

Highlights

Essential tremor poised for commercial availability

Affecting 10 million people in the US alone, essential tremor is the first brain application to earn FDA approval. The trial results were published in the *New England Journal of Medicine*, and the Centers for Medicare and Medicaid Services assigned the procedure a payment level.

Foundation explores the potential for focused ultrasound in cancer immunotherapy

The field of cancer immunotherapy is growing at a rapid rate, and the Foundation continues to explore the role of focused ultrasound for immune-based cancer treatments through several initiatives and partnerships.

Symposium validates the tipping point in the field

Record attendance and the increased number and quality of scientific presentations marked a successful 5th International Symposium on Focused Ultrasound.

• More than 800,000 copies of John Grisham's *The Tumor* are distributed

Crucial for increasing awareness of the Foundation and the technology, *The Tumor's* popularity exceeded expectations and earned national media coverage.

• Centers of Excellence program adds three new luminary sites

The University of Maryland, Stanford University, and Sunnybrook Health Science Centre in Toronto were selected Focused Ultrasound Centers of Excellence for their ongoing work to advance the field.



A MESSAGE FROM THE CHAIRMAN

Dear Friends,

The Focused Ultrasound Foundation was established with the vision that this remarkable, groundbreaking, therapeutic technology would improve the quality of life and decrease the cost of care for millions of patients around the world.

2016 was our most successful year, and as a result, we see this vision coming closer to reality. The dialogue has shifted from *if* focused ultrasound can become a mainstream standard of care to *when* it will.

Momentum Builds

Many milestones were met in 2016, as detailed in this report. Among the most notable:

- Treatment of essential tremor was approved by the FDA and CMS; trial results were published in the *New England Journal of Medicine*
- More than 800,000 copies of the John Grisham book *The Tumor* were distributed, increasing awareness of the potential of focused ultrasound
- Our fifth biennial International Symposium was the largest and most successful to date

The entire focused ultrasound ecosystem, from researchers to manufacturers and treatment sites, continues to grow at an accelerating pace.

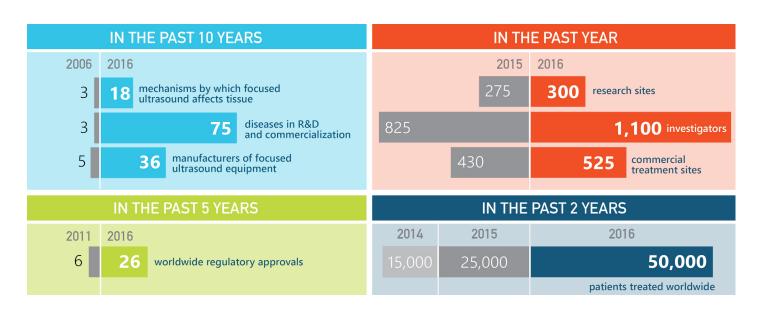
The number and diversity of mechanisms by which focused ultrasound affects tissue is expanding, creating the possibility to treat an even wider variety of medical disorders.

Indications currently in research, development and commercialization have skyrocketed to more than 75 from just a handful a decade ago. The numbers of research sites, investigators, regulatory approvals, commercial treatment sites and patients treated all show impressive growth.

As this momentum builds, the field continues to transition from the research stage to commercialization of the technology. Several years ago there were no organizations providing industry marketing reports on focused ultrasound; today there are 23, a powerful indication of the field's expansion.



We see our vision coming closer to reality. The dialogue has shifted from if focused ultrasound can become a mainstream standard of care to when it will.



Challenges Remain

Focused ultrasound is a highly disruptive technology that has the potential to revolutionize therapy to the same degree that MR scanning revolutionized diagnosis in the 1990s. A disruption of this magnitude in healthcare faces many impediments to its adoption.

While the Foundation has been more successful than anticipated in achieving our mission of accelerating development and adoption of focused ultrasound, we are constantly confronted with new challenges. In order to sustain our momentum and enable this technology to benefit more patients, focused ultrasound must become a commercial success, which thus far has proven elusive. The barriers and impediments that still must be addressed include:

- Lack of awareness and acceptance by patients and physicians
- Turf battles between medical specialties and between manufacturers of focused ultrasound equipment
- The need for compelling proof statements that support the value proposition from both financial and clinical perspectives
- Regulatory approvals
- Universal insurance reimbursement

Our Commitment Endures

Since our founding, we have served as a catalyst, driving growth and advancing the field of focused ultrasound. We are now in the enviable position of needing to further prioritize activities to address mission-critical bottlenecks and leverage resources to provide unique value and measurable impact.

With regard to mechanisms by which focused ultrasound may deliver benefits, our primary interest is in targeted drug delivery with blood-brain barrier opening, histotripsy (non-thermal destruction of tissue), and immunomodulation. In terms of clinical indications, we continue to focus on the brain: movement disorders, epilepsy, tumors – in particular glioblastomas – OCD, and depression. In addition, we are also concentrating on immune-oncology, pancreatic cancer, and pediatric indications.

We are working on increasing the efficiency and productivity of the organization with the goal of becoming better, not bigger. Our desire is to remain lean and nimble in order to stay true to our culture and values. This year we filled key vacancies in our scientific and development teams. The board is stronger and more engaged than ever with the addition of two new members – Dr. Charles Steger, former president of Virginia Tech, and Bill Hawkins, former CEO of Medtronic.

In the coming year, the Foundation will continue to move focused ultrasound beyond the tipping point and further accelerate development and adoption. Success will require increased awareness, further funding for research and development, and investment in commercial organizations. The Foundation will play an active role in all of these areas to to provide resources, connect, convene and influence stakeholders, and foster collaboration.

2016 marked the 10th anniversary of the Foundation. Instead of celebrating our accomplishments, we continue to be forward-looking and focus all of our efforts on the enormous amount of work remaining. In the coming year, the formula for success will continue to hinge on the Foundation's reputation as an authoritative, trusted, independent and unbiased third-party as well as on our highly skilled team, our Board, Council and donors — an amazing and inspiring force.

The revolution continues. Thank you for your continued support and for playing a pivotal role in decreasing death, disability and suffering for countless people.

Be well,

Neal E Kassell ME



Creating Knowledge: Research Milestones

The cornerstone of the Foundation's activities continues to be the research programs, which consume more than half of the expenditures and contribute to the rapidly expanding knowledge of focused ultrasound. The Foundation continues to be the largest nongovernmental source of support for focused ultrasound research.

ESSENTIAL TREMOR IS FIRST BRAIN APPLICATION TO GAIN FDA APPROVAL

The US Food and Drug Administration (FDA) approved focused ultrasound to treat essential tremor (ET).

The approval was based on data from a multicenter study of 76 patients funded by the Focused Ultrasound Foundation, the BIRD Foundation, and Insightec. The study results were published in the <u>New England Journal of Medicine</u>.

Following FDA approval, the Centers for Medicare and Medicaid Services <u>assigned the procedure</u> a <u>payment level</u>, the first step toward Medicare reimbursement. These approvals open the door to treat other brain indications including <u>Parkinson's</u> and <u>Alzheimer's disease</u>, <u>OCD</u> and <u>depression</u>, <u>epilepsy</u>, and <u>brain tumors</u>.

Peter suffered from ET, making everyday tasks like eating, drinking and dressing nearly impossible. Focused ultrasound changed his life.

Watch Peter's story >



CANCER IMMUNOTHERAPY PROGRAM

Immunotherapy is one of the most exciting areas in cancer research. Pre-clinical studies have demonstrated that focused ultrasound can <u>initiate a powerful anti-tumor immune response</u> and enhance the effect of immunotherapeutic agents. Focused ultrasound can also be used to increase the delivery of immunotherapeutics by increasing penetration into the tumors. The Foundation is currently funding several preclinical projects to assess focused ultrasound for immune-based treatment in models of glioma, melanoma, breast cancer, and pancreatic cancer.

Brain Tumor Consortium Investigates Immunotherapy

Recent research has demonstrated that immunotherapies can have beneficial effects in glioblastoma multiforme (GBM) – an aggressive, fatal brain tumor. The Foundation has created a <u>multisite consortium</u> to accelerate

progress in using focused ultrasound to increase the body's anti-tumor immune response. The first project brings together seven research sites to investigate the effects of different focused ultrasound modalities on the immune system. The modalities that produce the most promising results will be assessed in larger studies and/or in combination with immunotherapeutics.

Immunotherapy Summit Contributes to Momentum

In October, more than 40 experts from around the world gathered for the Focused Ultrasound and Immunotherapy Summit, held in partnership with the Cancer Research Institute. The group met to evaluate the current body of evidence, assess the value of ongoing work, and create a roadmap of projects to address gaps or questions. The goal is to reduce the time it takes for focused ultrasound and immunotherapy combination treatments to reach clinical adoption. Read the meeting summary >



Our staff celebrated Cancer
Immunotherapy Awareness Month
in June by participating in the
White Out Cancer initiative.



Creating Knowledge: Research Milestones

BRAIN PROGRAM

Pre-clinical Studies

Studies are ongoing in two new ways to destroy brain tumors. With researchers at the University of Virginia and the University of Michigan, the Foundation is investigating the feasibility of using <u>histotripsy</u>, a non-thermal method that mechanically destroys tissue, and <u>sonodynamic therapy</u>, which uses focused ultrasound to activate sonosensitizers to induce cell death.

New pre-clinical research is underway to treat Parkinson's disease. Researchers have demonstrated that focused ultrasound can safely enhance the delivery of antibodies that detect and eliminate proteins that build up in the brains of Parkinson's patients. Meanwhile, it has been demonstrated that focused ultrasound can introduce genes to the brain, which could help protect neurons and restore function in Parkinson's patients.

Clinical Trials

PARKINSON'S DISEASE

The pilot trial using focused ultrasound to treat the symptoms of tremor-dominant <u>Parkinson's disease</u> has been completed. The results were presented at the Symposium in August and have been submitted for publication.

A similar study investigating the feasibility and safety of treating the dyskinesia associated with Parkinson's disease is underway at a number of sites in the US, Canada, and Korea. Overall, 26 of the 31 patients have been enrolled.

Kimberly's Parkinson's made it impossible for this avid biker to balance safely. She was the first patient treated at the University of Maryland.

Watch Kimberly's story >



EPILEPSY

Researchers at the University of Virginia have started the <u>first clinical trial</u> using focused ultrasound to treat patients with <u>epilepsy</u>. The 15-patient study, supported by the Focused Ultrasound Foundation in collaboration with the Epilepsy Foundation, will assess the feasibility and safety of focused ultrasound to non-invasively destroy diseased brain tissue that causes seizures.

OBSESSIVE-COMPULSIVE DISORDER & DEPRESSION

In April, the Foundation convened a steering committee of neurosurgical, psychiatric, and technology experts to develop research protocols for treating medication-refractory <u>obsessive-compulsive disorder</u> (OCD) and <u>depression</u>.

DYSTONIA

Researchers in Japan have used focused ultrasound to treat patients with focal hand dystonia, a movement disorder characterized by involuntary, sustained muscle contractions that frequently cause twisting or abnormal

posture. The 10-patient clinical trial, supported by the Foundation, will assess the feasibility and safety of using focused ultrasound to ablate a target in the brain to treat the dystonia.

The world's first patient treated with focused ultrasound for dystonia plays his guitar during the treatment. **Read more** >





Creating Knowledge: Research Milestones

PEDIATRICS PROGRAM

The first guidelines for using focused ultrasound to treat <u>osteoid osteoma</u>, a benign but painful bone tumor affecting mostly young people, were published in 2016. The <u>comprehensive guidelines</u>, created by an international collaborative effort, provide a framework for patient selection, treatment, avoiding complications, and analyzing outcomes.

In 2015, the Foundation participated in a pediatric workshop where it was decided that osteoid osteoma would be the lead pediatric indication. Preliminary results from ongoing clinical trials in the US and Canada are promising. A worldwide patient registry has been established, and the Foundation will fund a US comparative study of focused ultrasound versus radiofrequency ablation.

Della suffered from an osteoid osteoma, a benign but painful bone tumor in her knee that made it difficult to concentrate in school, go to work, and even sleep. Seeking relief, she took part in a clinical trial for focused ultrasound treatment.

Watch Della's story >



CENTERS OF EXCELLENCE PROGRAM

Established in 2009, the Foundation's <u>Centers of Excellence program</u> brings together the best people and technical resources at luminary sites. The Centers are created through partnerships of academia, industry, and the Foundation to showcase the technology and serve as hubs for collaboration. In 2016, three new sites – the <u>University of Maryland</u>, <u>Stanford University</u>, and <u>Sunnybrook Health Sciences Center</u> in Toronto – earned the title, bringing the total to six Centers worldwide.





EXTERNAL RESEARCH AWARDS PROGRAM*

In 2016, we funded

5
new investigator-initiated projects

55 tal project

total projects funded 38

projects completed **97**%

presented results at meetings

76%

published results

\$3.8M

Funding provided for completed projects

→ \$25.5n

Follow-on funding earned



Factor by which the Foundation leverages donors' contributions

^{*}Unless specified, figures are since the Foundation's inception in 2006.

SYMPOSIUM MARKS TIPPING POINT FOR FIELD

In August, the Foundation hosted more than 400 participants - and an estimated 500 additional virtual attendees - at its 5th International Symposium on Focused Ultrasound in Bethesda, Maryland. Featuring more than 200 presentations – including updates on 15 clinical trials – the meeting covered a range of topics, including the use of focused ultrasound for movement disorders, psychiatric disorders, brain tumors and other cancers, bone and soft tissue diseases, women's health, cardiovascular conditions, and emerging applications.



All presentations and abstracts are available online >

KEYNOTE SPEAKERS OFFER VARIETY OF PERSPECTIVES



John Grisham was interviewed on stage by CBS correspondent Chip Reid about his involvement with focused ultrasound and writing *The Tumor*.

Watch Now >



Cancer Moonshot Executive Director Greg Simon inspired the audience to push the potential of focused ultrasound.

Watch Now >



NIH Data Expert Philip Bourne spoke on the power of data sharing to propel medical breakthroughs.

Watch Now >

SYMPOSIUM BY THE NUMBERS



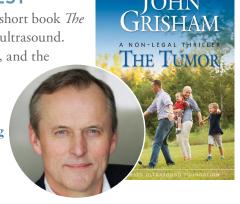


Increasing Awareness

In 2016, major inroads were made in increasing awareness of the potential of focused ultrasound amongst all stakeholders. The Foundation hosted 13 awareness events, allowing more than 1,000 people to learn about the technology.

JOHN GRISHAM'S THE TUMOR GARNERS HUGE INTEREST

With more than 800,000 copies distributed in its first year, John Grisham's short book *The Tumor* has had an immeasurable impact in spreading awareness for focused ultrasound. The book tells the story of Paul, who is diagnosed with a lethal brain tumor, and the future looks bleak with current medical options. However, fast forward 10 years when focused ultrasound could offer Paul a different future. The book caught the interest of more than 50 media outlets including *CBS This Morning, The Washington Post,* and Mashable. It is available on thetumor.org and as an e-book on Amazon, Barnes & Noble, and Google Play.



NO. 1 BESTSELLING AUTHOR

PATIENT VIDEOS HIGHLIGHT THE TECHNOLOGY

The Foundation released six new patient videos in 2016. Watch as they describe how focused ultrasound changed their lives.



Follow an essential tremor patient, and hear from experts around the globe.

Watch Now >



Watch as five patients share how focused ultrasound affected their essential tremor, Parkinson's disease, uterine fibroids, and painful bone tumors.

Watch Now >

GOVERNORS LEARN ABOUT FOCUSED ULTRASOUND

In August, <u>Virginia Governor Terry McAuliffe</u> visited the Foundation and met with the team and representatives from the University of Virginia (UVA) Health System, who gave him an update on UVA's focused ultrasound work. Because of a 2009 public/private partnership between the Commonwealth of Virginia, the Foundation, and others, UVA is the flagship of the Foundation's <u>Centers of Excellence program</u>.

More recently, former <u>Florida Governor Jeb Bush</u> and colleagues visited the Foundation to learn more about the technology and the Foundation's programs.

MEDIA COVERAGE

Focused ultrasound had over 315 media placements, a 70% increase over 2015.





THE WALL STREET JOURNAL.



STAT





WEBINARS HIGHLIGHT BRAIN TARGETING METHODS AND PARKINSON'S TREATMENTS

The Foundation hosted two leaders in focused ultrasound to share their work with the community.



Paul Fishman, MD, from the University of Maryland shared the state of the field for Parkinson's, including treatment gaps and focused ultrasound's potential.

Watch Now >

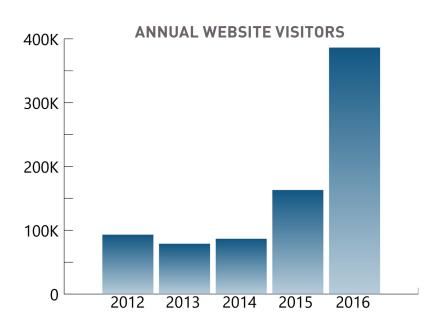


Vibhor Krishna, MD, SM, of Ohio State University discussed tractographybased targeting for the more precise treatment of essential tremor.

Watch Now >

WEB TRAFFIC AND SOCIAL MEDIA ENGAGEMENT SOAR

In 2016, the Foundation's <u>website</u> and social media channels saw the highest traffic of all time, due in part to John Grisham's short book, <u>The Tumor</u>. Meanwhile, our <u>monthly newsletter</u> continues to be popular with a circulation that has grown to nearly 9,000 subscribers.



385,780
website visits in 2016
WHICH IS A
140%
increase over the previous year

49%
of visitors use mobile devices

2:10
average time spent on site per visit





ers

The number of website visitors coming from social media increased by

272%

Cultivating the Next Generation

FOUNDATION RECOGNIZES YOUNG INVESTIGATORS AT SYMPOSIUM

<u>Eleven researchers</u> received Young Investigator Awards and were invited to share their work in presentations at the 2016 Symposium. The Foundation established the <u>Young Investigator Awards Program</u> in 2012 to encourage quality research by clinicians and scientists-in-training.





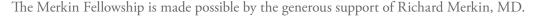
Thai-son Nguyen received the Global Intern Award and presented his research at the meeting. A student at the University of Michigan, Nguyen worked with his mentor, Zhen Xu, PhD, to demonstrate that histotripsy may be used to generate large or targeted lesions in the brain.

FRENCH RESEARCHER JOINS TEAM AS MERKIN FELLOW

Cyril Lafon, PhD, joined the Foundation as the 2016-2017 Richard Merkin Visiting Fellow.

<u>Dr. Lafon</u> is the Director of LabTAU, a research laboratory of INSERM – the French National Institutes of Health – located in Lyon. He was selected based on his innovative ideas and proven track record in developing focused ultrasound devices for patient use.

Lafon's work included collaborations with the Foundation's scientific team to develop technical improvements for transcranial thermal ablation for essential tremor and brain tumors, and to assess focused ultrasound's effects on the immune response to breast cancer.





INTERNSHIP PROGRAM UPDATE

The global intern program – now in its third year – offers students interested in the physical and life sciences an opportunity to engage in focused ultrasound research. In 2016, <u>21 students</u> were paired with mentors in 14 focused ultrasound laboratories around the world.

In 2016, <u>five student interns</u> joined the Foundation team at its Charlottesville, Virginia offices. Some worked on a therapeutic ultrasound system, which will be used in a Foundation-funded sonodynamic therapy research project at the University of Virginia. Others developed new software and study techniques to improve safety and functionality. This opportunity is supported in part by the Claude Moore Charitable Foundation and Virginia Bio.





FOUNDATION SUPPORTS WHITE HOUSE'S CANCER MOONSHOT

During his 2016 State of the Union address, President Barack Obama announced the establishment of a new Cancer Moonshot to accelerate cancer research. The initiative – led by Vice President Joe Biden – aimed to make more therapies available to patients as quickly as possible, in part by breaking down silos that are impediments to progress in cancer research in order to promote collaboration and data sharing.

Focused ultrasound has the potential to transform treatment and improve outcomes for patients with cancer. The Foundation contributed to the Cancer Moonshot in many ways, accelerating cancer research with this promising technology in order to bring it to patients as quickly as possible.

Cancer Moonshot Executive Director Greg Simon spoke at the Foundation's Symposium in August. His message inspired the audience to push the potential of focused ultrasound to advance cancer research. **Watch Now >**



FOUNDATION CHAIRMAN NAMED TO MOONSHOT PANEL

Foundation Chairman Neal F. Kassell, MD, was <u>selected to serve</u> on the National Cancer Institute's (NCI) Blue Ribbon Panel for the Cancer Moonshot. Dr. Kassell joined 28 luminaries in science and medicine to help the NCI inform the scientific direction and goals of the Initiative. In October, the panel issued their final report including recommendations for future research paths. <u>Read the report ></u>

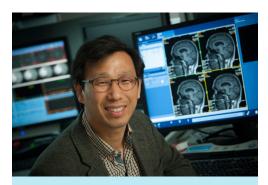
BUILDING UPON RELATIONSHIPS IN ASIA

As focused ultrasound rapidly finds a foothold in Asia, the Foundation strives to foster relationships and add value in the region with the help of many ambassadors, including Council members and fellows.

After a 2015 fellowship with the Foundation, Dong-guk Paeng, PhD, has returned to Jeju National University in Korea. He now works to help connect the Foundation with organizations, companies, and researchers making strides in the country.

In Japan, focused ultrasound may now be <u>positioned for commercial</u> <u>success</u> after nearly 20 years of activity in the country. There are systems installed at close to 40 sites, and devices have been approved to treat uterine fibroids, bone metastases, and the prostate.

Two new focused ultrasound companies in Taiwan, NaviFUS and EpiSonica, made strides in 2016. <u>NaviFUS</u> is working toward clinical trials to open the blood-brain barrier while <u>EpiSonica</u> has earned regulatory approval in Taiwan for uterine fibroids, adenomyosis, and palliative pain care of bone metastases. The Foundation has established relationships with these companies and continues to follow their progress.

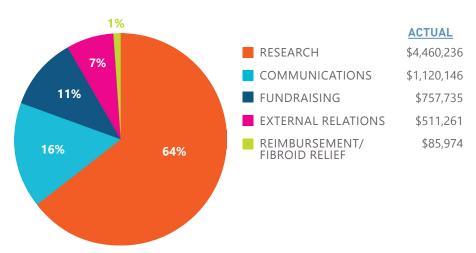


At the Foundation, Dong-guk Paeng helped lead efforts to develop safe and effective ways to use focused ultrasound, including histotripsy to expand the regions of the brain that can be accessed and treated with the technology.



ALLOCATION OF FUNDS

2016 TOTAL: \$6,935,352*



The Foundation spent just under \$7M in 2016 versus a budget of \$8.7M, and research programs represented 64% of the overall spending. The difference was mainly due to delays in initiation and completion of research projects as well as overall cost savings.

For 2017, spending is forecast to be \$10.3M, with the increase primarily related to research programs.

FUNDRAISING 2016 GOAL: \$8 MILLION

The Foundation raised \$9.6 million in 2016. Of this total, \$6.2 million were cash donations and the remaining \$3.4 million were multiyear pledges. The goal for 2017 is \$4 million in cash and \$4 million in pledges to be paid in 2018.

DONORS DOUBLED THEIR IMPACT

Our donors play a critical role in enabling us to realize our mission of advancing the field of focused ultrasound and benefit as many patients as possible in the shortest amount of time. In 2016, we had the good fortune to receive two \$1 million pledges of unrestricted funds to be matched 1:1, both of which were fulfilled. Matching gifts often inspire other donors to give as they appreciate knowing that the impact of their gift will be multiplied.

EXPANDED GEOGRAPHIC OUTREACH

The Foundation's expanded fundraising and awareness reach in 2016 can be attributed to Chairman Neal Kassell's participation in high-profile opportunities like the <u>Cancer Moonshot Panel</u>, CEO Roundtable on Cancer, and the <u>World Economic Forum</u>; the ongoing interest in John Grisham's, <u>The Tumor</u>; and opportunities to share information with influential audiences throughout the US and abroad. These efforts resulted in donations from 40 states (compared with 18 in 2015), and 6 foreign countries (compared with receiving only domestic donations in 2015).

FOUNDATION ACHIEVES TOP CHARITY RANKINGS

Our work depends on generous donors who, like us, believe in the potential of focused ultrasound to change the lives of millions of patients. Our commitment to these donors is paramount, and we are proud to say we hold the highest ratings given by <u>GuideStar</u> and <u>Charity Navigator</u> – leading online tools that assess nonprofits' financial and organizational transparency.

^{*}The Foundation's Audited Financial Reports are available on the website.

Turning Vision into Reality

TO OUR DONORS:

Your generosity enables us to fund groundbreaking research, convene the best minds to overcome barriers, and spread the word about the immense potential of focused ultrasound. We thank you for your support and the important role you play in advancing this technology that could one day impact the lives of many.

THANK YOU!

Below is a list of donors who contributed funds in 2016.

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