FOCUSED ULTRASOUND FOUNDATION

2018 YEAR IN REVIEW

Highlights

- **Groundbreaking Alzheimer's disease trial results published in *Nature Communications*, presented at AAIC, shared in major news outlets worldwide**
- **Focused ultrasound treatment for tremor-dominant Parkinson's disease approved by the FDA**
- **Cancer immunotherapy: First co-funded project with Cancer Research Institute selected; Parker Institute partnership established**
- **Neuropathic pain trial initiated in the US**
- **6th International Symposium on Focused Ultrasound attracts record number of attendees and presentations**
- **Foundation recognized as one of America's 10 Best Medical Research Organizations**
- **Veterinary, Asia, and FUS Partners programs expand**
- **Board strengthened with additions of Syaru Shirley Lin and Wick Moorman**
- **$10 million matching pledge is met: Thank you, donors**
- **Reimbursement for essential tremor expands within the US**
- **Media placements, social media reach new audiences**

FOCUSED ULTRASOUND FOUNDATION

1230 Cedars Court, Suite 206
Charlottesville, VA 22903
434.220.4993 www.fusfoundation.org

A MESSAGE FROM THE CHAIRMAN

Dear Friends,

The field of focused ultrasound is growing more rapidly and having more of an impact than any of us ever could have imagined. This progress was demonstrated in October as we convened the 6th International Symposium on Focused Ultrasound. Scientists and clinicians showcased the latest research in all aspects of the field during more than 250 presentations. The data included many first-in-the-world and first-in-human studies, evidencing how the field is both expanding in scope and marching toward widespread clinical adoption.

The success we've had to date is a result of the entire focused ultrasound community's efforts. The Foundation's team, Board of Directors, Council members, and donors, as well as the increasing number of manufacturers and the scientists and clinicians in research labs around the world, are all working toward a common goal of making this technology widely available as a standard of care in the shortest time possible.

Our mission of accelerating the development and adoption of focused ultrasound technology continues in force. And as the number of potential applications increases, it is apparent that the amount of work required to translate our vision to reality is challenging.

In the year ahead, the Foundation plans to increase its emphasis on advancing the clinical applications of focused ultrasound and facilitating the manufacturers' commercial success, both of which are key pieces in making this technology available to patients around the world.

Thank you for your support of this revolutionary technology, and we look forward to sharing many more milestones with you in 2019.

Be well,

Neal F. Kassell, MD

Creating Knowledge: Research Milestones

FOUNDATION RECOGNIZED AS ONE OF 10 BEST MEDICAL RESEARCH ORGANIZATIONS

In September 2018, the Foundation was included in Charity Navigator's list of America's 10 Best Medical Research Organizations. The site notes, "These charities are committed to funding cutting-edge research and finding breakthroughs for a spectrum of conditions and diseases. They are also dedicated to using donors' funds wisely in their journey to find a cure." Charity Navigator is the nation's largest independent charity evaluator and leading donor advocate, and the Foundation has earned four stars, the highest rating awarded by the site.

Creating Knowledge: Research Milestones

EXTERNAL RESEARCH AWARDS PROGRAM

The Foundation funded seven new External Research Awards projects in 2018, committing a total of $771,488. To date we have funded 68 projects totaling $6.9 million. Forty-nine of these projects have been completed, at a cost of $4.84 million, and 96 percent have been presented at scientific meetings. Sixty-nine percent have been published in peer-reviewed journals, and 26 have achieved follow-on funding from the National Institutes of Health and other foundations, totaling $39.6 million. All projects starting after January 2017 have royalty or SAFE agreements (simple agreements for future equity) to ensure the Foundation receives compensation for successful projects, so that we can reinvest in research to further accelerate the field.

Completed external projects, cumulative

49	96%	69%	26
projects completed	results presented at scientific meetings	results published	projects completed with follow-on funding

$4.8M → **$39.6M** → **x8**

Funding provided for completed projects

Follow-on funding

Factor by which the Foundation leverages donors' contributions

BRAIN PROGRAM

2018 saw the publication, presentation, and widespread media coverage of a groundbreaking, first-ever clinical trial involving the repeated, transient opening of the blood-brain barrier (BBB) in Alzheimer's disease patients by Dr. Nir Lipsman and his team at Sunnybrook Health Sciences Centre in Toronto, Canada. Within five months of the publication of the trial results, the first US patient with Alzheimer's disease was enrolled in a clinical trial. Also glioblastoma clinical trials were initiated in the US, Korea, and Canada. This exciting news is just the beginning, and we expect numerous research projects combining therapeutic agents and BBB opening for many neurological diseases in the coming years.

FUSF Brain Program projects, internal and external, cumulative

33	44	24
technical projects	preclinical studies	clinical trials

101

Total Brain Projects

Creating Knowledge: Research Milestones

BRAIN PROGRAM (CONT.)

The Foundation funded 19 new brain research projects last year (in addition to 16 ongoing projects), including five technical, nine preclinical, and five clinical. Below are some highlights of our robust, ongoing brain research program.

Technical Projects

The Foundation supported a number of technical projects that seek to make focused ultrasound safer, faster, and more effective for brain treatments. Project goals included: 1) focusing ultrasound through the skull with greater precision and efficiency; 2) improving patient selection processes and treatment planning with more accurate prediction of treatment outcome; 3) improving treatment monitoring by rapidly visualizing tissue change or tissue temperature in three dimensions; and 4) increasing safety by reducing the likelihood of dangerous bubble formation during treatment.

Preclinical Laboratory Studies

Last year, the following topics were examined in completed preclinical studies: Can the BBB be safely opened with focused ultrasound in aged Alzheimer's mice (follow-on project)? Is sonodynamic therapy affected by the ultrasound frequency? Can sonodynamic therapy with fluorescein be used to treat glioma? Can unwanted side effects of focused ultrasound treatment be reduced? And, do different focused ultrasound modalities stimulate differential immune responses to glioblastoma (study completed at three of six sites)? Preclinical studies were also initiated last year (but not yet completed) on the following topics: In the post-stroke brain, can delivery of stem cells and mitochondria via focused ultrasound improve outcome? And, can cavernomas be treated with sonodynamic therapy?

Clinical Trials

2018 saw much progress in clinical (human) trials investigating focused ultrasound to treat various conditions including Alzheimer's and Parkinson's diseases, dyskinesia (involuntary movements), amyotrophic lateral sclerosis (ALS), brain tumors, epilepsy, depression, Obsessive-Compulsive Disorder (OCD), and neuropathic pain.

Alzheimer's Disease

In July results of a landmark trial at Sunnybrook Health Sciences Centre in Toronto, Canada, using focused ultrasound to temporarily open the BBB in Alzheimer's patients were published in *Nature Communications* and presented at the Alzheimer's Association International Conference (AAIC) in Chicago, Illinois. The trial is the first small but critically important step in a process that could lead to using disruption of the BBB to help patients with Alzheimer's disease; it has also opened the door for treatment of brain tumors and degenerative diseases.

In October researchers at the West Virginia University (WVU) Rockefeller Neuroscience Institute in Morgantown, West Virginia, treated the first of ten patients in a groundbreaking, first-ever US clinical trial utilizing focused ultrasound to open the BBB in patients with early Alzheimer's disease.

Alzheimer's Disease Clinical Trial Update

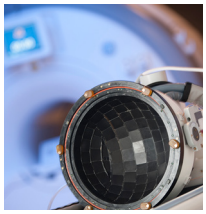
- Alzheimer's disease pilot (Canada) – published in *Nature Communications*
- Alzheimer's disease (Canada) – initiated
- Alzheimer's disease (US) – initiated, first patient treated

Creating Knowledge: Research Milestones

BRAIN PROGRAM/Clinical Trials (Cont.)

Parkinson's Disease

Results of a 10-patient clinical trial using focused ultrasound to alleviate dyskinesia due to Parkinson's or the medicines that treat the disease were published in the *Journal of Neurosurgery*. In this trial at Yonsei University Medical Center's Brain Research Institute in Seoul, Korea, led by Dr. Jin Woo Chang, the target treatment area was the nucleus in the brain at the internal portion of the globus pallidus. There was significant improvement in the patients' movement disorders measured at six months and one year, as well as improved quality of life and no persistent adverse events. Due to Dr. Chang's efforts and similar pilot work in the US, an international pivotal study is now underway with the goal of achieving US Food and Drug Administration (FDA) and international regulatory approval of focused ultrasound for treatment of Parkinson's dyskinesia.



Importantly, the treatment of tremor-dominant Parkinson's disease has a target and treatment approach identical to that of essential tremor (ET). Insightec, the manufacturer of the Exablate Neuro system for ET, announced in December that the ET-approved device has also earned FDA approval to treat patients with tremor-dominant Parkinson's disease.

Parkinson's Disease Clinical Trial Update

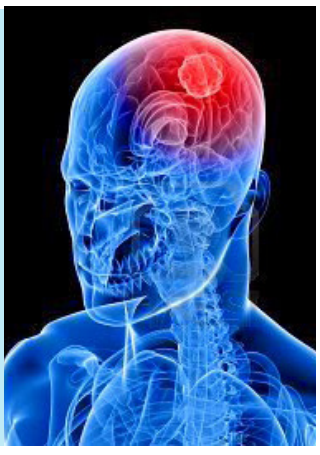
- Parkinson's dyskinesia pilot (Korea) – published in *Journal of Neurosurgery*
- Parkinson's dyskinesia pivotal (INTL) – initiated, 21 patients treated
- Parkinson's dyskinesia subthalamic nucleus (INTL) – initiated, 31 patients treated
- Parkinson's, tremor-dominant (US) – FDA approved treatment under ET approval
- Parkinson's tractotomy pilot (Japan) – initiated, 5 patients treated
- Parkinson's BBB opening workshop conducted – white paper distributed

Brain Tumors

The groundbreaking Alzheimer's trial in Canada has enabled the rapid initiation of several new BBB opening projects. One pilot trial investigating focused ultrasound to treat glioblastoma was completed this year in Canada, and three others were initiated in Canada, Korea, and Taiwan; the pediatric brain tumor trial in the US is ongoing.

Brain Tumor Clinical Trial Update

- Pediatric brain tumor, SEGA pilot (US) – 2 patients treated
- BBB, glioblastoma pilot (Canada) – completed, 5 patients treated; paper accepted by *Scientific Reports*
- BBB, glioblastoma maintenance (Canada) – initiated, 3 patients treated
- BBB, glioblastoma maintenance (Korea) – initiated, first patient treated
- BBB, glioblastoma (Taiwan/NaviFUS) – initiated, 4 patients treated
- BBB, glioblastoma pre-surgery (US) – first patient treated



Creating Knowledge: Research Milestones

BRAIN PROGRAM/Clinical Trials (Cont.)

Epilepsy

Three trials studying the use of focused ultrasound to treat epilepsy were initiated this year in the US and Taiwan, including a first-in-human treatment in the US at The Ohio State University College of Medicine in Columbus, Ohio. Up to 10 patients with medication-refractory lobe focal onset epilepsy will be enrolled in this trial. Patients will receive transcranial focused ultrasound therapy to ablate a specific part of the brain involved in epilepsy.

"We're pursuing this clinical trial because we know there's a large unmet clinical need. More than 20 million people worldwide live with uncontrollable seizures because no available treatment works for them," said Vibhor Krishna, MD lead investigator. "Our goals are to test the safety of this procedure and study changes in seizure frequency in these patients." Watch a video below with Dr. Krishna describing this clinical trial.

Epilepsy Clinical Trial Update

- Epilepsy, hypothalamic hamartoma pilot (US) – first patient treated
- Epilepsy, antearior nucleus thalamus pilot (US) – initiated
- Epilepsy, neuromodulation with NaviFUS (Taiwan) – initiated

Mental Health

Patients continue to be treated in pilot trials in Canada studying the use of focused ultrasound to treat depression and OCD. The Korean depression study has been submitted for publication, and additional pilot studies are in development in the US.

Mental Health Clinical Trial Update

- Depression pilot (Canada) – 6 patients treated
- Depression pilot (Korea) – submitted for publication
- OCD pilot (Canada) – 3 patients treated
- OCD pilot (US) – protocol completed, under FDA review

Neuropathic Pain

Researchers at the University of Maryland Medical Center in Baltimore, Maryland, became the first team in the US to treat neuropathic pain using focused ultrasound. Led by Dheeraj Gandhi, MD, (pictured below), the early-stage pilot trial aims to establish the safety of destroying a small target in the brain to treat chronic neuropathic pain, which is defined as pain caused by damage or disease affecting a part of the sensory nervous system.

Neuropathic Pain Clinical Trial Update

- Neuropathic pain pilot (Central, UMD) – 3 patients treated
- Neuropathic pain pilot (Craniofacial, UVA) – 3 patients treated

Creating Knowledge: Research Milestones

BODY PROGRAM

Clinical Trials

Pancreatic Cancer

We are in the process of organizing three clinical trials of focused ultrasound with immunotherapy components for pancreatic cancer in the US, the United Kingdom, and Germany. Additionally, groundwork has been completed on the pancreatic cancer registry, involving 100 patients at 10 centers.

Other Body Program Clinical Trials

Patients continue to be treated in trials examining the use of focused ultrasound to treat osteoid osteomas and facetogenic back pain. The first seven patients have also been enrolled in the international osteoid osteoma registry.

Body Program Clinical Trial Update

- Osteoid osteoma comparative (US) – 8 patients treated
- Osteoid osteoma registry (INTL) – initiated, 7 patients enrolled
- Facetogenic back pain x-ray guided, pilot (Canada) – 8 patients treated
- Knee osteoarthritis (Japan) – follow-up completed, publication in process

CANCER PROGRAM

Lockhart Memorial Prize Awarded

Graeme Woodworth, MD

The Foundation and the Lockhart family recently presented Graeme Woodworth, MD, Professor of Neurosurgery at the University of Maryland School of Medicine in Baltimore, Maryland, and Director of its Brain Tumor Treatment & Research Center, with the 2018 Andrew J. Lockhart Memorial Prize. Created in memory of Andrew Lockhart, who passed away from a rare abdominal cancer, the $75,000 award is given to an investigator who has made outstanding contributions in advancing cancer treatment using focused ultrasound and who demonstrates great potential for further achievements in the field. Dr. Woodworth is researching the use of focused ultrasound to open the BBB to provide treatment options for patients with brain tumors and other brain diseases.

Treatment of Cholangiocarcinoma Liver Tumors Project Begins

Eli Vlaisavljevich, PhD, and colleagues in the Department of Biomedical Engineering and Mechanics at Virginia Polytechnic Institute and State University (Virginia Tech) in Blacksburg, Virginia, began a new study seeking to optimize focused ultrasound-based histotripsy (mechanical cell disruption) applications to destroy life-threatening liver cancers in preclinical models: hepatocellular carcinoma, liver metastases, and cholangiocarcinoma (bile duct) tumors. The project, titled "Noninvasive Focused Ultrasound Ablation for the Treatment of Cholangiocarcinoma Liver Tumors," is being funded by the Foundation.

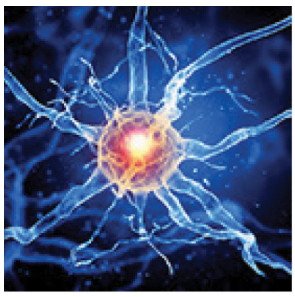
Eli Vlaisavljevich, PhD

Creating Knowledge: Research Milestones

CANCER IMMUNOTHERAPY PROGRAM

The Foundation currently has a portfolio of more than 20 preclinical laboratory studies and clinical trials to assess focused ultrasound for immune-based treatment of glioblastoma, melanoma, breast cancer, and pancreatic cancer. We have recently established key partnerships with leading organizations in the field of cancer immunotherapy – including the Cancer Research Institute (CRI) and the Parker Institute for Cancer Immunotherapy – to explore and assess the full potential of focused ultrasound, particularly in combination with other immune-based therapies, to treat a variety of cancers. These collaborative efforts will help to advance more streamlined and rigorous research that will accelerate progress toward clinical trials, while also enabling better standardization in the field and increased consistency of protocols.

Trial Combining Focused Ultrasound and an Immuno-oncology Drug for Breast Cancer Continues



Four additional patients have been treated in a first-of-its-kind pilot trial at the University of Virginia (UVA) in Charlottesville, Virginia, combining focused ultrasound with the cancer immunotherapy drug pembrolizumab (Keytruda®) to treat Stage 4 metastatic breast cancer, bringing the total number of patients treated to six out of 15.

Foundation and CRI Announce First Co-funded Grant Award

Gavin Dunn, MD, PhD

The CRI and the Foundation jointly selected a focused ultrasound-enhanced cancer immunotherapy project for co-funding: "The Immunologic and Genomic Effects of Focused Ultrasound in Glioblastoma". This is the first grant awarded since the two organizations established their formal cancer immunotherapy partnership. The recipient, Gavin Dunn, MD, PhD, a neurosurgeon at Washington University in St. Louis, Missouri, will use a preclinical model of glioblastoma to investigate which types of focused ultrasound best increase tumor exposure to the immune system and how soundwaves affect the immune cells within the tumor. The goal is to use the data to inform the design of clinical trials that will combine ultrasound and specific immune-based treatments.

Foundation and Parker Institute for Cancer Immunotherapy Exploring Ways to Collaborate

The Foundation is working with the Parker Institute for Cancer Immunotherapy to identify projects that will explore and assess the potential of focused ultrasound in combination with immune-based therapies to treat a variety of cancers. "We are thrilled to work with the Parker Institute to further the current research scope of focused ultrasound and cancer immunotherapy," says Foundation Chief Scientific Officer and Director of the Foundation's Cancer Immunotherapy Program, Jessica Foley, PhD. Adds Foundation Chairman Neal F. Kassell, MD, "Establishing these collaborations is essential to optimize our impact in the field. Our combined expertise and resources will have an amplified effect in driving progress and ultimately improving the lives of patients."

Focused Ultrasound Cancer Immunotherapy Scientific Advisory Board Established

A group of experts in the field of cancer immunotherapy and focused ultrasound has been formed to provide advice and counsel on the activities of the Foundation's Cancer Immunotherapy Program. The role of the Board will include high-level assessment of research proposals in the field of immunotherapy and guidance in the overall direction of the program, including in the initiation of collaborative projects, workshops, etc. Members of the Board include: Jill O'Donnell-Tormey, PhD – CRI; Theresa LaVallee, PhD – Parker Institute for Cancer Immunotherapy; Tim Bullock, PhD – University of Virginia; Kathy Ferrara, PhD – Stanford University; Chandan Guha, MD – Montefiore/Albert Einstein; and Gavin Dunn, MD, PhD – Washington University in St. Louis.

Creating Knowledge: Research Milestones

VETERINARY PROGRAM

Five canine patients with soft tissue tumors were treated with focused ultrasound at the Virginia-Maryland College of Veterinary Medicine in Blacksburg, Virginia. Three canine patients were also enrolled in a study investigating focused ultrasound to speed wound healing at the Oklahoma State University Center for Veterinary Health Sciences in Stillwater, Oklahoma. In this study focused ultrasound is being assessed as a means of enhancing delivery of an antimicrobial agent (or drug) to treat hygromas, a condition where repeated pressure on a bony joint produces significant swelling.

Veterinary patient Maddi Lynn

Convening the Community

2018 SYMPOSIUM

In October, a record number of clinicians, scientists, and industry representatives from around the globe convened in Virginia for the Foundation's 6th International Symposium on Focused Ultrasound. It was our largest and most successful symposium to date with more than 450 attendees from 23 countries, 250 scientific presentations, and more than 1,100 livestream viewers. Scientific presentations focused on the latest research in neurological indications such as Alzheimer's and Parkinson's disease, brain tumors, epilepsy, and psychiatric disorders. Cancer immunotherapy, veterinary medicine, and applications for focused ultrasound in the liver, lung, and pancreas were also among the important topics discussed.

Keynote and special lecture speakers included: technology innovator Gary Shapiro, President and CEO of the Consumer Technology Association; healthcare advocate and policy expert Scott Whitaker, AdvaMed CEO; and Openwater founder and CEO Dr. Mary Lou Jepsen, who has been included in TIME magazine's list of the world's 100 most influential people and CNN's list of top ten thinkers. The Symposium presentation videos are now available online, and a summary document will soon be available as well.

2020 SYMPOSIUM: MARK YOUR CALENDAR

Our 7th International Symposium on Focused Ultrasound will take place November 8-12, 2020, at the Hilton McLean Tysons Corner in Northern Virginia.

WORKSHOPS

Parkinson's Disease Workshop

Experts gathered in October for a Foundation-sponsored invitational workshop to discuss the BBB and Parkinson's disease and ways to further the development and adoption of focused ultrasound. More than 30 participants from healthcare, industry, academia, government, and the Foundation worked to identify opportunities and challenges for delivering therapeutic agents across the BBB to find new and innovative treatment options for Parkinson's. The Foundation is grateful for the work of Drs. Paul Fishman and Nir Lipsman, who organized and led the workshop. A summary of the workshop's major outcomes is now available on our website.

MEETINGS SPONSORED

The Foundation sponsored and/or exhibited at multiple scientific meetings in 2018 including: the Seattle Science Foundation 9th Annual Neuroanatomy Fellows Course in Seattle, Washington; the Society of Thermal Medicine (STM) in Tucson, Arizona; the International Symposium for Therapeutic Ultrasound (ISTU) in Nashville, Tennessee; the 2018 Ontario Gairdner International Symposium Focused Ultrasound: a New Frontier for Brain Therapy in Toronto, Canada; and the ESPR/HIFU Symposium (40th Post Graduate Course of the European Society for Pediatric Radiology) in Berlin, Germany.

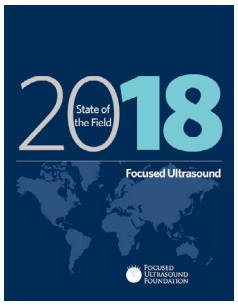
Fostering Collaboration

WORKING GROUP ESTABLISHED WITH MEDICAL IMAGING AND TECHNOLOGY ALLIANCE

The Medical Imaging & Technology Alliance (MITA) and the Foundation have formed a partnership to raise awareness of focused ultrasound technology among policymakers, insurance payors, and medical specialty societies; advocate for common goals related to commercialization; and advance the field toward clinical adoption. A Focused Ultrasound Working Group – including members from seven focused ultrasound companies – has been established and a work plan created that enables the group collectively to advocate for common goals and demonstrate the enormous potential of focused ultrasound to a wide range of decision makers. MITA, a division of the National Electrical Manufacturers Association, is the collective voice of medical imaging equipment manufacturers, innovators, and product developers.

2018 STATE OF THE FIELD REPORT RELEASED

Every year, the Foundation surveys stakeholders to assess and report on the status of focused ultrasound technology. The 2018 State of the Field Report is now available and includes charts, graphs, and data summaries, with new sections this year delineating research sites working with specific mechanisms of action and technical aspects of focused ultrasound. Additionally, there is considerably more content related to the commercialization sector – an area crucial to widespread adoption of this technology. The report is available online.



Cultivating the Next Generation

Foundation Fellows, Interns, and Global Scholars, Cumulative

17	48	72	47
Fellows	Interns	Global scholars	Institutions represented

INTERNS & GLOBAL SCHOLARS

The Foundation's local internship program welcomed seven students last year who pursued a wide variety of projects, from graphic design and the newly launched FUS Partners Program to technical projects including 3D-printed acoustic lenses and software tools intended to automate and simplify research. Additionally, the Foundation selected 20 2018 global scholars from 14 academic institutions across five countries.

Of note, 17 of the 41 2017/2018 global scholars had abstracts accepted for inclusion at the Foundation's 6th International Symposium on Focused Ultrasound. Global intern Brooke Ma's abstract – "Effects of focused ultrasound on delivery of intranasal GDNF DNA nanoparticles to the rat brain" – received the highest peer-reviewed rating among submissions and earned her travel support to attend and present her work at the Symposium.

Last year, the Foundation's internship program was named in memory of Board of Directors member Charles Steger, PhD. The Foundation's summer technical internships are generously funded by the Claude Moore Charitable Foundation.

Cultivating the Next Generation

MERKIN FELLOWS UPDATE

Our 2017 Merkin Fellows renewed in 2018 for a second year. This year French researcher Frédéric Padilla, PhD, from the Laboratory of Therapeutic Applications of Ultrasound (LabTAU) in Lyon, France, worked on projects investigating the potential of focused ultrasound to sensitize breast tumors to immunotherapies, as well as promoting brain tumor response to radiosurgery by combining radiosurgery with focused ultrasound when treating diffuse tumors such as glioblastoma multiforme (GBM). Merkin Scholar Francesco Prada, MD, a neurosurgeon from the Istituto Neurologico Carlo Besta in Milan, Italy, has been working on a preclinical study on sonodynamic therapy to tackle glioblastoma and several projects at UVA, including studying the clinical use of microbubbles in an intraoperative setting. Prada was recently named Brain Program Director for the Foundation.

Francesco Prada, MD (left) and Frédéric Padilla, PhD (right)

Overcoming Barriers

REIMBURSEMENT

Essential Tremor Reimbursement Coverage Expands

Medicare expanded coverage of focused ultrasound to treat essential tremor using Insightec's Exablate Neuro device in an additional nine states (Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, West Virginia, Kentucky and Ohio), bringing the total number of states covered to 25.

REGULATORY

FDA Approves Focused Ultrasound for Tremor-Dominant Parkinson's Disease

The FDA also approved focused ultrasound to treat patients with Parkinson's disease whose main symptom is tremor, with the Exablate Neuro device from Insightec. This approval was based on a clinical trial of 27 patients at UVA and the Swedish Neuroscience Institute in Seattle, Washington. The results of that study, which was funded in part by the Foundation, were published in *JAMA Neurology* in December 2017.

FDA Session with Focused Ultrasound Community Conducted at 2018 Symposium

As part of the Symposium this year, staff from the FDA discussed with the focused ultrasound community the importance of forging collaborations early and often with the FDA. Panelists also answered questions and discussed comments about challenges and opportunities for working together more effectively.

Increasing Awareness

EVENTS & SPEAKING OPPORTUNITIES: SPREADING THE WORD ABOUT FUS

In April, Foundation Chairman Neal F. Kassell, MD, presented in Hong Kong through various opportunities with the Harvard Club and Yale Club, American Chamber of Commerce, Gleneagles Hospital leadership, and private events at the Hong Kong Club and Foreign Correspondents Club. Special thanks to Board member Syaru Shirley Lin, PhD, and Council member Bernice Szeto, who coordinated and hosted events and facilitated valuable introductions during the trip.

In April, brothers Mark Allen and Greg Allen – both Foundation donors – organized a day of awareness events in Oklahoma City during which Foundation Board member John Grisham and Foundation Chairman Neal F. Kassell, MD, spoke to a large number of people. More than $200,000 was raised from connections made in Oklahoma City.

LIVE INTERVIEWS CONDUCTED AT AAIC MEETING

FUSF staff interview Nir Lipsman, MD, at AAIC

Watch Now >

The Foundation was on hand at the Alzheimer's Association International Conference (AAIC) in Chicago this summer when results were presented from the first-ever clinical trial of focused ultrasound to open the BBB in Alzheimer's patients. Chief Scientific Officer Jessica Foley, PhD, and Director of Clinical Relationships Suzanne LeBlang, MD, interviewed study investigator Nir Lipsman, MD, PhD, live from the meeting. The video can be viewed on the Foundation's Facebook page and website.

Additionally, in an interview coordinated by the Foundation, Deborah Kan – founder of Being Patient, the popular Alzheimer's patient support organization – interviewed Dr. Lipsman about his research.

ASIA PROGRAM NEWS

The Foundation formalized a strategy to cultivate relationships with laboratory research sites, clinical research sites, commercial treatment sites, manufacturers, philanthropists, and investors in Asia. Syaru Shirley Lin, PhD, was elected to the Foundation Board, and Jessica Che-yi Chao and Bernice Szeto joined the Foundation Council. Chao and Foundation consultant Dong-Guk Paeng, PhD, visited seven focused ultrasound research sites in Taiwan. Foundation Chairman Neal F. Kassell, MD, engaged more than 100 contacts through six presentations and six meetings in Hong Kong. Media interviews were conducted during the trip, garnering coverage in the *South China Morning Post* and *S&P Global*.

CTA "LET'S GO HUMANS" VIDEO FEATURES ESSENTIAL TREMOR PATIENT

During the Symposium, Gary Shapiro, President and CEO of the Consumer Technology Association (CTA™), delivered a keynote address – "Why Focused Ultrasound and Other Innovations Must be Allowed to Flourish" – and debuted an inspiring, three-minute video featuring Julia, an essential tremor patient whose life was changed by focused ultrasound treatment. The video was produced by CTA's "Let's Go Humans" initiative, which is the tech industry's "rallying cry for supporting and championing the kinds of emerging technology that betters our world." It can be viewed on our website.

Julia, essential tremor patient

Watch Now >

Increasing Awareness

PRESENTATIONS AND PUBLICATIONS

Presentations

Foundation staff along with former and current research fellows attended 34 scientific meetings and presented at 12. Highlights include John Snell, PhD, Technical Director of the Foundation's Brain Program, presenting at the American Society for Stereotactic and Functional Neurosurgery in Denver, Colorado, and Jessica Foley, PhD, the Foundation's Chief Scientific Officer, presenting both at Duke University in Durham, North Carolina, and at the 40th International Engineering in Medicine and Biology Conference, held in Honolulu, Hawaii.

Merkin Scholar Francesco Prada, MD, presented at both the Congress of Neurological Surgeons, in Houston, Texas, and the 49th Congress of the Italian Neurological Society, in Rome, Italy.

Published Papers

Members of the Foundation's scientific team published six scientific papers in 2018, on topics ranging from tumor ablation and its potential to enhance immunological therapy to transcranial magnetic resonance imaging-guided focused ultrasound thalamotomy for tremor.

MEDIA COVERAGE INCREASING, REACHING NEW AUDIENCES

Media coverage of focused ultrasound skyrocketed in 2018, with nearly 500 news stories appearing this year versus approximately 380 in 2017. Thanks in large part to the Foundation's presence at the Consumer Electronics Show (CES) in Las Vegas, Nevada, in January, we have also seen a major increase in consumer media coverage, which helps raise awareness among a much broader audience. Media highlights include: the Associated Press, *Forbes*, the *Huffington Post*, *Wired*, *Tech Nation*, NBC News, CNBC, the *Boston Globe*, the *Miami Herald*, the *South China Morning Post*, NPR, *Virginia Business*, the *Toronto Star*, and *Scientific American*.

Read More Below:

NEWSLETTER SUBSCRIBERS NUMBER MORE THAN 10,000

Our monthly newsletter eclipsed 10,000 subscribers in 2018. This year featured 210 stories and profiles that focused on donors, researchers, companies, and patients. In 2019 the newsletter is moving to a twice-monthly format due to the increasing amount of content and media coverage in the field of focused ultrasound.

Increasing Awareness

PATIENTS SHARE PERSONAL, LIFE-CHANGING FUS SUCCESS STORIES

Patient testimonials continue to serve as a moving and helpful tool in raising awareness about focused ultrasound by amplifying the life-changing, human impact of the technology. Many patients whose lives were drastically improved by focused ultrasound treatment were profiled this year by the Foundation.

Tammy | Neuropathic Pain

Faced with an expensive radiation therapy, Tammy researched other options and stumbled upon the focused ultrasound trial at the University of Maryland. In September, she became the first patient to be treated there.
Read More >

Ron | Parkinson's Disease

Ron sees tangible evidence of how far he has come since he was the second patient treated at The Ohio State University Wexner Medical Center in a clinical trial investigating focused ultrasound for Parkinson's dyskinesia.
Read More >

WEBSITE AND SOCIAL MEDIA

Social Media in 2018

8,600	229,000	352,000	49,000	47,800
Referrals to our website from social media	Facebook reach	Twitter impressions	LinkedIn impressions	Views on the Foundation YouTube channel

The Foundation continued to increase website traffic and grow social media reach in 2018. Visits to our website grew by 17 percent over 2017. On the social media front, our more strategic approach and increased posting volume resulted in higher engagement rates and thousands more people reached than in the previous year. Please be sure to follow us on Facebook, Twitter, LinkedIn, Instagram, YouTube, and Medium.

FOUNDATION BLOG GROWS

The Foundation blog continues to share opinion pieces – often authored by members of our staff, positioning them as experts in the field – on topics related to focused ultrasound and medical technologies. In 2018 we increased our post frequency and began working with outside leaders and partners to vary the topics and content offered. Blog topics this year included: "Is a Parkinson's Disease Clinical Trial Right for Me?" by Tim Meakem, MD; "Collaboration: Commercialization in the Evolving Focused Ultrasound Landscape," by Emily White, MD; "Glioblastoma Multiforme: Tragedy and Hope for the Cancer That Killed Senator John McCain," by Nir Lipsman, MD, PhD; and "Pancreatic Cancer: Tumor Ablation Using Focused Ultrasound and the Challenges of Immunotherapy," by Joo Ha Hwang, MD, PhD. If you have an idea for a blog, please let us know.

Aggregating and Sharing Knowledge

LABTAU LAUNCHES MOOC

The Laboratory of Therapeutic Applications of Ultrasound (LabTAU) in Lyon, France, in collaboration with the Foundation, launched the first presentation dedicated to therapeutic ultrasound in its Massive Online Open Course (MOOC). MOOCs are free online courses that provide a flexible way to learn new skills or become familiar with a new topic; this MOOC is targeted toward physicians, students, and patients who are interested in learning about the clinical and technical research in the field of focused ultrasound. World-renowned experts in the field will provide 12 unique presentations covering a variety of topics, such as technical explanations of various focused ultrasound applications and clinical case reviews.

WEBINARS REACH LARGE AUDIENCE ONLINE

The Foundation hosted three webinars in 2018 aimed at providing current information about emerging areas of interest or promising research from experts in the field. Optum's Distinguished Engineer, Rick Hamilton, led a webinar in April entitled, "Blockchain: A Healthcare-Focused Introduction," that provided a non-mathematical introduction to blockchain operation in healthcare-centered use cases. In May, Philip Bourne, PhD, Stephenson Chair of Data Science and Director of the Data Science Institute at UVA, led a webinar that explored data science in biomedicine. He addressed successes and failures thus far, whether or not we are seeing a paradigm shift, and what organizations and researchers can do. Lastly, in September, best-selling author, business strategist, and serial entrepreneur Salim Ismail led a webinar entitled, "Accelerating Adoption of New Technologies," which explored ways to accelerate the adoption of new technologies in legacy environments and included tips for how to help adapt to the coming disruptions in healthcare. These webinars have collectively been viewed more than 1,000 times.

Rick Hamilton - Blockchain: A Healthcare-Focused Introduction

Watch Now >

Philip Bourne, PhD - Exploring Data Science in Biomedicine

Watch Now >

Salim Ismail - Accelerating Adoption of New Technologies

Watch Now >

Finances

ALLOCATION OF FUNDS IN 2018

The Foundation spent $8,526,318 in 2018. Research comprised 61 percent of our spending with 10 percent allocated to development, and 14 percent to administrative costs. Our commitment to our donors is paramount, and we are proud to say that in addition to being included in Charity Navigator's recent list of America's 10 Best Medical Research Organizations, we continue to hold the highest ratings by both GuideStar and Charity Navigator.

Finances

FUS PARTNERS LAUNCHED

In April, the Foundation launched FUS Partners, a new program aimed at fostering relationships among focused ultrasound manufacturers seeking assistance with FUS-related activities, including financing, partnerships, technology transfer, and academic research opportunities. The program aims to systematize and formalize activities in which the Foundation had already been engaging, on an increasingly ad hoc basis, related to connecting the focused ultrasound commercial sector with investors and collaborators around the world.

One early success story in 2018 involved helping HistoSonics close its latest financing with additional investment from friends of the Foundation, facilitated by the FUS Partners program. The round, led by Foundation Board member and serial entrepreneur Fred Moll (Auris Surgical Robotics Inc., Intuitive Surgical, Hansen Medical), solidly positioned HistoSonics for future growth.

In the fall of 2018, the program was also covered in *Virginia Business*, featuring interviews with Foundation Chairman Neal Kassell, MD, and FUS Partners Managing Director Emily White, MD.

FOUNDATION ORGANIZATION

Three important 2018 hires occurred at the Foundation. Avanti Godbole joined the development team full-time after working at the Foundation throughout her Capstone project for the Frank Batten School of Leadership and Public Policy at UVA. Paige Rice now works closely with the Chairman and the development team in support of the Foundation's mission. Lastly, Emily Whipple, PhD, has signed on as Director of Strategic Initiatives to help develop and implement projects and programs that promote the adoption of focused ultrasound.

Syaru Shirley Lin, PhD and
Charles W. "Wick" Moorman IV

The Foundation also welcomed two new Board of Directors members, Syaru Shirley Lin, PhD, and Charles W. "Wick" Moorman IV. Previously a partner at Goldman Sachs, Lin led the firm's efforts in private equity and venture capital in Asia. She was also a founding board member of both Alibaba Group and Semiconductor Manufacturing International Corporation. Lin will leverage her experience in finance and understanding of Asia to help the Foundation further progress there. Moorman, former CEO of Norfolk Southern and Amtrak, joined the Board in June. He also serves on the Board of Directors of Chevron Corporation, Duke Energy, the Georgia Tech Foundation, the Nature Conservancy of Virginia, and Oracle.

Lastly, we were saddened to lose our friend and Board of Directors member Charles W. Steger, PhD, who passed away in May.

To honor Dr. Steger's passions for education and focused ultrasound, the Foundation has named its internship program in his memory. The Charles Steger Focused Ultrasound Internship Program will encompass the Foundation's local and global internship programs. Integral to the Foundation's mission, these internships are designed to foster interest in focused ultrasound technology among the next generation of researchers.

Charles W. Steger, PhD

$ Fundraising

FOUNDATION MEETS $10 MILLION MATCHING PLEDGE

In July 2017, an exceptionally generous anonymous donor pledged $10 million of unrestricted funds to be matched 1-for-1 by 2022. This transformative gift inspired donors who recognized the opportunity to more quickly fund additional focused ultrasound research, and who appreciated that their contribution would be doubled. Thanks to their support and enthusiasm, the $10 million match was met in November 2018.

2018 FUNDRAISING UPDATE

The fundraising goal for 2018 was $5 million in cash and $5 million in pledges, to be paid in 2019. Approximately $6.5 million in cash and $2 million in pledges was raised toward our goal for a total of $8.5 million. In addition, the Foundation raised more than $5 million from the Commonwealth of Virginia to support focused ultrasound research at UVA. We also received $10 million in cash via the matching pledge.

Turning Vision into Reality

TO OUR DONORS:

The Foundation was created to improve the lives of millions of people with serious medical disorders by accelerating the development and adoption of focused ultrasound. Because of your generous support, we are on the cusp of a time when focused ultrasound is on track to become the standard of care for a variety of diseases and conditions, thus reducing death, disability, and suffering for countless patients. We appreciate your helping our vision become a reality.

THANK YOU!

Donors Who Contributed in 2018

Anonymous (15)
Adams Charitable Foundation
Tessa G. Ader
Allen Family Charitable Foundation
American Fidelity Foundation
Ms. Alice Anderson
Mr. Harry Anderson
Ms. Donna Avery
The Honorable Gerald L. & Robin D. Baliles
The Paul and Merrill Barringer Family Fund
D.N. Batten Foundation
David and Carolyn Beach Fund in the Charlottesville Area Community Foundation
Anson and Debra Beard
Mr. Ronnie F. Bell
Mr. and Mrs. John H. Birdsall
Bocock/Hitz Fund in the Charlottesville Area Community Foundation
Mr. Bernard T. Bress
The Briar Foundation
Ambassador and Mrs. W.L. Lyons Brown
W.L. Lyons Brown, Jr. Fund, Inc.
The Carson Family Charitable Trust
Douglas E. Caton
Jeanne and John Chamales
Chericoke Foundation
Claude Moore Charitable Foundation
Cooley Godward Kronish, LLC
Jim and Becky Craig
Linda and Carlton Crenshaw
CSX Corporation
Ms. Betsy Dalgliesh
Mr. and Mrs. Terrence D. Daniels
Mr. and Mrs*. John Stewart Darrell
Ms. Donna Davis
The DiFerdinando Family
Mrs. Frances M. Dulaney
Edward C. Smith, Jr. 2006 Revocable Trust
Ellen & Ronald Block Family Foundation
Enbridge Foundation
Mr. and Mrs. Albert D. Ernest
Mr. Jim Filgut
Stephanie and Lawrence Flinn, Jr.
Florence Bryan Fowlkes Fund of the Community Foundation for a greater Richmond
Cynthia K. and W. Heywood Fralin
Spencer and Joy Frantz
Mr. and Mrs. Norman Rickard Frisbie
The Fruehauf Foundation
Mr. and Mrs. Ronald J. Gilbert
Richard and Leslie* Gilliam
Judge Douglas Ginsburg
Mr. Manaram Gnanasekera
The Rick & Susan Goings Foundation
Ms. Shannon M. Gonzalez
Good Street
Mr. and Mrs. William H. Goodwin, Jr.

* Deceased

Donors Who Contributed in 2018

The Gordon Foundation, a Donor Advised Fund of Renaissance Charitable Foundation

Nancy and Bruce Gottwald

Mr. and Mrs. Grant

Grills Family Foundation

Mr. Harold Hamm

Frank J. Hanna, Jr.

Karen and Bert Harris

Dr. J. Noland Harvey

Hassenfeld Family Foundation

Joy Hayes

Eric and Rosy Heinsohn

Ms. Lee Heller

Dr. and Mrs. Samuel Hellman

Michael J. Henke and Judy S. Campbell

Herndon Foundation

Mr. and Mrs. Landon Hilliard

Mr. and Mrs. Thomas J. Hill

Mr. Manh T. Hoang

Todd and Jen Hochrein

Kim and Ross Hollander

Horton Foundation Fund in the Charlottesville Area Community Foundation

Bill and Cessie Howell

Mr. Anthony R. Ignaczak and Mrs. Laura E. Ignaczak

The Janet Stone Jones Foundation

Dr. Mary Lou Jepsen

Jericho Capital

Dr. Joe and Sally Gieck Fund in the Charlottesville Area Community Foundation

Mr. John C. Cullather, Cancer Fund of the Community Foundation for a greater Richmond

Ms. Debbie Johnson

Rupert and Mary Ellie Johnson Charitable Fund

Mr. and Mrs. William Johnson

Lou and Dan Jordan

The Joseph and Robert Cornell Memorial Foundation

Jody Ragland Darden Charitable Gift Fund, a component fund of the North Carolina Community Foundation

Ms. Janice M. Karon

Carita D. Corse and Edward J. Kelly, III

Mr. and Mrs. Donald A. King, Jr.

Carl and Nancy Krietler

Mr. and Mrs. Fritz R. Kundrun

Mr. and Mrs. David C. Landin

Gabriela and Kevin Lee

Mr. Harry Lester

Dr. Stanley H. Levy

Harriettjo and James Lineberger

Robert Lloyd and Margaret P. Lloyd

Mr. Alan Longshore

Hunt and Christine Lowry

Mr. Heinz O. Luedecke, Jr.

Mr. and Mrs. John Lukens

The Luminescence Foundation, Inc.

John and Dudley Macfarlane

Ms. Sharlynn Mar

Anthony F. & Susan M. Markel Fund of the Community Foundation for a greater Richmond

Ms. Brenda K. Mattingly

The McCutcheon Foundation

The Melville Foundation

Richard Merkin, M.D.

Mr. Stephen Meyer

Mr. Chris Minikon

Mr. Charles W. Moorman and Ms. Bonnie W. Moorman

Jim and Lynda Morley

Mr. and Mrs. Wes Myhre

Paula and Rob Newcomb

Mr. and Mrs. Terry Newmyer

Nunley Family Fund

Oscar F. Smith/Marjorie Smith Charles/Angie Newman Johnson Fund in the Charlottesville Area Community Foundation

Ms. Haley Ottley

Mr. Edward P. Owens

Ms. Diane Pallot

Thomas T. Rankin

Cynthia M. Reusche

Paige and Joe Rice

The Rimora Foundation

Robertson Foundation

Mr. John G. Rocovich, Jr.

The Rosenstiel Foundation

Rotgin Family Fund in the Charlottesville Area Community Foundation

Mr. Fabian Rush

Mr. and Mrs. Edward M. Schaaf, III

Mimi O' Connell Scully

Seagears Family Foundation

Mr. and Mrs. Charles H. Seilheimer, Jr.

Mr. and Mrs. Charles H. Seilheimer, III

Jeanne S. Shaw

Sherry Sharp, of the Community Foundation for a greater Richmond

Anne* and Conrad Shumadine

Mr. Adam Siegel

Albert H. Small, Sr.

Mr. and Mrs. C. Ray Smith

Mrs. Joe D. Smith, Jr.

Burkhard Spiekermann

Starr Hill/Red Light Fund in the Charlottesville Area Community Foundation

Stevenson Family Charitable Trust

Mr. Charles Stoll

Michael A. and Lynn D. Tanner

Mrs. Fay Taylor

Ms. Betty Terrell

Ann and Charles Thacher

John and Susanne Trible

Merle K. Turner

VBS Foundation

Mr. and Mrs. Jerry Wagner

Westhill Management Co. Ltd.

Westwind Foundation

Whitney & Anne Stone Foundation

William R. Kenan, Jr. Charitable Trust

Mr. Richard G. Wise

Kurt and Alana Woerpel

Andrew J. Lockhart Memorial Prize

Mr. Gregory Clark

Lauren and Ross Levine

Mr. and Mrs. Eugene Lockhart

George and Helen Massaro

Jay and Emily Teeter

In Memory Of

Eugene Barfoot:
Jeanne Barfoot

Genevie Barnard:
Mr. Richard Barnard

G. Waddy Garrett:
Mrs. G. Waddy Garrett

Leslie Gilliam:
Marvin W. Gilliam, Jr.

Wilbur L. McBay:
Ms. Sharon McBay

Elly Reed and Wilson Reed:
Mr. Poulson Reed

Dr. Charles W. Steger:
Mr. and Mrs. Allen D. Martin

In Honor Of

Michie O'Day:
Bill and Judy Boland

Rick and Barbara Frisbie:
H. Allen Curran & Jane W. Curran

Ashley Lockhart:
Sarah Page and Richard B. Maxwell, III
Page Maxwell

* Deceased

Focused Ultrasound Foundation Board of Directors

Neal F. Kassell, MD
Chairman, Focused Ultrasound Foundation
Former Co-chair of Neurosurgery, University of Virginia

Dorothy N. Batten
Founder, iThrive Initiative
Former Director, Landmark Communications, Inc.

Eugene V. Fife
Founding Principal, Vawter Capital, LLC
Former Chairman, Goldman Sachs International

John R. Grisham
Author

William A. Hawkins III
Lead Director, Immucor, Inc.
Former Chairman & CEO, Medtronic

Daniel P. Jordan, PhD
President Emeritus, Thomas Jefferson Foundation, Inc.

Edward J. "Ned" Kelly, III, JD
Former Chairman, Institutional Clients Group, Citigroup

Syaru Shirley Lin, PhD
Adjunct Faculty, Chinese University of Hong Kong
Director, Goldman Sachs Asia Bank

Edward D. Miller, MD
Former CEO, Johns Hopkins Medicine

Frederic H. Moll, MD
Co-founder, Intuitive Surgical
Chair & CEO, Auris Surgical Robotics, Inc.

Charles W. "Wick" Moorman IV
Former Chairman & CEO, Norfolk Southern
Former CEO, Amtrak

Steve H. Rusckowski
President and CEO, Quest Diagnostics Inc.
Former CEO, Philips Healthcare

Carl P. Zeithaml, PhD
Dean and F. S. Cornell Professor of Free Enterprise, McIntire School of Commerce, University of Virginia

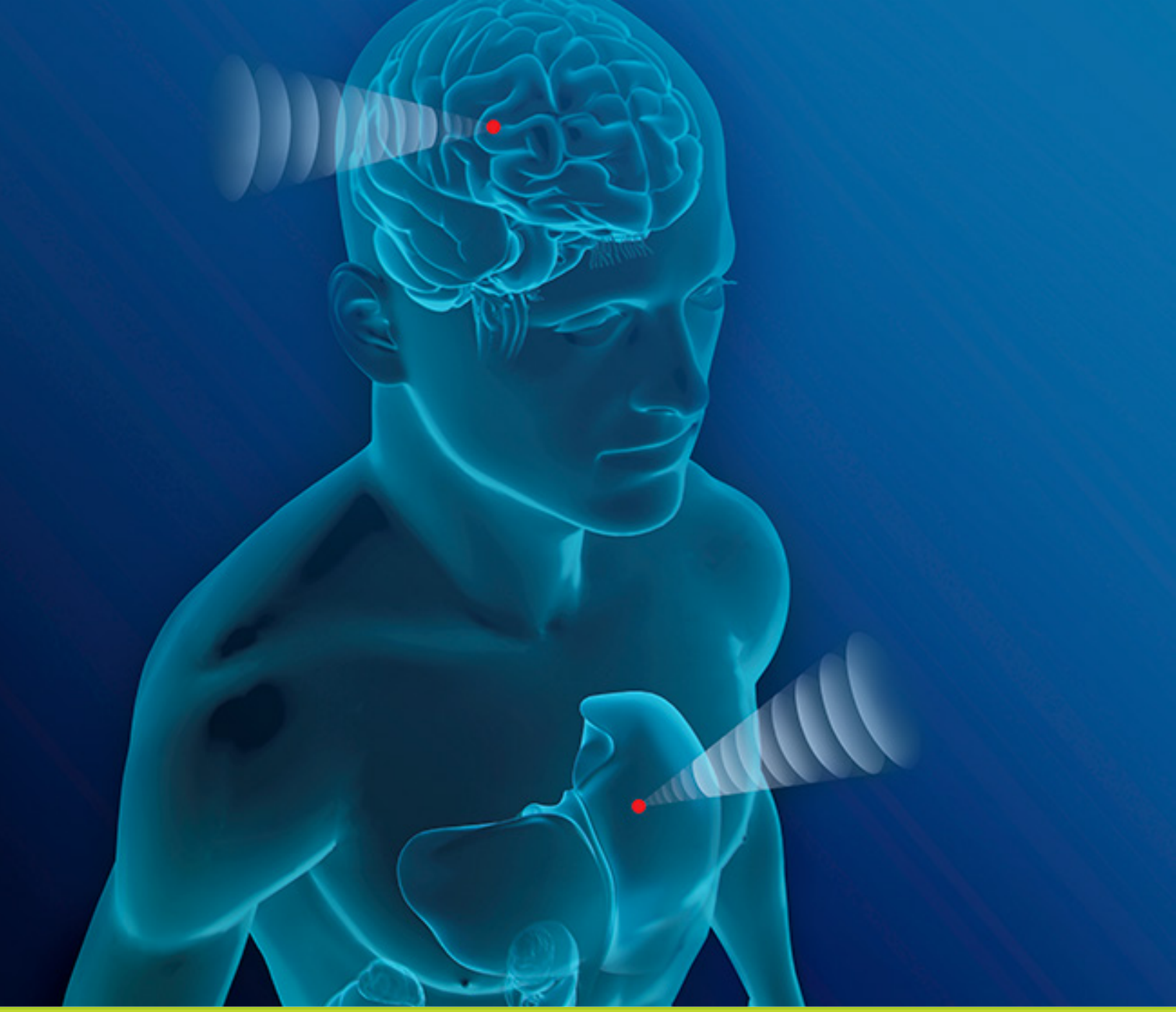
Focused Ultrasound Foundation Council Members

Co-chairs
Jane P. Batten
Charles H. Seilheimer, Jr.

.....

John B. Adams, Jr.
Ellen Block
Charles F. Bryan, Jr., PhD
Nancy J. & Thomas N. Chewning
Jessica Che-yi Chao
Marguerite & Norwood Davis
Rick Hamilton
Diane Heller
Cecelia S. & William J. Howell
Dean L. Kamen
Ann Kingston
Harry Lester
Amanda Megargel
Jonna & Tony* Mendez
Michael Milken
Paula F. Newcomb
Wyndham G. Robertson
Mary Lou Seilheimer
Alice H. Siegel
Aaron Stern, MD, PhD
Fredi & Howard Stevenson
Bernice Szeto
Jane M. Tolleson
Andrew C. von Eschenbach, MD
Meredith Jung-En Woo, PhD
Linda K. Zecher

* Deceased



If you would like additional information or want to discuss how you can support our mission, please contact:

Nora Seilheimer
nseilheimer@fusfoundation.org or 434.326.9830

www.fusfoundation.org

FOCUSED ULTRASOUND FOUNDATION

1230 Cedars Court, Suite 206
Charlottesville, VA 22903
434.220.4993 www.fusfoundation.org