



FOUNDATION
FIGHTING
BLINDNESS

Driving Research
SAVING SIGHT

ANNUAL REPORT 2016

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Gift Planning

Please consider remembering the Foundation Fighting Blindness as part of your will, trust or other estate plan. For more information visit our planned giving website at

<http://myplantofightblindness.org/>

**FOUNDATION
FIGHTING
BLINDNESS**

Chairman's Message

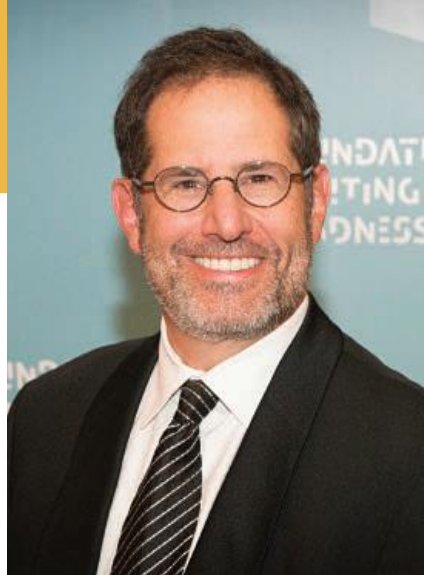
David Brint, *Chairman*

Welcome to the 2016 annual report of the Foundation Fighting Blindness. As this is the beginning of my tenure as the Foundation's chair, having replaced a legend, Gordon Gund, I am particularly honored to bring you this report. Again this year, we have exciting news to share.

During its 46-year history, the Foundation, through its investments, has supported the most promising research on potential treatments for inherited retinal degenerations being done across the globe. These investments have enabled a new level of understanding of how the retina works and what goes wrong when retinal cells stop working. They have also led to breakthrough discoveries in the search for cures. The strongest evidence of these results is the number of potential therapies moving out of the lab into clinical trials and toward the marketplace. For example, Spark Therapeutics is seeking U. S. Food and Drug Administration (FDA) approval for its gene-replacement therapy for a form of Leber congenital amaurosis (LCA2). This therapy, intended to treat blindness caused by mutations in the RPE65 gene, has received both breakthrough therapy and orphan disease product designation by the FDA. If approved, it could become the first-ever approved gene therapy for an inherited retinal disease and the first for any inherited disease in the United States!

The Foundation has continued to pursue strategic goals in 2016 including attracting biotech and pharma companies into the field and funding research that can be pursued by these entities once proof of concept is provided. Also important is our focus on filling the gaps that will encourage pharma and biotech to pursue retinal disease clinical trials, including locating patient populations through the My Retina Tracker program, providing agreed-upon clinical endpoints measures and getting their use approved by the FDA, and conducting natural history studies so industry and the FDA can measure treatment progress. Our ProgStar program for Stargardt is concluding, and a new initiative in Usher syndrome is beginning. FFB has always been strategic about the way we deploy funds. Our goal is to maximize the leverage those funds bring to the field.

I invite you to spend a few minutes reading this report for much more information about the important advances being made in



retinal disease research – many of them thanks to Foundation Fighting Blindness funding. There is tremendous reason to be optimistic about the potential for vision-restoring treatments. But, as we marvel at the advances the vision science community has made, we also need to remember there is much more work to be done. And, in most cases, the most expensive part of the work – clinical trials and actually moving treatments to the patients who need them – is still ahead of us.

In short, we have much to be proud of. And lots more work to do, science to invest in, and money to raise. My pledge to you is that my colleagues in FFB's leadership and I will continue to steward your donation dollars carefully and strategically based on the guidance of our world-class Research Oversight Committee and our Scientific Advisory Board.

I have a vision of the future I'm sure you share. It's a future in which a family receiving the bad news that a loved one is losing or at risk of losing their vision due to a retinal degenerative disease is also told about their treatment options! Together we can make this vision a reality.

It is my privilege to serve as the chairman of the Foundation Fighting Blindness, but I cannot emphasize enough the critical role you, our generous donors and supporters, play in making the progress FFB has enabled possible.

Thank you for your continued support.

Sincerely,

A handwritten signature in black ink that reads 'David Brint'.

CEO Report

Bill Schmidt, CEO

Throughout its 46-year history, the Foundation Fighting Blindness has been the world leader in the field of retinal degenerative disease research. This year, the Foundation surpassed the \$700 million milestone in money raised to advance this vision-saving research. That fundraising success, coupled with our work with pharmaceutical partners and the best retinal researchers in the world, provides over 10 million Americans and millions more people worldwide who have lost vision due to retinal disease with the true promise of restored sight.

The Foundation is led by a remarkable group of volunteers and is advised by the best minds in retinal disease research in the world – please see pages 9–12 for our Board leadership and members of our Scientific Advisory Board. In addition, we are also a local organization with 43 volunteer-led chapters across the United States. These dedicated volunteers raise funds, increase public awareness, and provide support to families affected by retinal diseases in their communities.

Wise stewardship of donation dollars and strategic investments in research are ingrained values for the Foundation. We are extremely proud of how far our work has moved the field of retinal degenerative disease research. This year, thanks to accelerated progress in clinical and translational research in labs across the United States and throughout the world, more FFB funds are being invested in later stages of the research continuum; that is, in the testing of specific treatments and potential cures in human subjects.

Over our history FFB has, on average, invested above 70 percent of our annual revenue budgets in research and public health education programs. We will continue to work to maintain our high average annual spending in these key program areas. For more information about FFB's financial management, see the Treasurer's Report on page 6.

Thanks to these sustained investments, Foundation-funded researchers are achieving remarkable success with a wide range of promising therapies for saving and restoring sight. Below are just a few examples of the research providing hope to millions affected by inherited vision loss.

Gene Therapy Restores Vision

The Foundation is funding translational research and clinical trials of gene therapy that have restored vision in patients who were virtually blind from a childhood form of retinitis pigmentosa.



Thanks to the treatment, they can now enjoy some of life's simple joys, like reading and playing baseball.

Developing Drugs to Preserve Vision

The Foundation is funding research on potential drug therapies that work by slowing or preventing the loss of retinal cells, thereby saving vision. Many of these treatments are cross-cutting, meaning they're designed to work for a wide range of retinal conditions, regardless of the genetic defect.

Harnessing the Power of Stem Cells

Foundation-funded researchers are using stem cells derived from a variety of sources, including a person's own skin, to create healthy retinal cells that can potentially restore vision. Stem-cell treatments hold great promise for people with advanced vision loss.

Funding the Best in Retinal Research

The Foundation has funded studies at hundreds of prominent institutions throughout the world, including, but not limited to:

- Wilmer Eye Institute, Johns Hopkins University School of Medicine
- Massachusetts Eye and Ear Infirmary, Harvard Medical School
- Institut de la Vision, Paris, France
- Moorfields Eye Hospital, University College London
- Scheie Eye Institute, University of Pennsylvania

These impressive advancements would not be possible without the generous support of our donors. We can all feel very good about the progress being made, but let us remember there is also a lot more work to do. I hope we can count on your continued support.

If you have questions, I invite you to contact me at BSchmidt@FightBlindness.org.

Sincerely,

A handwritten signature in black ink that reads "Bill". The signature is written in a cursive, slightly slanted style.



2016

Charting Significant Research Progress!

While finding treatments and cures for inherited retinal diseases is a decades-long pursuit, the year-over-year progress, including that made this year, is extremely encouraging. Specifically, the Foundation's investments in research and technology and its pursuit of biotech and pharmaceutical partners are achieving remarkable success in the discovery and testing of a wide range of promising therapies to prevent, treat, and cure blindness caused by retinal degeneration.

"Due to the Foundation Fighting Blindness' unwavering support of research over its 46-year history, retinal degenerative disease research is leading the medical field in advancing treatments for inherited diseases into the clinic. As a result, the prospect for many treatments for inherited retinal degeneration has never been more promising. FFB support has allowed these groundbreaking advances to be achieved," said Stephen Rose, PhD, FFB Chief Research Officer.

Nowhere is this accelerating progress more evident than in human studies – clinical trials – for promising vision-saving therapies. As the "era of clinical trials" continues, FFB's unique role in building bridges between early lab and translational research and the considerable financial resources that later-stage human clinical trials require – resources that can only be provided by the pharmaceutical industry – is particularly evident.

The following are examples of the impressive research progress that has been made over the past year. The Foundation Fighting Blindness played a critical role in the advancement of all these emerging therapies.

Pursuing FDA Approval for a Gene Therapy

Thanks to vision restoration in a clinical trial for children and young adults who were virtually blind, Spark Therapeutics, a Philadelphia company which has its roots in FFB funding, has

sought U.S. Food and Drug Administration (FDA) approval for its RPE65 gene-replacement therapy. The treatment helps restore vision by delivering copies of a light-sensitive gene to surviving cells in the retina. If approved by the FDA, it will be the first approved gene therapy for the eye and the first for any inherited condition in the United States!

Big Pharma Investment in Promising Retinal Disease Therapies

In 2015, RetroSense Therapeutics received FDA authorization to launch a clinical trial of its optogenetic gene therapy. By harnessing surviving cells in the retina, the emerging treatment holds promise for restoring some vision to people who are completely blind, regardless of the gene mutation causing their disease.

In 2016, the company began treating the trial's first patients. No inflammation or ocular adverse events were seen in any of the trial participants, and biological activity within the eye was confirmed. Thanks to the potential of this therapeutic approach, the international pharmaceutical company Allergan purchased RetroSense for \$60 million.

In 2016, Spark Therapeutics, the Philadelphia-based, gene-therapy company responsible for developing a treatment targeting retinal diseases caused by mutations in the RPE65 gene described above, purchased Genable Technologies, Ltd., an Irish bio-pharmaceutical company developing a gene therapy, RhoNova™, for the treatment of autosomal dominant retinitis pigmentosa (adRP).

In 2016, Biogen and AGTC established a milestone-based collaborative development and commercialization program for XLRS and XLRP gene therapies exceeding \$1 billion in total funding. Biogen will be granted a license to the XLRS and XLRP



programs and the option to license discovery programs for three additional indications at the time of clinical candidate selection.

Stem Cells for RP Move Into Human Studies

In 2015, two companies, ReNeuron (U.K.) and jCyte (California), received FDA authorization to launch clinical trials of their stem-cell therapies for retinitis pigmentosa (RP).

In 2016, both companies reported they were treating patients without any serious adverse events. While ReNeuron did not disclose how many participants had received its cell injections, jCyte reported they had treated nearly two dozen people. Both clinical trials, which are initially focused on safety, are the first-ever stem-cell trials for RP.

Gene Therapy Leads to Sustained Vision Benefits

In 2016, researchers at the University of Oxford (U.K.) reported that the vision benefits of its gene therapy for people with choroideremia had been sustained for the first patients treated in its clinical trial, which launched in 2013. Gene therapy clinical trials for people with choroideremia are now underway (or being launched) at Bascom Palmer Eye Institute in Miami, the University of Alberta, Children's Hospital of Philadelphia, the University of Pennsylvania, and Massachusetts Eye and Ear Infirmary.

In 2016, several other clinical trials for potential treatments are advancing impressively, including gene therapy studies for achromatopsia, Usher syndrome, Stargardt disease, and retinoschisis.

FFB's Clinical Research Institute Advances Human Research

In 2016, the Foundation's Clinical Research Institute continued to boost the global retinal research field with patient natural history studies such as ProgSTAR (Stargardt disease); its patient registry, MyRetinaTracker.org; and a consortium of clinical

experts ready to quickly and effectively launch more clinical trials for vision-saving therapies. In 2017, the consortium will launch a natural history study for people with Usher syndrome and RP caused by mutations in the gene USH2A.

SparingVision

The Foundation Fighting Blindness Clinical Research Institute (FFB-CRI), Bpifrance (BPI), and the Fondation Voir et Entendre (FVE) announced the formation of SparingVision, a company headquartered in France, to advance a promising, emerging therapy for the treatment of blinding retinal disease retinitis pigmentosa (RP) into a clinical trial and, ultimately, out to the international marketplace. A total of € 15.5 million in tranche funding has been announced, with FFB-CRI and BPI each investing €7 million and FVE providing €1.5 million. SparingVision's goal is to launch a clinical trial for RdCVF in 2019.

FDA Clinical Trial Endpoints Meeting

FFB-CRI – along with the FDA, National Eye Institute (NEI), and the Association for Research in Vision and Ophthalmology (ARVO) – hosted a one-day public workshop to review clinical trial design considerations and outcome measures for potential treatments for inherited retinal diseases. As a result of the meeting, the FDA validated an endpoint measurement tool known as EZ Area, which efficiently and effectively measures viable photoreceptors in a patient's retina. EZ Area, developed by researchers funded by FFB-CRI, will greatly help drug developers and pharmaceutical companies design and launch human studies for treatments for people with retinitis pigmentosa.

Therapy Review Meetings

FFB-CRI organized and hosted a dozen therapy review meetings that brought together the world's leading drug development experts to evaluate the status of emerging stem-cell, gene, and pharmaceutical treatments for inherited retinal diseases. The goal of these meetings was to determine what preclinical studies companies and researchers needed to do to move potential therapies into human studies. The meetings also helped FFB-CRI determine which companies and treatments warranted investment.

FOUNDATION FIGHTING BLINDNESS

MY RETINA TRACKER®

Track Your Vision. Drive the Research.



Gordon and Llura Gund Family Challenge Raised More Than \$111 Million for Retinal Disease Research

A Message of Thanks!

In April 2014, we launched the Gordon and Llura Gund Family Challenge. Our goal was to raise in total gifts and multiyear pledges more than \$100 million for research before June 30, 2016, by matching any new or increased commitments to the Foundation of \$25,000 or more. Our purpose for doing this was to accelerate the progress of the Foundation's already highly promising research efforts to find treatments and cures for retinal degenerative diseases.

We are thrilled to be able to share with you that the Challenge was a huge success. Due to the generosity of its 260 donors, and gift matching funds from us, the challenge raised \$111.6 million. These funds, under the stewardship of FFB's Research Oversight Committee, will now be invested into research that moves promising therapies from the lab into clinical trials and, eventually, to the patients who need them. Importantly, this infusion of funds will allow FFB to increase the size and scope of its research portfolio, including the number of studies that can be funded in emerging therapies that show promise across multiple diseases, among them, gene and stem-cell treatments.

When we joined the Berman family and others 46 years ago to begin the journey to end blindness, very little was known about the retina, retinal degenerative diseases, and the visual process. At that time, almost no research was going on to build this knowledge, and no clinical trials were in the offing for possible treatments.

Today, thanks in large part to FFB's persistently innovative research support backed by thousands of donors and volunteers over the years, 20 such trials are underway with many more in the pipeline. The addition of the match program's support, coupled with the ongoing generosity of all FFB's donors and volunteers, will ensure that amazing research advancements in our understanding of inherited retinal disease and treating it will continue and accelerate.

Our great thanks to the Gund Challenge donors and all FFB supporters who are literally helping to preserve and restore sight!

With our warmest best wishes,

Gordon Gund
Co-Founder, Chairman Emeritus

Llura Gund
Co-Founder, President,
New Jersey Chapter

“Gordon and Lulie and the match they enabled are an incredible and everlasting gift to all of us and the thousands that will benefit. This match will expand and perpetuate the FFB mission. It will create more momentum, more clinical trials, more progress, more success. Sight.”

BRUCE AND BONNIE SAWYER
Bruce and Bonnie Sawyer were donors to the Gordon and Llura Gund Family Challenge.

Treasurer's Report

Haynes Lea, *Treasurer*

I have the pleasure of providing you the statement of Foundation Fighting Blindness' activities and financial position for the fiscal year that ended on June 30, 2016. Thanks to the continued generosity of our donors, the Foundation is in a strong financial position to continue its work to advance research on treatments and cures for retinal degenerative diseases.

Fiscal year 2016 was a particularly momentous one for the Foundation due to the unprecedented success of the Gordon and Llura Gund Family Challenge. As you have read elsewhere in this report, the challenge surpassed its goal, raising \$111.6 million to further FFB's investment in vision-saving research and treatments. The success of the Gund Challenge will allow us to increase the size and scope of our research investments in preclinical and clinical trial work, leading to what we expect to be broad research and treatment applications.

We will now embark on careful stewardship of the Challenge funds guided by FFB's Research Oversight Committee's strategic



Finally, our direct-response membership program added \$2 million in annual revenue.

In summary, our strong financial position is allowing FFB to make significant investments in critical, emerging research including in such promising areas as stem-cell and gene therapies. I join all those affected by retinal degenerative diseases in thanking our many donors for their generous support of our mission. Our promise in return is to remain good stewards of these dollars and

The plan calls for a \$20 million investment in basic discovery, translational, and proof-of-concept research every year for the next five years.

plan. The plan calls for a \$20 million investment in basic discovery, translational, and proof-of-concept research every year for the next five years. The committee, after evaluating the potential of current retinal disease research and related science, including gene and stem-cell therapy, concluded that this level of support for preclinical investigative work has the best chance of leading to U.S. Food and Drug Administration (FDA) authorized clinical trials and ultimately FDA-approved treatments.

In other fundraising, FFB's dinners and other social events continue to do well. FY 2016 revenue from the events program was \$9.9 million. FFB's VisionWalk program is now in its 11th year and has surpassed the \$40 million mark for earned revenue.

maintain our high annual investments in the key program areas of research and public health education.

Sincerely,

A handwritten signature in black ink that reads "Haynes P. Lea". The signature is fluid and cursive, written over a light grey background.

Actual Results— Year Ending June 30, 2016

Statement of Activities

REVENUE AND SUPPORT

Contributions.....	55,074,000
Special events, net of direct.....	8,168,000
Bequests	4,134,000
Other revenue	4,899,000
Total Revenue	\$72,275,000

EXPENSES

Research	16,352,000
Public Health Information	2,260,000
Management.....	2,729,000
Fundraising	7,228,000
Total Expenses	\$28,569,000

Change in unrestricted net assets	6,849,000
Change in temporarily restricted net assets.....	34,167,000
Change in permanently restricted net assets	2,690,000
Total Change in Net Assets	\$43,706,000

Statement of Financial Position

ASSETS

Cash and investments	96,910,000
Pledges receivable, net	52,028,000
Other assets.....	1,474,000
Trusts and other funds	7,600,000
Fixed assets, net.....	1,630,000
Total Assets.....	\$159,642,000

LIABILITIES

Accounts payable and accrued liabilities.....	3,211,000
Research grants payable.....	9,081,000
Deferred revenues.....	1,146,000
Liabilities under trusts and other funds	1,614,000
Total Liabilities	\$15,052,000

NET ASSETS

Unrestricted net assets	8,730,000
Unrestricted net assets for research.....	14,238,000
Temporarily restricted net assets	118,432,000
Permanently restricted net assets.....	3,190,000
Total net assets	144,590,000
Total Liabilities and Net Assets	\$159,642,000

Year Ahead— Target Spending Allocations

70% Research Including Grants



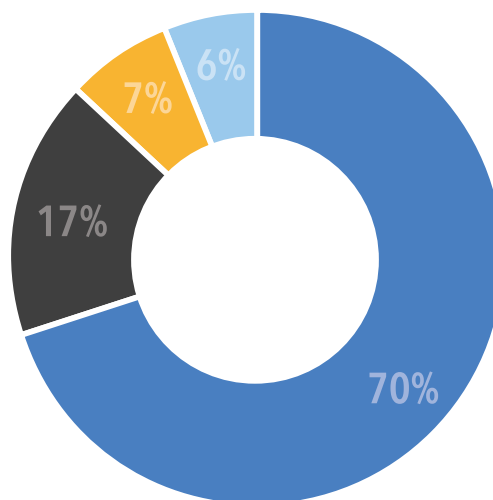
17% Fundraising



7% Public Health Education



6% Administration



2016 Research Grants

2016 Research Investments

In its focused pursuit of preventions, treatments, and cures for the entire spectrum of retinal degenerative diseases, the Foundation evaluates and selects for support a diverse research portfolio. That portfolio is focused on six priority areas: genetics, gene therapy, the cellular mechanisms of retinal diseases, clinical structure and functional relationships, novel medical therapy, and regenerative medicine.

Highlights of 2016 Funding

Research Center grant funding	5,490,714
Individual Investigator grant funding	5,042,225
Alan Lattes Career Development grant funding.....	742,775
Clinical Research Institute clinical studies and grant funding	2,085,852
Total 2016 funding:	\$13,361,566

For a complete list of all 2016 Foundation Fighting Blindness grant recipients, please visit: www.blindness.org/funded-grants.

Grant Spending

29% Clinical Structure and Functional Relationships

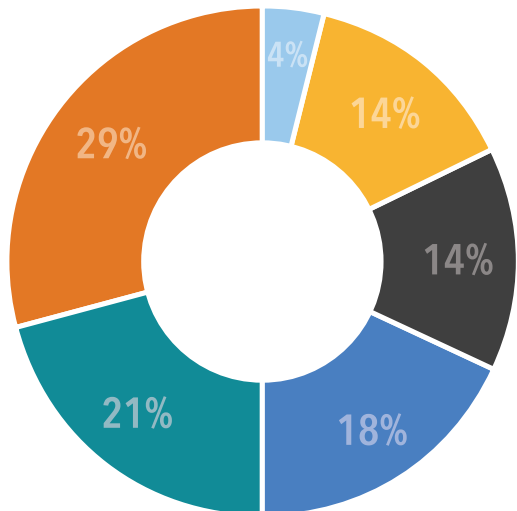
21% Genetics

18% Gene Therapy

14% Novel Medical Therapy

14% Cellular and Molecular Mechanisms

4% Regenerative Medicine



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2016 Snapshot



Top-Left: Singer-songwriter Judy Collins performed at a reception and dinner held at the Museum of Modern Art in New York to thank donors to the Gordon and Llura Gund Family Challenge. The Challenge raised over \$111,000,000 for new research. **Top-Right:** Udita Jain (left) and Alexa Ovalle (right) met at Visions2016. Both have LCA. They enjoyed the conference and getting to know each other. **Bottom:** Dozens of 2016 Houston VisionWalk volunteers were guests on the morning program Great Day Houston to help promote the walk. A total of 360 walkers participated, including 34 teams, raising over \$85,000.



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