

# Time to Be **Revolutionary**

In the United States alone —

**1,500** people die from cancer every day

**200,000** women have  
hysterectomies because of  
uterine fibroids each year

**1,000,000** people are  
living with Parkinson's disease



FOCUSED  
ULTRASOUND  
FOUNDATION

**The need is clear  
and so is our mission.**

IT'S ABOUT PATIENTS: **SAVING TIME, SAVING LIVES**





# What's the **big idea?**

Imagine treating cancer, Parkinson's disease, epilepsy and brain tumors without surgery, radiation or the side effects of chemotherapy.

With further research and development, these achievements may be possible through Focused Ultrasound, an early-stage, noninvasive therapeutic technology.

Unfortunately, it takes decades for a major medical technology like Focused Ultrasound to become mainstream. Every year we shave off that process equates to reduced death and suffering for countless people, including our family, our friends and maybe ourselves.

**THE FOCUSED ULTRASOUND FOUNDATION IS DEDICATED TO IMPROVING THE LIVES OF MILLIONS WORLDWIDE BY MAKING FOCUSED ULTRASOUND AVAILABLE IN THE SHORTEST TIME POSSIBLE.**



## Dear Friends, Supporters and Colleagues,

The potential of focused ultrasound has never been more apparent. Effective therapies to treat cancer, Parkinson's disease, epilepsy and brain tumors without surgery, radiation or the side effects of chemotherapy are now on the horizon, no longer beyond it.

As this report reflects, a great deal of progress has been made during the last several months, including the launch of the first U.S. clinical trial using focused ultrasound to treat Parkinson's disease; the first fully approved focused ultrasound treatment for cancer in the U.S.; the most comprehensive, largest international meeting of the focused ultrasound clinical community ever; and the development of a roadmap to help patients with liver tumors.

But we still need to shorten the distance. Thirty years is too long for patients and their families to wait for medical breakthroughs. Yet, the best interests of patients may not always align with a for-profit company's strategic plan or an academic institution's research agenda. Add to this misalignment of interest roadblocks like insurance reimbursement and regulatory hurdles, and one begins to understand why it takes decades for a game-changing technology like focused ultrasound to become mainstream.

For the Focused Ultrasound Foundation, the bottom line is getting better treatments to the patients who need them—after all, if you or a loved one is sick, soon is not fast enough. Working in collaboration with the pioneering physicians, scientists and industry leaders, we are making 2012 another successful year for the field, and even more importantly, for the patients. We are proud to serve as the catalyst for focused ultrasound's development and adoption and an incubator to foster collaboration—collaboration being the ultimate force multiplier for human capital.

"The revolution has begun," and we are at a magic moment where the actions we take now have the potential to improve the lives of millions worldwide. Help us achieve our goal of making focused ultrasound available in the shortest time possible. Be revolutionary, and be well. The best is yet to come.

Kind regards,

A handwritten signature in black ink, appearing to read 'Neal F. Kassell'. The signature is fluid and cursive, written in a professional style.

**Neal F. Kassell, MD**  
Chairman  
Focused Ultrasound Foundation



## THE REVOLUTION HAS BEGUN

### **1st** PARKINSON'S DISEASE

Clinical Trial in US Launched

**\$572,000** in Research  
Awards to **6** CUTTING-EDGE  
PROJECTS

**350** people from **24** countries  
attend **3rd** INTERNATIONAL  
SYMPOSIUM on Focused  
Ultrasound

FOUNDATION-FUNDED  
RESEARCH exceeds  
**\$8 million** mark

**World's 1st** Essential  
Tremor Clinical Trial Complete

**15** YOUNG INVESTIGATORS  
Recognized

**\$40 Million**  
contributed since **2006**

AT A GLANCE **2012 PROGRESS**

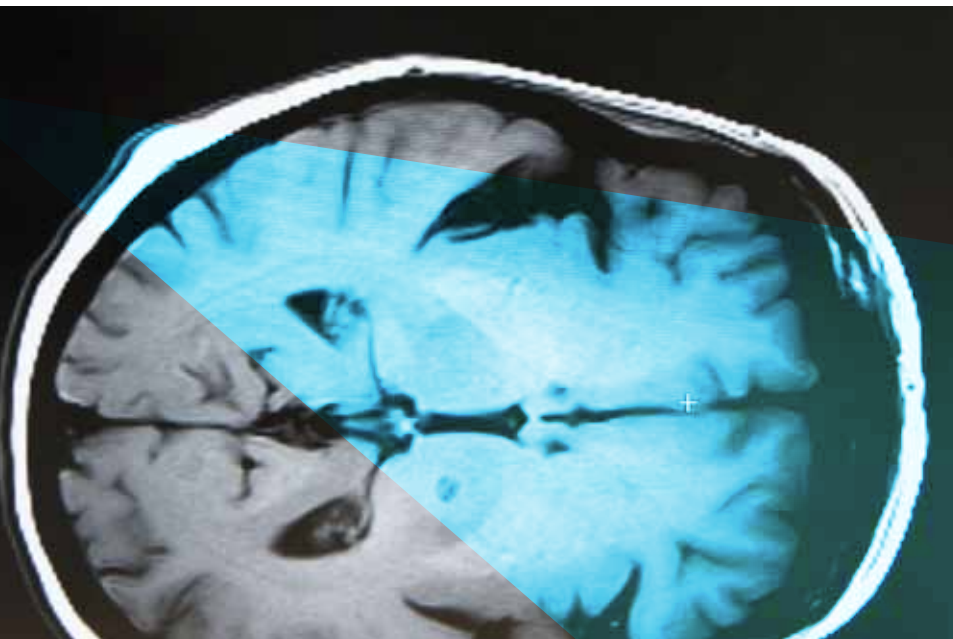
## Take Risks Be Bold

The Focused Ultrasound Foundation is unique in the world of medical philanthropy in that we are advancing a promising medical technology and are interested in multiple diseases and conditions rather than a cure for one specific indication. Significant progress is being made on a number of fronts.

### Essential Tremor

Our first-in-the-world essential tremor research continued making excellent progress in 2012. A total of 20 patients have been treated in Foundation-funded studies, including 15 patients at the University of Virginia and 5 at the University of Toronto. The debilitating tremors of all 20 patients were markedly reduced, and the patients continue to do very well. Simple tasks like getting dressed, eating or pouring a glass of water are now possible.

Encouraged by these promising results, the device manufacturer, InSightec, is organizing a larger, pivotal study, the final step towards full FDA approval. This trial has received the “go ahead” from the FDA and will begin in mid-2013.



**“For thousands of Parkinson’s patients, focused ultrasound may offer a dramatic improvement in quality of life. This program is a fast-track way to make that happen.”**

— G. Frederick Wooten, Jr., MD  
Professor of Neurology  
University of Virginia

### Parkinson’s Disease

In 2012, the first six patients in the United States were treated for Parkinson’s disease using noninvasive focused ultrasound. These treatments were part of a clinical trial the Foundation organized and is funding at the University of Virginia. A total of 30 patients with tremor-dominant Parkinson’s will be treated in this sham-controlled trial. In addition, the Foundation is organizing trials to treat patients with Parkinsonian dyskinesia (involuntary movements) and anticipates treatments beginning by the end of 2013.



**Left:** Neurosurgeon Dr. Michael Schwartz talks with Tony Lightfoot prior to his focused ultrasound treatment for essential tremor at Sunnybrook Hospital in Toronto on December 18, 2012.

**Right:** Tony Lightfoot celebrates after regaining the use of his right hand.

## Brain Tumors

Approximately 200,000 new cases of brain tumors are diagnosed annually in the United States alone. With these patients in mind, the Foundation is directing groundbreaking studies to develop focused ultrasound treatments that could offer an alternative to invasive brain surgery, a complement or replacement to radiation therapy, and the means to deliver drugs directly to the tumor. A Foundation-funded brain tumor study opened at the University of Toronto in 2012, and we anticipate a second study opening at the University of Virginia in 2013.

## Epilepsy

In 2012, the Foundation initiated an Epilepsy Research Initiative in an effort to help the approximately 50 million people worldwide, including mostly children and the elderly, who suffer from epilepsy. At this stage, we are developing a roadmap to address current technical challenges and are optimistic that a first in the world clinical trial for epilepsy can be launched in 2014.

## Pancreatic Tumors

In 2012, the Foundation began funding research at the University of Washington aimed at improving the treatment of pancreatic cancer by using focused ultrasound to enhance drug delivery. Estimates indicate that focused ultrasound could annually benefit as many as 161,000 patients suffering from pancreatic cancer worldwide.

## Research Awards

Six new research awards totaling \$571,800 were made in 2012 for studies exploring the use of focused ultrasound in early detection of tumor masses, opening the blood-brain barrier to facilitate the delivery of drugs in treating Alzheimer's disease and other neurological and neurodegenerative diseases, as well as in the treatment of conditions as varied as osteoarthritis, head and neck cancer and pelvic disease.

## Accelerate Breakthroughs Encourage Bold New Ideas

### Fellowships

In 2012, the Foundation provided a fellowship to Jean-François Aubry, PhD, of the Institut Langevin in Paris to pursue research efforts aimed at improving focused ultrasound brain treatments. This fellowship is funding a visiting associate professorship at the University of Virginia, allowing Aubry, one of the world's leading ultrasonic therapy experts, the opportunity to collaborate with researchers at the UVA Focused Ultrasound Center and with the Foundation's Brain Program team. Together, they will work to overcome technical barriers with the goal of making patient treatments better, faster and safer.

### Interns

Launched in June 2012, this program enabled eight bright and gifted college students to work on a variety of research projects in collaboration with the Foundation's scientific and medical team. These internships are designed to foster interest among the next generation of researchers in the development of focused ultrasound as a clinical tool, and to address real-world challenges, the conquering of which could expedite the adoption of the technology. Each project represents a valuable contribution to the field of focused ultrasound, and two of their papers were presented as posters at the 3rd International Symposium on Focused Ultrasound.







Neal Kassell, MD, Chairman and Founder of the Focused Ultrasound Foundation, with 2012 Young Investigator Award recipients left to right: Jonathan Kopechek, Ph.D.—Boston University; Scott Burks, Ph.D.—National Institutes of Health; Min Jung Park, M.D.—Samsung Medical Center, South Korea; Sin Yui Yeo, M.Sc.—Eindhoven, The Netherlands; Anne Cain-Nielsen—University of Michigan; Beatrice Cavallo-Marincola, M.D.—Sapienza University of Rome, Italy; Roel Deckers, Ph.D.—University of Utrecht, The Netherlands; Vasant A. Salgaonkar, Ph.D.—University of California, San Francisco; Stephen Monteith, M.D.—Thomas Jefferson University; Emilee Minalga, Ph.D.—University of Utah; Louise Dickinson, M.D.—University College, London. Not shown: Sarfraz Ahmad, Ph.D.—University of Dundee, UK; Muna Aryal, Ph.D.—Boston College and Brigham and Women’s Hospital; Ji Hee Kim, M.D.—Yonsei University College of Medicine, South Korea; Abhijit Patil, M.D.—Jasiok Hospital and Research Center, India.

## Young Investigators

Funded in part by a grant from the National Cancer Institute, the Foundation awarded 15 early-career scientists with Young Investigator Awards in 2012, which enabled these young researchers to attend and present their research at the 3rd International Symposium on Focused Ultrasound. The NCI funding was provided through the National Institutes of Health (NIH) Conference Grant Program, which supports high-quality conferences that are relevant to the scientific mission of the NIH and to public health.





## Collaboration: The Ultimate Force Multiplier for Human Capital

### 3rd International Symposium on Focused Ultrasound

A short distance from the National Institute of Health's headquarters in Bethesda, Maryland, the Foundation convened more than 350 clinicians, scientific researchers, industry leaders and government agency representatives from 24 countries at the 2012 symposium. Held on a bi-annual basis, this robust scientific program included more than 170 oral and poster presentations, a 50 percent increase over the 2010 symposium. As evidenced by the research as well as the enthusiasm of the attendees, the technology, the science and the commercialization of focused ultrasound is marching forward at an accelerated rate. The future of focused ultrasound has never been more promising.

**“If you want  
to go fast,  
go alone.  
If you want  
to go far, go  
together.”**

-African Proverb

### Liver Workshop

Because of focused ultrasound's potential to transform the treatment of liver tumors, the Foundation remains committed to the development of a clinical trial for this common and life-threatening disease. In June 2012, the Foundation organized a world-class working group to spearhead an effort to treat liver cancer with focused ultrasound. Twenty experts and key opinion leaders in this area, including clinicians, scientists and industry leaders, met to discuss clinical, regulatory and technical barriers that must be addressed to make focused ultrasound liver treatments available to patients. The same group met again in October 2012 and is working to develop a consensus paper outlining the path forward. This paper will be published in the *Journal of Therapeutic Ultrasound* in 2013.

### Brain Technical Workshop

In July 2012, the Focused Ultrasound Foundation's Brain Program hosted its first invitational mini-workshop to tackle important imaging problems with the help of a world-class team of magnetic resonance imaging (MRI) experts from academia and industry. This workshop was a highly successful collaborative problem-solving session that generated solutions for improving the efficiency and safety of transcranial MR-guided focused ultrasound treatments. Some of the solutions identified during the workshop are already being applied in patient treatments and are expected to reduce treatment time by improving the quality of the MRI scans.

**Opposite Page:** (Left to right) Peter Scardino, M.D.—Memorial Sloan-Kettering Cancer Center; Joost Willems, M.D.—University Medical Center Utrecht, The Netherlands; Merel Huisman, University Medical Center Utrecht, The Netherlands; Brain Workshop 2012; Emilee Minalga, Ph.D.—University of Utah; Yuchi Chu, Ph.D.—Alpinion US, Inc.; Rajiv Chopra, Ph.D.—University of Toronto; Lynne Golumbic—InSightec, Ltd.; Linsey Phillips, Ph.D.—University of North Carolina; Wladyslaw Gedroyc, M.D.—St. Mary's Hospital, London; Abhijit Patil, M.D.—Jasiok Hospital and Research Center, India; Daniel Pajek—University of Toronto; Kim Butts Pauley, Ph.D.—Stanford University; Beatrice Cavallo-Marincola, M.D.—Sapienza University of Rome, Italy; Jin Woo Chang, M.D., Ph.D.—Yonsie University Colledge of Meicine, South Korea.

## A Trusted Source Timely, Accurate Information

Focused ultrasound continues to attract significant interest, and focused ultrasound-related stories were covered more than 50 times by the national, international and local media in 2012.



**“Sound Waves  
Instead of Scalpels”**



**“Brain Surgery  
That’s Not Invasive”**



**“Trial Investigates Focused  
Ultrasound for Parkinson’s  
Disease Tremor”**



**“Scalpel-free Surgery Gives  
Patients with Tremor  
Disorder Steady Hands”**



**“The Sound of Progress”**

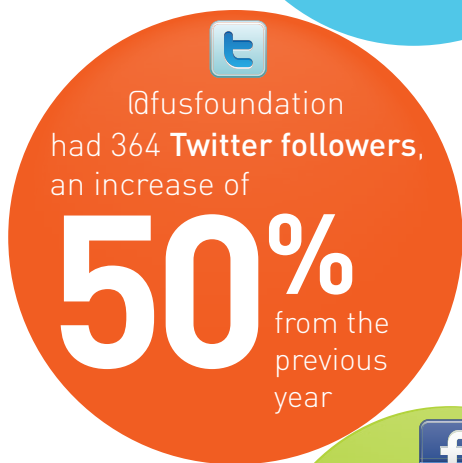
The Focused Ultrasound Foundation's website, [www.fusfoundation.org](http://www.fusfoundation.org), serves as the encyclopedia of focused ultrasound and is a trusted source of information for researchers and patients. Visits to the website, as well as subscribers to our monthly newsletter and followers and fans of our social media programs, continue to enjoy robust growth.

## As of December 2012:



### JOURNAL OF THERAPEUTIC ULTRASOUND

In 2012, the Foundation launched an online, open-source journal in collaboration with the International Society for Therapeutic Ultrasound and BioMed Center. A 25-member editorial board has been selected and the first issue will be released in early 2013. The Journal provides a much-needed platform for rapidly sharing information about new developments and best practices in real time.



# Financial Highlights

At the Focused Ultrasound Foundation, we know donors have choices when it comes to where to invest their philanthropic dollars, and we are grateful you choose to place your financial support in us. We value every dollar and every donor, and take responsibility for ensuring that your gifts are used with an approach that is market-driven and results-oriented.

Our programs are designed to provide an adrenaline rush in the field and achieve progress faster. Towards this end, we deliberately have no endowment and prefer to deploy our resources as quickly as possible with the belief that the best use of your capital is funding research and programs, not sitting in an endowment or reserve fund.

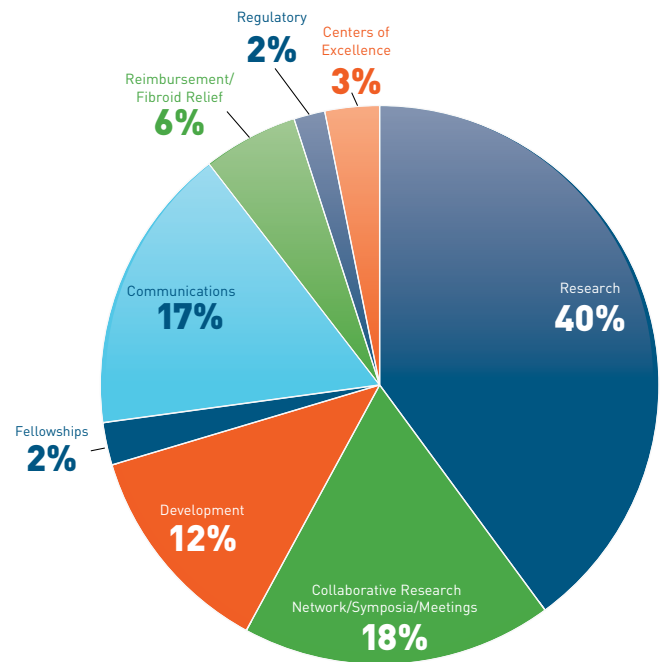
**Our strategic focus is patients.**

**The litmus test of every action and expenditure is “will this help patients?”**

## 2012

### Use of Funds

Program	Total
Research	1,893,073
Collaborative Research Network/Symposia/Meetings	853,987
Fellowships	116,875
Communications	792,102
Reimbursement/Fibroid Relief	260,947
Regulatory	85,387
Centers of Excellence	149,561
Development	590,869
<b>Total</b>	<b>4,742,801</b>

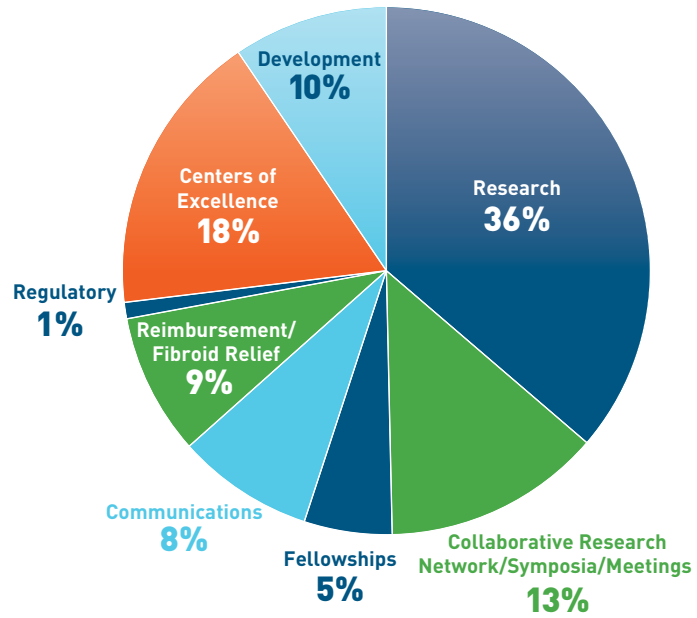


Administrative costs comprised 14% (\$663,992) of the total budget, fully allocated above.

Fully audited financials and our most recent IRS Form 990 are also available.

## 2006-2012 Use of Funds

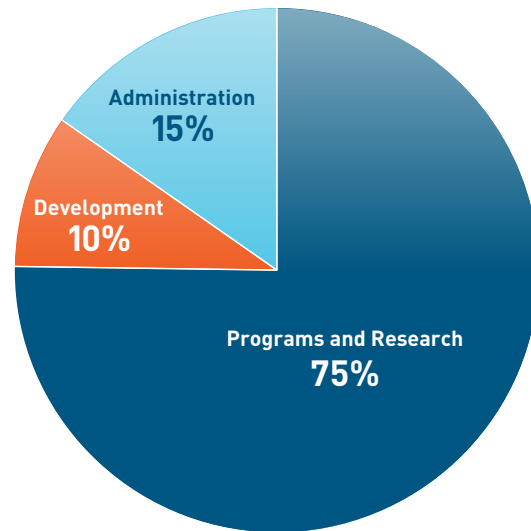
Program	Total
Research	8,731,267
Collaborative Research Network/Symposia/Meetings	3,215,882
Fellowships	1,296,076
Communications	2,018,738
Reimbursement/Fibroid Relief	2,083,079
Regulatory	240,853
Centers of Excellence	4,196,302
Development	2,281,624
<b>Total</b>	<b>24,063,821</b>



Administration costs comprise 15% (\$3,680,386) of the total budget, fully allocated above.

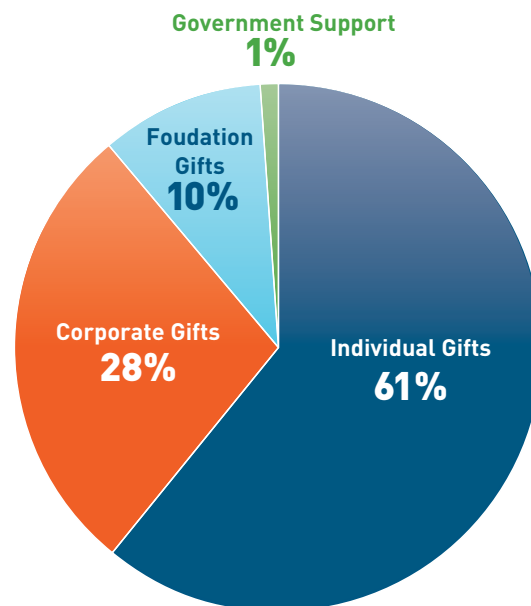
## 2006-2012 Summary of Expenses

Programs and Research	18,101,829
Development	2,281,624
Administration	3,680,368
<b>Total</b>	<b>24,063,821</b>



## 2006-2012 Contributions by Source

Individuals	24,354,637
Corporations	11,175,570
Foundations	3,970,050
Government	619,000
<b>Total</b>	<b>40,119,257</b>



## Foundation Supporters

Thanks to nearly 200 donors, more than \$40 million has been contributed to the Focused Ultrasound Foundation since our inception in 2006. New gifts and commitments made in 2012 account for \$5.6 million of this total. The generosity of these people, foundations, organizations and corporations enables our efforts to develop breakthrough treatments using focused ultrasound to improve the lives of millions worldwide.

This report lists all who have supported the Foundation as of March 1, 2013. Also listed are the many friends and family members to whom they paid tribute with their donations.

**Your gifts are changing lives, and maybe even changing the world. Thank you!**

“My tremor is now so minor in my right hand that I forget how difficult life had been before the procedure.”

-Susan Stephens



Susan Stephens, Patient #15 in the Essential Tremor Trial, wanted to be able to pour milk for her grandchildren. *Now she can.* Here she is with her husband Tom and the grandkids.

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Adler Scherman Foundation  
Alpinion US Inc.  
Bob and Gloria Bailie  
Baker Construction Group, Chicago  
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Anonymous (9)

#### Honoraria

##### In Honor of:

Daniel P. Jordan given by the  
President's Discretionary Fund in  
The Charlottesville Area Community  
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Neal F. Kassell and Daniel P. Jordan  
given by Mr. Thomas N.P. Johnson III  
Diane Heller given by Douglas and  
Elizabeth Kinney  
The John and Eleni Rafetto Family  
given by Mitch Landgraf

#### Memorials

##### In Memory of David Heller:

Adler Scherman Foundation  
Baker Construction Group, Chicago

Bernstein Law Firm  
Lois Berry  
Ellen and Ronald Block Family  
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BNR Partners LLC  
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Sudler Property Management  
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Fund  
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##### In Memory of:

Cornelia Keller given by Mr. and Mrs.  
Dennis W. Barnes  
Cornelia Keller given by Ms. Joann  
W. Kellogg  
Cornelia Keller given by Ms. Eileen  
M. Neal  
Cornelia Keller given by Ms. Dorothy  
S. Schoeneman  
Cornelia Keller given by Mrs.  
Caroline Keller Winter  
Bertrand L. Taylor III given by Fay  
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\* Denotes supporters who are deceased.

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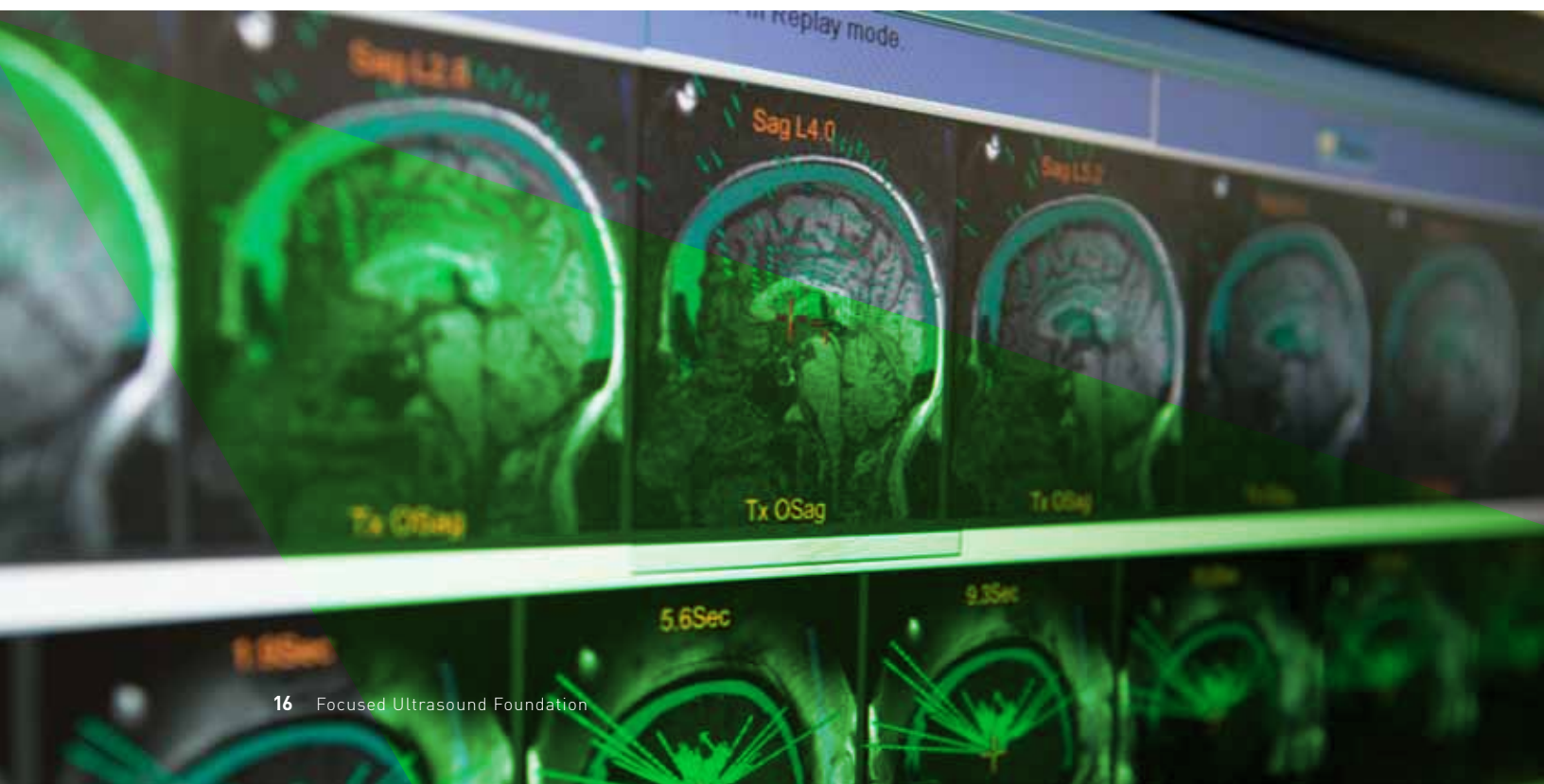
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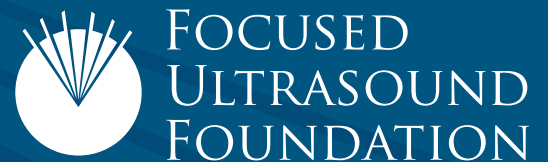
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**It's All About Patients SAVING TIME = SAVING LIVES**

If you have questions, would like more information or want to make a gift, please contact **Kimberly Skelly**, Director of Development, at **434-326-9830** or **kskelly@fusfoundation.org**. You can also find additional information on our website at **www.fusfoundation.org**.



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