an Ambulatory Surgery Center Administrator (CASC) by ASCA. She currently serves on the Large Urology Group Practice Association (LUGPA) Board of Directors.

Faculty Biographies continued



David M. Carpenter

As the Chief Executive Officer of Minnesota Urology, the largest independent urology medical group in the upper mid-west, Dave is privileged to offer his experience as a medical group administrator and business leader. Prior to arriving at Minnesota Urology, Dave spent 9 years as Chief **Executive Officer of Physicians Neck** and Back Clinics (PNBC), a Minnesotabased medical practice specializing in the non-operative treatment of chronic spinal disorders. Prior to PNBC, Dave was a company co-founder and Vice President of Prevention First, Inc., a healthcare solutions company offering programs to reduce workers' compensation costs associated with back and upper extremity injuries.

Before arriving in Minnesota, Dave served eight years as a faculty member within the University of Florida College of Medicine. During his tenure at UF, Dave worked closely with the late Dr. Michael Pollock, Ph.D., and Arthur Jones, founder of Nautilus and MedX exercise/ rehabilitation equipment, to develop international programs for the prevention and rehabilitation of chronic spinal disease. He has lectured and taught throughout the world in the area of resistance training and active spinal exercise rehabilitation and has authored and co-authored more than 50 scientific articles. Dave holds a master's degree in Exercise Science from the University of Florida and is a certified facilitator of The 7 Habits of Highly Effective People. He and his wife Jenifer have a twin daughter (Chloe), and son (Hudson). Dave enjoys golf, woodworking, leathercraft, relaxing in his hand-built tree house overlooking the St. Croix River, and caddying for his son.



Josie Cox

Josie has served as the Director of Revenue Cycle for Urology San Antonio, P.A. since August 2018. Josie holds a Bachelor of Science degree in Business Management. She spent much of her professional career in El Paso, Texas growing revenue cycle teams primarily at the University Medical Center of El Paso, hospital-based clinics and a multi-specialty medical practice.



Matt Daniels

Matt Daniels is a Director of Leadership and Organizational Development with HCA Healthcare's Leadership Institute. He's been with HCA for just under 2 years and is responsible for professional, leadership and organizational development initiatives supporting the company's Operations and Service Lines Group (OSG). Matt has 18 years of professional experience spanning education, coaching, government contract and risk-management consulting, and sales/operations. His areas of expertise include facilitation, team and culture building, curriculum design and coaching.

Prior to joining HCA, Matt managed operations and sales initiatives for a start-up hearing technology company. Prior to that, he spent 9 years as a secondary education teacher and coach in two of the most prestigious public-school systems in the country. Throughout that time, he served as a successful high school football head coach for 4 years (an assistant for 5) and taught Advanced Placement (AP) Psychology, Marketing, US History, and Leadership Development. Prior to becoming an educator, Matt spent 6 years as a consultant in Washington, D.C., mainly

assisting clients in the assessment of their exposure to possible corruption violations in high-risk geographies.

Matt holds a Master of Education from the University of North Texas as well as his Bachelor of Arts in Economics and Sociology from Wake Forest University. Matt and his wife, Lindsey, reside in Franklin, TN and have 3 daughters (Mackenzie- 5 ½, and twins Samantha and Keeley- 2), and a boxer dog named Frankie.



E. Scot Davis

E. Scot Davis received a Bachelor of Arts in Political Science and a Master of Public Administration from Memphis State University. He also earned a Master of Business Administration from Christian Brothers University. Davis has nearly 30 years of physician practice management experience with expertise in operational efficiency, physician recruitment, joint venture arrangements and compensation modeling. Davis has served in various executive level positions including formerly serving as the CEO of Arkansas Urology, located in Little Rock. Arkansas and played an instrumental role in its development and evolution. Davis' extensive contributions to healthcare prior to Arkansas Urology include service as the CFO of Baptist Medical Group and CFO of Northeast Arkansas Clinic in Jonesboro. Davis is also a member of the Medical Group Management Association and is a Certified Medical Practice Executive. He has served on LUGPA's Board of Directors since 2019.

Faculty Biographies continued



Erika Ferrozzo

Erika Ferrozzo is the CEO of Idaho Urologic Institute and Surgery Center of Idaho. Erika joined IUI/SCI in May of 2021. In her time at IUI/SCI, Erika has focused on revenue recovery, improved care line processes, and has implemented various lean process improvements that have resulted in significantly improved patient, staff, and provider satisfaction. Erika has an exceptional ability to implement change management strategies, achieving operational objectives and establishing effective teams. She has a proven track record leading primary care, surgical specialties, ambulatory surgery centers, and specialty divisions with exceptional provider workplace satisfaction, patient satisfaction, and employee engagement.

Erika earned a Master's in Public Health, Healthcare Administration from National University and received the Presidents Chair Award for Academic Excellence, a Bachelor of Science in Kinesiology with an emphasis in Sports Medicine from San Diego State University and is a member of the Gamma Phi Beta honors society for academic excellence, service, and character. In addition, Erika is a certified Lean Six Sigma Black Belt, a certified HBI Revenue Cycle Leader, and is a certified HBI Patient Access Specialist.

Erika is a board member for the Idaho American College of Healthcare Executives, is a board member for the Idaho MGMA, is a board member for the KYRA committee with the Boys and Girls Club, and volunteers with Boys and Girls Club philanthropy committees.



John Lengauer VP, Dispensing Solutions, Specialty Networks

John is the VP, Dispensing Solutions for Specialty Networks. John has nearly 25 years of experience in the healthcare industry, with expertise in long-term-care (LTC) pharmacy operations, Medicare Part D and as of the last 10 years, implementing and supporting physician dispensing programs. John is an active advocate in fighting for patient choice and fair pharmaceutical reimbursement for providers.

Prior to joining Specialty Networks in 2014, John held local and regional managerial positions in pharmacy operations for 3 different LTC pharmacies over the course of 16 years.



Hector Santana, MBA, MAcc

Hector Santana is the Chief Financial Officer for Rio Grande Urology in El Paso, Texas. Over the past 12 years, Mr. Santana has helped to lead the development of various projects, including a second radiation center, an Advanced Prostate Cancer Clinic, an in-door pharmacy, a clinical research partnership, and a Path-Lab partnership that incorporates AI technology. Mr. Santana has played an integral part in expansion of Rio Grande Urology and Rio Grande Cancer Specialists now consisting of 22 providers at five locations in both West Texas and Southern New Mexico. He has overseen an increase in productivity by over 40% during his leadership at RGU while maintaining a set core of values that advance the group's mission statement.



David S. Morris, MD

Originally from Cleveland in East Tennessee, Dr. Morris attended The Baylor School in Chattanooga, TN. He graduated Summa Cum Laude from Vanderbilt University and then earned his doctorate from Vanderbilt University School of Medicine. Dr. Morris completed his residency training at The University of Michigan in Ann Arbor, MI with a special research interest in genetics that predict the aggressiveness of prostate and bladder cancers. Since completion of training, he has been with Urology Associates in Nashville, Tennessee. He serves the group as President and the Co-director for the Advanced Therapeutics Center. The ATC center also works closely with the Clinical Research Department as a center for multiple phase 2 and 3 trials primarily focused on GU oncology.

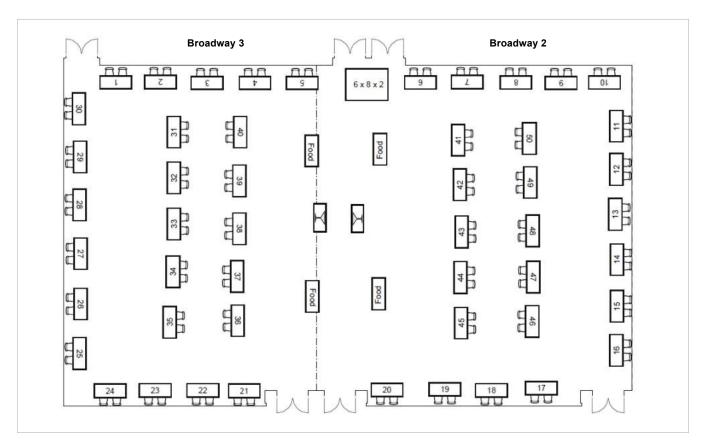


Alan D. Winkler, MHSA, FACMPE

With forty years of experience in healthcare, Alan D. Winkler has served as the Executive Director of Urology San Antonio, P.A. since October 2012. Alan holds a Master's degree in Health Services from the University of Arkansas for Medical Sciences and has worked in private and corporate settings with physicians of many specialties. Alan is a Fellow in the American College of Medical Practice Executives and served on its board of directors for nine years, concluding as its chair.

LUGPA 2024 Ambulatory Surgery Center Academy

Exhibit Hall Floor Plan



Industry Partners	Table #
Accord BioPharma	20
Akumin	11
Annexus Health	09
Astellas Oncology & Pfizer Oncology	41
AstraZeneca	22
Bayer	36
Besse Medical and Specialty GPOs	17
Specialty Practice Network, a part of	
the Cencora family of companies	
Biote	13
Blue Earth Diagnostics, Inc.	04
Boston Scientific	08
Cipla USA Inc.	18
Cleveland Diagnostics	30
Dedicated IT	05
Dendreon Pharmaceuticals, LLC	14
Doc Lab Inc.	03
ECMed	16
Endo Pharmaceuticals	23
enGene	39
Fellow	06

Industry Partners	Table #
Ferring Pharmaceuticals	02
Ibex Medical Analytics	24
Johnson & Johnson	45
Lantheus	38
Modernizing Medicine	37
Molecular Testing Labs	42
Novartis	43
Pathnostics	19
Preveta	21
Sciteck Diagnostics	15
Softwave TRT	28
Sumitomo Pharma America	25
Sun Pharmaceuticals, Inc.	07
Telix Pharmaceuticals	10
Tolmar, Inc.	40
TRIARQ Health	27
TruCore	26
UroGen Pharma	12
Verity Pharmaceuticals	01
Vision RT	44

Industry Roundtable Discussion Notes

TOPIC	NOTES
Akumin AKUMIN®	
Annexus Health ANNEXUSHealth	
AstraZeneca AstraZeneca	
Modernizing Medicine ModMed Modernizing Medicine	
ObjectiveHealth TRANSFORMING CARE	
Pfizer Pfizer	
Softwave TRT SoftWave Tissue Regeneration Technologies	
vision RT ViSi⇔∩ rt	

Urology Starts With YOU

We're here to partner with YOU.

Learning from YOU.

Committed to helping YOU...

...Because at Pfizer, we are inspired by YOU.

