A Guide to Age-Related Macular Degeneration

FOUNDATION FIGHTING 3LINDNESS

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Introduction

If you or a loved one has AMD, you may want to learn more about the condition. This booklet addresses many questions people have about the disease and outlines current treatments and research efforts of the Foundation Fighting Blindness to develop effective therapies for AMD.

It is important to remember that the information in this booklet is not meant to replace an expert medical diagnosis. If you suspect that you have macular degeneration or any eye condition, you should consult an ophthalmologist immediately.

What is Age-Related Macular Degeneration?

Age-related macular degeneration is an eye disease that causes the loss of central vision. Specifically, AMD causes degeneration of light-sensitive cells in the macula, the central portion of the retina which enables us to perceive fine visual detail. The macula helps us with activities such as reading, driving and threading a needle.

When you read an eye chart, your doctor is testing your central vision or visual acuity. The word "macula" comes from the Latin word for "spot." The macula is five millimeters in diameter, about the size of a pencil eraser. It covers roughly 10 percent of the retina. The very center of the macula is called the fovea. The fovea is the most sensitive portion of the macula.

To understand macular degeneration, it is first helpful to know how the eye works. The eye is like a complex machine in which a number of intricate parts work together. (You'll find a diagram of the human eye on page 3 of this booklet.) The retina is the delicate, innermost layer of tissue lining the back of the eye. It contains a layer of light-receiving photoreceptor cells and several other layers of cells directly connected to the brain by the optic nerve.

If you think of the eye as a camera, then the retina is the film where images are recorded. There are two types of photoreceptor cells in the retina: cone cells and rod cells. Densely packed within the macula, cone cells are responsible for central vision and the ability to perceive colors and details. Rod cells are prominent in the rest of the retina outside the macula and provide peripheral and night vision. Both cone and rod cells convert light into electrical impulses. These impulses travel through several types of nerve cells in the retina and then to the optic nerve. The optic nerve carries these electrical impulses from the eye to the visual cortex of the brain, where "seeing" actually occurs.

Beneath the retina is the retinal pigment epithelium (RPE), which supports photoreceptors by providing nutrition, waste removal and other critical functions. Beneath the RPE is a layer of blood vessels called the choroid which provides oxygen and nourishment to the retina.

Vitreous gel Optic nerve Macula Fovea Retina

Anatomy of the Human Eye

What are the Symptoms of Age-Related Macular Degeneration?

The symptoms of macular degeneration, like those of other retinal diseases, can vary greatly in severity. The most common symptoms are blurry central vision and difficulty seeing details. People with AMD may have blind spots, resulting in a distorted, dark or empty area in or near the center of vision. Patients may notice distortions of lines and shapes in everyday objects (e.g., crooked doorframes), in tests given by an eye doctor or in the print they read (e.g., distorted letters). Color vision may also be diminished. Peripheral vision usually remains unaffected.

Because age-related macular degeneration can begin in one eye, the unaffected eye will often compensate for vision loss. It may be some time before the second eye is seriously affected enough for an individual to notice vision problems. In other cases, patients will notice a sudden loss of vision. If you experience sudden vision loss or distortion, it is important that you consult your eye doctor immediately.

The images below are identical. The image on the left is as the scene looks with normal vision, while the image on the right illustrates the distorted central vision that may result from AMD.





What are the Types of Age-Related Macular Degneration?

There are two types of AMD: "dry" and "wet." Dry AMD accounts for approximately 90 percent of all AMD cases. However, wet AMD is more likely to cause severe vision loss.

Dry AMD is characterized by drusen, which are small yellow-white deposits that accumulate under the RPE cell layer (under the retina). They tend to cluster in the macular (central) region. Drusen are comprised of proteins and waste products from photoreceptor cells. Patients can have lots of drusen and yet have normal central vision. If one eye has dry AMD, the other eye often shows signs of dry AMD as well.

In the later stages of dry AMD, drusen deposits can also cause the death of RPE cells — a condition called geographic atrophy. Since RPE cells are necessary for proper photoreceptor functioning, geographic atrophy can also cause severe loss of central vision.

Patients with many drusen deposits are also at risk of developing wet AMD, which is associated with significant vision loss due to the growth of abnormal, leaky blood vessels under the RPE and retina. Growth of these blood vessels is termed choroidal neovascularization.

As previously stated, wet AMD is less common than the dry form, but it accounts for most of the severe vision loss caused by AMD. Vision loss from wet AMD is often rapid.

What Causes Age-Related Macular Degeneration?

The precise causes of AMD are becoming better understood every day. Foundation-funded researchers have discovered that both genetic (inherited) and lifestyle factors influence the risk of developing this disease.

AMD tends to run in families. An early study estimated that 15 to 20 percent of people with AMD have one or more first-degree relatives (parents, children, siblings) who are also affected. Another study found that first-degree family members of patients with AMD have more than twice the risk of developing the disease when compared with the general population. The most current research has identified specific genetic variations associated with increased risk for developing AMD.

How Genes Cause Disease

The nucleus of every human cell contains a complete set of genes, the fundamental building blocks of life. Experts believe humans have approximately 20,000 genes. Inherited from our parents, they determine family traits like eye and hair color, the shape of one's face, and even diseases.

Each gene instructs the cell to create a specialized protein that performs a specific task for the cell. Sometimes, the instructions within a gene become altered. These alterations, also known as mutations or variations, can interfere with the proper coding of a protein. The resulting protein cannot perform its function within the cell, thereby hampering the cell's well-being and causing disease. Over a lifetime, the cumulative effects of the mutant gene and its dysfunctional protein can lead to late-onset diseases like AMD.

The Foundation's Genetic Research Program

The Foundation Fighting Blindness' genetic research program is working to better understand which genes are involved in the development of AMD. Foundation-supported researchers have identified genes with mutations that increase the risk of developing the disease.

Much of the research effort to develop treatments and cures for macular degeneration is based on the understanding gained from genetic discoveries. When a disease-causing gene is identified, it provides a clear target for preventions, treatments and cures.

An additional benefit of genetic research is that it will eventually allow doctors to identify and treat at-risk patients well before they experience vision loss. Early, pre-symptomatic diagnosis will also enable patients to avoid exposure to environmental risk factors that further increase the risk of developing AMD.

What Environmental and Behavioral Factors Increase the Risk of Developing AMD?

Researchers have discovered several risk factors seemingly associated with AMD.

These include age, cigarette smoking, hypertension (high blood pressure) and/or cardiovascular disease, a diet high in certain vegetable fats, prolonged sun exposure and race.

Age

A person's age is a significant risk factor for AMD. People who are 55 years of age or older are at greatest risk.

Cigarette Smoking

Cigarette smoking has been implicated as the most significant, modifiable environmental risk factor for AMD. Many studies show that smokers have as much as twice the risk of developing AMD as non-smokers.

Elevated Blood Pressure

Results from an epidemiological study suggest that severe AMD can be associated with moderate to severe elevations in blood pressure. This study examined blood pressure and cholesterol levels and the use of antihypertensive medication in 644 study participants with and without AMD.

Patients with the "wet" form of AMD were more than four times as likely to have moderate to severe hypertension as patients without AMD. General cardiovascular disease also seems to be associated with a higher risk of developing AMD.

Dietary Fat Intake

Studies have found that high intake of monounsaturated, polyunsaturated, and vegetable fat is associated with an increased risk of developing wet AMD. These fats are all commonly found in snack foods such as potato chips, french fries, cakes, and commercially prepared pies. The consumption of processed baked goods was also associated with a risk of developing wet AMD.

In the same study, researchers also found that individuals who ate two or more servings of fish per week showed a lower risk of developing AMD. Fish are high in healthy omega-3 fatty acids.

Consumption of nuts also appears to provide some protection against AMD. Recent studies have shown that consumption of foods rich in antioxidants may lower AMD risk. Colorful fruits and vegetables, which are rich in the carotenoids, lutein and zeazanthin, may also be protective.

Researchers are conducting further studies to better understand the role of diet in the onset of AMD.

Sun Exposure

Studies show that ultraviolet light exposure can damage cells through a process called oxidative stress. Some researchers have theorized that ultraviolet light exposure may damage the macula and lead to AMD. However, light exposure studies have not yet found a definitive link to the development of AMD.

Race

Race is considered a risk factor for the development of AMD. Caucasians are at the greatest risk for developing AMD, while risk among African-Americans is the lowest.

Controlling these Risk Factors

An awareness of environmental factors that increase the risk of disease can help people reduce or eliminate exposures when possible. However, in some cases, risk factors are biological in nature (e.g., age, race) and cannot be controlled.

Nonetheless, if you or a family member has these risk factors, then regular ophthalmology examinations can help detect the disease in its early stages, enabling a patient to seek treatment before serious vision loss occurs.

As mentioned earlier, a healthy diet appears to be associated with a decreased risk in developing AMD. Diets low in saturated fats and high in fruits and vegetables seem to be beneficial. In particular, diets high in green leafy vegetables, such as spinach, kale, collard greens, etc., have been shown to decrease the risk of getting AMD.

How is Macular Degeneration Diagnosed?

Even before macular degeneration begins affecting vision, it is usually detectable by a thorough eye exam. The doctor will examine the eye with special lenses to view the interior of the eye through the pupil. Other instruments and tests for macular degeneration include:

An **ophthalmoscope** allows a doctor to view the retina and look for disease characteristics (e.g., drusen) that are consistent with AMD.

Fluorescein angiogram tests allow inner eye structures to be examined. A vegetable dye, injected into the patient's arm, moves through the bloodstream, including blood vessels in the eyes. Photos are then taken of the retina and macula, which can identify the presence of drusen deposits, blood vessel growth and leakage from blood vessels.

Visual acuity tests measure the eye's ability to distinguish details and shapes at specific distances in specific lighting situations. This typically involves a standard eye chart.

An **Amsler grid** allows a person to check for symptoms of central vision loss from AMD. It looks like a piece of graph paper, with a spot marking the center of the grid. Patients are asked to look directly at the spot, one eye at a time. To patients with AMD, the lines on the grid can seem blurred or wavy, or the spot is not visible.

Color tests may be used to determine the status of your cone cells, which perceive color.

Does Macular Degeneration Lead to Total Blindness?

The vast majority of people with AMD retain peripheral vision — seeing objects off to the side — and can learn to optimize the use of their remaining vision, sometimes with the use of devices such as magnifiers or computer-based text enhancing devices. However, many people with advanced AMD will be classified as "legally blind."

Legally blind individuals are those whose visual acuity with glasses or contact lenses, if needed, is 20/200 or worse in their better eye; or whose total visual field, regardless of acuity, is restricted to a 20-degree diameter.

Most cases of dry AMD progress gradually over a period of years. Vision may remain stable between annual eye examinations, and many patients retain a reasonable amount of peripheral vision.

However, wet AMD tends to progress more rapidly. Patients can experience severe vision loss in as little as a few days.

For this reason, it is important to see a doctor promptly if you notice changes in your central vision.

How Can I Prevent Losing My Vision to AMD?

The best prevention is regular eye exams, which can lead to early detection and diagnosis. Because wet AMD can progress rapidly, and more treatments are becoming available, ongoing care from an ophthalmologist is essential. He or she will determine how frequently you should be examined. And an ophthalmic exam is especially important if a close blood relative has been diagnosed with macular degeneration.

The American Academy of Ophthalmology recommends that patients over the age of 65 undergo annual eye exams so that age-related eye diseases such as cataracts, glaucoma and AMD can be detected and treated promptly.

Individuals at risk — for example, those with a family history of AMD — should undergo regular eye examinations by an eye-care professional after the age of 50. The doctor may recommend daily self-monitoring of vision with the use of an **Amsler grid**. Ask your doctor if he/she feels that such monitoring is needed. An Amsler grid looks like graph paper. If the lines on the grid appear distorted or can't be seen at all, it may signal that the disease is progressing and immediate medical attention is necessary. Frequent use of an Amsler grid allows patients to monitor their vision between visits to the doctor.

The Foundation has provided a free Amsler grid in this packet and recommends that patients place the grid in a convenient spot for daily use.

Are There Treatments Available for AMD?

Thanks to investments in research from organizations like the Foundation Fighting Blindness, more and better treatments for AMD are emerging every day. Most current therapies are geared toward minimizing vision loss from wet AMD.

The Foundation is also funding dry AMD research as well as genetic and biological studies designed to identify the root causes of AMD. Such studies will eventually lead to preventions, treatments and cures. The Foundation's ultimate goal is to eliminate vision loss from AMD.

The Foundation also supports investigations of cell-based therapies, which offer hope for restoring vision to people who have lost most or all of their sight to AMD and other retinal degenerative diseases.

Research is moving at a fast pace. The Foundation Fighting Blindness will keep you abreast of developments in the field through its printed and electronic newsletters and online at www.FightBlindness.org.

Always consult your ophthalmologist before pursuing any treatment for AMD or any other retinal degenerative disease.

Current AMD Treatments

AREDS formulation — The Age-Related Eye Disease Study (AREDS) a landmark investigation conducted by the National Eye Institute (NEI) determined that antioxidant supplementation can slow the progression of AMD. The AREDS formulation is an over-the-counter antioxidant supplement recommended for people who are at risk of developing more advanced forms of either dry or wet AMD.

The AREDS formulation includes the antioxidants beta carotene, vitamin E, and vitamin C, as well as the nutrients zinc and copper. The AREDS formulation contains specific amounts and forms of antioxidant nutrients; do not try to substitute multivitamins or dietary nutrients for the AREDS formulation.

The NEI recently completed a second AREDS study (AREDS2) to evaluate the potential benefits of the antioxidants lutein and zeaxanthin and the omega-3 fatty acids docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA). The results of AREDS2 showed that DHA and EPA did not confer additional benefit in reducing AMD risk. The researchers from AREDS2 did recommend that beta carotene in the original formula be replaced with lutein, because beta carotene can increase lung cancer risk in current and former smokers. For more information on the AREDS2 study, visit www.areds2.org.

Lucentis® (ranibizumab) — Developed by Genentech, Lucentis is effective in reducing the risk of losing vision from the abnormal blood vessel growth under the retina associated with wet AMD.

The treatment was approved by the FDA and made available in 2006. A two-year study showed that 95 percent of people with wet AMD who received monthly injections of Lucentis experienced no significant loss in visual acuity. Genentech also reported moderate visual improvement in 24.8 percent of participants treated with a 0.3 mg dose of Lucentis and 33.8 percent of participants treated with a 0.5 mg dose. However, a 2013 study reported that the beneficial effects of Lucentis may diminish over time for some patients.

A colorectal-cancer drug called Avastin® — a drug similar to Lucentis — has been used "off-label" by some ophthalmologists to treat wet AMD. In 2012, the NEI completed a two-year clinical study of Avastin for the treatment of wet AMD to better determine the drug's long-term safety and effectiveness. In the study, Avastin was compared to Lucentis. Results of the study showed that the drugs were similar in safety and efficacy.

EYLEA® (alflibercept) — Regeneron's wet AMD treatment, Eylea, blocks the development of unhealthy blood vessels underneath the retina. Regeneron reports that, in clinical trials, Eylea treated wet AMD as effectively as Lucentis, but with fewer intraocular injections. Typically, patients are treated monthly with Eylea for three months and every other month thereafter. Eylea was FDA-approved in 2011.

Vision-Enhancing Implantable Telescope — The FDA has approved the use of an implantable miniature telescope (IMT) for enhancing the central vision of people with end-stage, untreatable age-related macular degeneration (AMD). The IMT provides improved central and detailed vision by focusing and magnifying images onto the functional, outer regions of the recipient's retina. People with advanced AMD normally experience degeneration of the macula or central region of the retina. The IMT was developed by VisionCare Ophthalmic Technologies.

Emerging AMD Treatments Currently in Clinical Trials

RetinoStat® — Oxford Biomedica, a gene therapy company in the United Kingdom, has launched a Phase I clinical trial of its gene therapy for the treatment of wet AMD. Known as RetinoStat, the treatment works by blocking the growth of leaky, unhealthy blood vessels under the retina that cause vision loss in wet AMD. The study is taking place at the Wilmer Eye Institute at Johns Hopkins.

Advanced Cell Technology (ACT) — The biopharmaceutical company ACT has launched a Phase I/II clinical trial of its cell-based therapy for people with dry AMD. Participants in the study are receiving transplants of retinal pigment epithelial cells derived from stem cells. The company believes the treatment may slow the progress of the disease, saving and potentially restoring vision. The Foundation funded earlier lab studies of this treatment approach which made ACT's clinical trial possible.

Acucela Inc. — A Seattle-based developer of eye-disease therapies, Acucela is conducting a three-year, Phase 2b/3 clinical trial of emixustat hydrochloride (formerly ACU-4429) for the treatment of advanced dry agerelated macular degeneration (AMD), a vision-robbing retinal condition also known as geographic atrophy (GA). Emixustat hydrochloride is designed to reduce the accumulation of toxins that cause damaging lesions in the central area of the retina in people with GA.

Other Emerging Treatments in Clinical Trials — Dozens of other potential AMD treatments are in clinical trials in the United States and around the world. Many were made possible by preclinical research funded by the Foundation. These therapies include eye drops, ocular injections, gene therapies, stem cell treatments and pharmaceutical agents. To learn more about these studies, visit www.FightBlindness.org.

Other Key AMD-Related Research Initiatives

Complement Factor H (CFH) gene — In early 2005, Foundation-funded researchers identified variations in a gene known as CFH which are implicated in as many as 50 percent of all cases of AMD. In early 2006, these same investigators found that variations in CFH, along with variations in two other newly identified genes, factor B (BF) and complement component (C2), are present in 74 percent of AMD cases.

Though the environmental and genetic causes of AMD are complex and not completely understood, these landmark findings confirm a genetic influence on the development of AMD. And these genes provide a clear target for the development of future, more effective therapies.

Specifically, the CFH finding strongly suggests that the immune system and related inflammatory responses are key factors in the development of AMD.

Future therapies may be directed toward stopping the effects of CFH variations and other related genes.

Scientists have identified other genes that are related to AMD risk and believe more AMD–related genes will be found in the future.

FFB continues to fund genetic research for AMD because the identification of genetic risk factors will give experts the best targets for treatments that will prevent AMD-related vision loss before it occurs.

FFB does not endorse specific treatments for AMD or other retinal degenerative diseases. Consult an ophthalmologist to determine what treatment is optimal for you.

This document may not reference every available AMD clinical trial or treatment.

For the latest information on AMD treatments, research and clinical trials, please visit the website of the Foundation Fighting Blindness at www.FightBlindness.org.

Comprehensive AMD clinical trial information is also available at www.clinicaltrials.gov.

If I Have Drusen Deposits, Does That Mean That I Have AMD?

Not necessarily, although the presence of drusen may indicate that your eyes are at an increased risk for developing AMD. Drusen deposits contain complex lipids (fats), protein and other components, and can accumulate as a person ages. There are two basic types of drusen: hard and soft.

Hard drusen are small, round, solid deposits that accumulate under the retina and RPE without causing damage and vision loss. Many people start accumulating hard drusen by the age of 40, sometimes at younger ages. Small hard drusen alone generally do not impair vision. Soft drusen tend to be less well circumscribed, and are larger in size than hard drusen. Large soft drusen are associated with dry AMD.

If a patient has sufficient numbers of intermediate-size drusen or one large soft druse, an ophthalmologist may recommend prophylactic vitamin and mineral replacement therapy. The National Eye Institute-sponsored Age-Related Eye Disease Study (AREDS) demonstrated that such patients can reduce the risk of vision loss by taking a particular combination of vitamins and minerals.

Are Cataracts Associated with Macular Degeneration?

AMD and cataracts are two different conditions. Cataracts are a clouding of the lens in the front of the eye. AMD affects the retina in the back of the eye. However, both cataracts and AMD are diseases that are usually related to advancing age, so it is not unusual for an older individual with macular degeneration to also develop a cataract, or vice versa. Furthermore, some of the environmental risk factors associated with AMD — for example, smoking — are also risk factors for developing cataracts.

Cataracts that significantly interfere with vision can be surgically removed. However, cataract surgery cannot improve vision loss caused by retinal degeneration. It is important to discuss the details of your individual case with an ophthalmologist.

How Can I Take Part in a Clinical Trial?

Clinical trials are research studies designed to test the safety and effectiveness of experimental therapies in humans. They are usually set up with rigorous standards and authorized by the FDA as well as by an Institutional Review Board comprised of physicians and ethicists qualified to judge the scientific merit of a clinical study. If an experimental treatment is found to be safe and beneficial, it will be made available to the public.

It is important to keep in mind that there are no guarantees that an experimental treatment offered through a clinical trial is more effective than standard therapies. Until the trial is complete, researchers will not be able to fully assess the treatment's safety and effectiveness. When discussing treatment options for AMD, patients may want to ask their ophthalmologist if there are clinical trial treatments that should also be considered.

The Foundation Fighting Blindness maintains a National Patient Registry to help researchers and ophthalmologists find patients for research studies and clinical trials. To learn more about clinical trials currently recruiting patients, please visit the Foundation Fighting Blindness online at www.FightBlindness.org or visit www.clinicaltrials.gov.

Can I Donate My Eyes to the Foundation for Research?

The Foundation coordinates a National Eye Donor Program to meet the increasing need of researchers to study human retinal tissue. Valuable retinal tissue is obtained after death from persons affected by retinal degenerative disorders in cooperation with members of their families.

By participating in the Eye Donor Program, you can make a personal investment in the search for answers about macular degeneration. The Eye Donor Program has already greatly aided research efforts. This precious anatomical gift involves no cost to the donor's family or estate. Contact the Foundation for additional information.

How Can the Foundation Fighting Blindness Help Me?

The Foundation Fighting Blindness helps patients and families in many ways. In particular, it operates a research program devoted to retinal degenerative diseases, including macular degeneration. Through generous donations from people like you, this program is helping to advance promising preventions, treatments and cures.

The Foundation also provides a comprehensive listing of ophthalmologists nationwide who specialize in diagnosing and treating macular degeneration. Through our print and electronic newsletters, we provide information on treatments, clinical trials and research to keep patients abreast of developments in the field.

The Foundation also has an expansive network of volunteer-led chapters nationwide which help to raise funds, increase public awareness and provide support to their communities. To find a chapter in your area, visit the Foundation's website, www.FightBlindness.org.

Make the Most of the Next Visit to Your Eye Doctor

Basics Questions to Ask

- 1. What is the name of my eye condition?
- 2. What is my visual acuity (central vision)?
- 3. What is my visual field (side vision)?
- 4. Am I likely to lose more vision?
- 5. Are there other tests?
- 6. What about a second opinion?
- 7. Are there any surgical options? What are they?

8. Is there any medicine or treatment that would help my condition?

9. Are there any optical or non-optical aids that can help me use my remaining vision to the fullest extent possible?

10. Should I have a low vision evaluation? If so, can you recommend a specialist?

11. Are there any mobility aids to help me move around more safely?

12. Do any of your other patients have this condition? Would they be willing to talk with my family and me?

13. Do you have any educational materials that describe this condition?

14. Are there any organizations that provide services to individuals with this or related eye conditions?

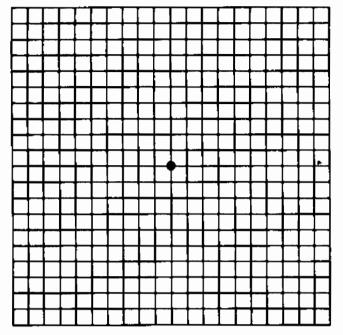
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Macular Degeneration Self Test

(See instructions on other side.)

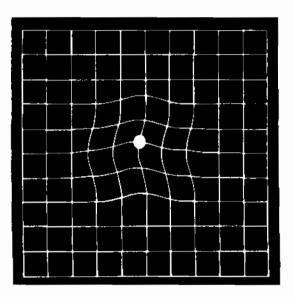


This test is designed as a reference, and may help you to detect changes in your vision. It should not be used as a substitute for a doctor's examination.

Foundation Fighting Blindness www.FightBlindness.org 800-683-5555

Instructions:

- **1.** While covering one eye, look at the dot in the center of the grid on the other side of this card.
- 2. If lines around the dot are wavy or distorted (as below), you may have a macular problem. Consult your eye care professional as soon as possible.
- 3. Repeat test daily.



| The Foundation Fighting Blindness is dependent on individuals to fund medical research. Your donation will make a difference in covering the cost of these publications, and | FOUNDATIGN FIGHTING 3LINDNESS | FOUNDATIGN FIGHTING SLINDNESS |
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| Low Vision Resource Guide: List of services and organizations useful to people with visual impairments. Genetic Testing: Discusses the process of genetic testing to help make informed decisions. Physician Referal: Geographical listing of retinal specialists familiar with retinal degenerations. | Our publications are also available on our website. To reduce the cost of postage and handling, please visit www.FightBlindness.org. If you do not have access to the Internet, please indicate your information request on the reverse side, and limit your selections to three (3) items. | Disease Information: Retinitis Pigmentosa Retinitis Pigmentosa Usher Syndrome Stargardt Disease Bardet-Biedl Syndrome Best Disease Choroideremia Retinoschisis Leber Congenital Amaurosis |

The urgent mission of the Foundation Fighting Blindness is to drive the research that will provide preventions, treatments, and cures for people affected by macular degeneration, retinitis pigmentosa, Usher syndrome, and the entire spectrum of retinal degenerative diseases.

The Foundation Fighting Blindness is the world's largest non-governmental source of funding for retinal degenerative disease research.

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