

A World Without Vision Loss From Diabetes

An Interview with S. Robert Levine, MD,
 Founder and Chief Executive Officer, Mary Tyler Moore Vision Initiative, and Executive Producer, *Being Mary Tyler Moore*

EDITORS' NOTE Dr. S. Robert Levine graduated summa cum laude from Loyola-Stritch Medical School in 1979 and completed his specialty training in Internal Medicine and Cardiovascular Disease at Mount Sinai Medical Center in New York City. He was the founding director of Mount Sinai's Cardiac Health & Rehab Program. He has led the development of the Mary Tyler Moore Vision Initiative (MTM Vision) to honor his wife—who suffered from vision stealing diabetic retinal disease—and help make her dream of a world without vision loss from diabetes a reality. Mary Tyler Moore was diagnosed with diabetes at 33 and by 49 she had lost her ability to do many of the things she loved most due to diabetes-related vision loss.



Dr. S. Robert Levine

With MTM Vision, Levine is disrupting the status quo, as Mary did throughout her life, to call attention to the fact that: we don't know what we must about retinal disease in diabetes in order to cure it; the current way we diagnose it and plan treatment is outmoded and directed toward later stage disease; and, there are known obstacles that must be overcome in order to accelerate the development of new treatments that can stop vision loss and ultimately cure blindness from diabetes. He has brought together the best and the brightest scientists and clinicians in the world to solve this life-changing complication of diabetes, the leading cause of blindness in working-age adults globally.

Levine partnered with Mary as a vocal advocate for diabetes research. Mary, as JDRF's International Chairman from 1984-2017, used her public recognition, personal experience with type 1 diabetes (T1D), and grace to support JDRF's research and advocacy programs and offer hope to T1D families. Meanwhile, Levine played an instrumental role within JDRF by helping transform its strategy and operations as they experienced rapid growth and expanding influence. He led initiatives that built a grass-roots health research advocacy program that is arguably one of the most effective in modern U.S. history. He helped develop the strategy and processes to manage a JDRF research budget that grew from \$10-12 million per year to over \$100 million per year, helping them navigate the transition from small-scale bench research to large-scale research center and mission-driven initiatives. With his guidance, JDRF expanded to support

clinical trials targeting the translation of scientific advances into therapeutic benefits for people with diabetes.

In the late 1990's, Levine served a three-year term on the NIH's National Institute of Diabetes, Digestive and Kidney Diseases Advisory Council, and he was a contributor to the Congressionally mandated Diabetes Research Working Group's report on future opportunities and needs in diabetes research.

With his wife, Levine authored a chapter for the textbook *The Essentials of Stem Cell Biology* entitled: "It's

Not About Curiosity, It's About Cures: Stem Cell Research – People Help Drive Progress." He also authored a chapter entitled "Nutrition in the Adult Years" for Victor Herbert & Genell Subak-Sharpe's: *Total Nutrition: The Only Guide You'll Ever Need*, and (with Laura L. Adams) a chapter entitled "Collaborating with Consumers to Advance Health Knowledge and Improve Practice" for Regina Herzlinger's *Consumer-Driven Healthcare: Implications for Providers, Payers and Policymakers*.

Levine is an executive producer of the documentary film, *Being Mary Tyler Moore*. He provided the filmmakers unprecedented access to Mary's life and estate, loved ones, colleagues, and friends. *Being Mary Tyler Moore* explores Mary's personal and professional journey as an iconic star, businesswoman, and advocate. Through the telling of her life story, this documentary film shows how Mary revolutionized the portrayal of women in the media and empowered generations of women from all races and economic backgrounds to dream big, work hard, and make it on their own.

ORGANIZATION BRIEF The Mary Tyler Moore Vision Initiative (MTM Vision) is a one-of-a-kind nonprofit uniting the world in the fight against diabetes-related vision loss and blindness. MTM Vision (marytylmoore.org) enables significant research breakthroughs and supports global scientific collaboration to realize Mary's dream of a world without vision loss and blindness from diabetes. MTM Vision brings together global leaders and innovators from diverse fields, including universities, pharmaceutical and medical device companies, government agencies, tech firms, the entertainment industry, and people and families with diabetes, all to advance research for a cure for diabetic retinal disease. The Mary Tyler Moore Vision Initiative is a fund

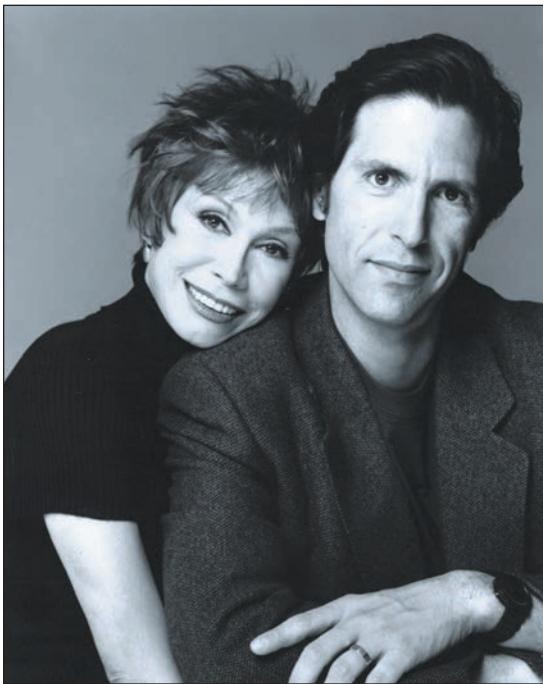
of the Entertainment Industry Foundation (EIF), a 501(c)(3) tax-exempt organization. EIF is a Charity Navigator Four-Star Charity that meets all 20 Better Business Bureau charity standards and carries the Candid Platinum Seal of Transparency.

What was the vision for creating the Mary Tyler Moore Vision Initiative, and how do you define its mission?

Mary and I were married for over 33 years. She was an optimist and a risk-taker. She lived with diabetes for most of her adult life and bravely faced many of its serious complications, the most challenging of which was her near blindness from diabetic retinal disease (DRD). Not wanting future generations to suffer as she did, she dedicated herself to doing what she could to help find cures for diabetes and its complications, helping to raise billions of private dollars to fund diabetes research and, through her advocacy for federal government funding, billions more for support for the programs of the National Institutes of Health. She dreamed of a world without diabetes and its complications and, importantly, a time when no one would face vision loss and blindness from it, and she knew that this could only be achieved through the promise of research.

Mary was a beloved actor and role model. She gave people with diabetes and their families hope. Young people with diabetes could aspire to "be just like Mary," succeeding in anything they chose to do and overcoming any limits imposed by diabetes. People looked to her for inspiration, and she never took that for granted. She always felt it was a blessing to be able to advocate for and help people living with diabetes and lead them in the search for cures.

The Mary Tyler Moore Vision Initiative's "vision" is a world without vision loss and blindness from diabetes. Our mission is to accelerate the development of new methods to preserve and restore vision in people with diabetes. I established and lead MTM Vision to honor Mary's contributions to diabetes research and keep her promise that one day people with diabetes will be able to live joyful and independent lives free from vision loss and blindness. While Mary did not see a cure for diabetes in her lifetime, her legacy of leading efforts to ensure that future generations would not suffer as she did lives on through our work.



Mary Tyler Moore and Dr. S. Robert Levine

Will you provide an overview of the Mary Tyler Moore Vision Initiative Roadmap?

Our “Creating a World Without Vision Loss from Diabetes Roadmap” has three principal phases:

Phase 1 (Our “Cure Platform”) is designed to provide our global collaborators in academia and industry with critical path resources and tools, such as a bio-bank of human eyes for detailed study, to overcome barriers to progress and accelerate the translation of scientific advances into benefits for people with or at risk for DRD.

Phase 2 assembles large databases of retinal images, visual function data, and clinical information to enable artificial intelligence-generated insights into the more effective diagnosis of DRD and a better understanding of its progression and best candidates for specific treatments. Phase 2 will also establish a core research resource for identifying therapeutic targets for new drug development discovered and validated in human tissue via cellular and molecular-level analysis.

Phase 3 will include seeding specific “science-with-a-mission” programs focusing on protecting

the retina from the deleterious effects of diabetes and restoring lost visual function via retinal regeneration or replacement.

Will you discuss Mary Tyler Moore Vision Initiative’s programs?

Through our Workshops and Symposia – which have brought together global leaders from academia, industry, government agencies, nonprofits, and people personally affected by diabetes – we are uniquely bringing a new focus to the unmet needs and scientific challenges in better understanding DRD origins and impacts, predicting its progression, and developing new therapeutic approaches to preserving and restoring vision in people with diabetes. We are further leading in building collaborative networks willing to share their data to more quickly meet these needs and overcome the challenges.

In Phase 1 of our Roadmap, we have launched three major, field-changing programs:

1. To better define DRD, we are leading a global undertaking to update the 50-year old “staging system and severity scale” for DRD. Our update will be a multidimensional and modern staging system, which uses advanced testing technologies and AI tools to enhance diagnosis, improve care and outcomes, and accelerate the development of new therapies and will include measures of visual function, retinal nerve vitality, systemic and social factors, and, importantly, the patient perspective. The early output of this program has been the publishing of six papers (one from each of our six working groups of global experts, including over 50 KOLs from 12 countries) in the influential, peer-reviewed journal, *Ophthalmology Science*, which describe the state of our knowledge and identify promising measures of retinal health and function that might be included in a new staging system.

2. To lead in enabling the study of the human condition, we have built a bio-bank of human ocular biospecimens (from post-mortem donors) at the University of Michigan’s Kellogg Eye Center and Caswell Diabetes Institute, creating a unique and highly valuable research resource and database which we will share with our academic and industry collaborators for their research.

3. To validate promising measures of retinal health identified in our staging update program and which have the potential to be used to improve diagnosis and care, and accelerate drug development research (by establishing new regulatory pathways), we have partnered with the federally funded DRCR Retina (Clinical Trials) Network and developed our first two clinical trials to better assess selected, objective measures of visual function identified by our Visual Function Working Group. We picked promising measures of visual function to be our first variables tested based on preliminary unpublished data from one of our collaborators which suggests that as many as 30 percent of children, adolescents, and young adults with diabetes and normal retina images/ophthalmologic exams (no DRD per current staging system) already have measurable loss of visual function.

To leverage the value of our Phase 1, we are organizing a public-private consortium through which academic and pharmaceutical industry partners will be able to access samples and data that we are generating, contribute their relevant data to enhance the power and utility of our shared databases, and participate in the planning of new projects and collaborative research.

We have brought together the best and the brightest researchers, data scientists, and clinicians in the world to help solve this life-changing complication of diabetes, the leading cause of blindness in working-age adults, globally. Our partners include JDRF (now called “Breakthrough T1D”), the University of Michigan’s Elizabeth Weiser Caswell Diabetes Institute and the Kellogg Eye Center, the Beetham Eye Institute at Joslin Diabetes Center, Harvard Medical School, and the Entertainment Industry Foundation (EIF).

We are challenging the global research community to do more to find cures and new ways to prevent vision loss and blindness from diabetes, including through earlier diagnosis and retinal protective treatments. We are calling attention to the fact that we don’t know what we must know about DRD to cure it, and must work together to achieve the goal of a world without vision loss and blindness from diabetes.

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Have there been advances made in the treatment of diabetic retinal disease (DRD)?

While there have been important advances, they are not without issues of access, cost, side effects, and failure rates. For instance, Mary’s DRD required “pan-retinal photocoagulation (laser) therapy.” Her retina specialist had to literally “burn the village to save it” – burning out, with the laser, hundreds of tiny areas of her peripheral retina to save the central retina from the consequences of DRD. This preserved Mary’s ability to read for a time, but at the high cost of her peripheral vision and her related ability to navigate safely, particularly in low light. More recent advances include “anti-VEGF” drugs, which are injected directly into the eye to inhibit the genesis of the fragile blood vessels responsible for some of DRD’s blinding effects. However, these drugs are expensive, require monthly injections over prolonged periods, and have failure rates of up to 50 percent in preventing the progression of the vascular component of DRD.

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How critical are metrics to measure the impact of the Initiative’s efforts?

We have already made a significant impact in our field through several key efforts. These include engaging with leading global researchers and clinicians, collaborating with the premier U.S. retina research clinical trial network (DRCR Retina Network) and its international counterparts, and partnering with top U.S. academic medical centers and diabetes and eye research nonprofits. We also work closely with the National Eye Institute and the National Diabetes, Digestive, and Kidney Diseases Institute of the NIH. Our success is evident in our workshops and symposia, strengthened industry relations, publications in top ophthalmology journals, and collaborations with major media companies and the Entertainment Industry Foundation. Our efforts have raised interest and focus on the scientific and clinical unmet needs and challenges of DRD. We have mapped a path forward for the field to achieve a shared mission and purpose – accelerating the development of new ways to preserve and restore vision in people with diabetes and create a world without vision loss and blindness from diabetes.

Going forward, the metrics for our success will include the level of investment by biotech and major pharmaceutical companies in drug development pipelines aligned with our efforts. Further success metrics will consist of greater public awareness of the threat to vision posed by diabetes, improved rates of screening and specialist referral, earlier diagnosis, and better patient outcomes. Or, more simply, more people with diabetes know they are at risk for vision loss and blindness and seek early evaluation and care, and retina specialists and primary care clinicians have more tools and treatments to offer their patients with diabetes to preserve and restore vision.

You served as executive producer on the documentary, *Being Mary Tyler Moore*. What do you hope viewers will take away from the documentary?

For those familiar with Mary’s work, I wanted to remind them why they loved her and what she may have meant to them as a role model. For those unfamiliar with Mary, I wanted them to witness her brilliant talent, hear her voice, and appreciate her kindness, generosity, and grace. I wanted audiences to recognize the barriers of the prevailing attitudes about women’s roles in the ‘60s and ‘70s and how Mary broke through those barriers and modeled a new way of thinking for and about women. I wanted people to gain a broader understanding of who Mary was; she was a door opener for other women, an innovator, and an entertainment business entrepreneur. Beyond the Hollywood persona and studio owner, she was Mary – the person who suffered pain but remained optimistic and resilient. Mary was willing to take risks and determined to push through difficulties. She wrestled with her challenges and overcame them, all while sustaining what I call her “eternal smile.” I wanted people to know the Mary I knew and see her through my eyes, with love and gratitude.

There has been much written about the special bond that you and Mary Tyler Moore had during your more than 30 years of marriage. What made the relationship work so well?

We just “fit.” I was shy and cautious; she was more outgoing and willing to take risks. She drew me out; I gave her stability. We each had standing in our worlds and had our professional accomplishments, but we were both missing someone with whom we could just

relax and safely be ourselves, show our vulnerabilities, and share our strengths. We partnered well in purpose-driven efforts, such as our work together as diabetes research advocates, and each had our independent pursuits which were personally gratifying. Because we accepted one another, supported one another, provided a mirror for the other to enable reflection, and loved one another without judgment – because, if you have seen the documentary, *Being Mary Tyler Moore*, I made her a tuna sandwich in the middle of the night, just because.

Mary Tyler Moore faced many challenges during her life. What was it like to be by her side as she displayed such resilience and strength throughout her life?

Mary did not have an easy life growing up. A distant father and alcoholic mother created a chaotic home and pressed her to find safety and stability elsewhere. She found it in dance at the Ward Sister’s School of Dance Arts. There, she learned a dancer’s work ethic and discipline. She loved ballet and understood what every ballerina knows: to succeed, to create something that audiences have never seen, to be a “star,” your toes will get bloody. This dancer’s determination and dedication to the craft and the other members of the troupe – despite whatever personal pain she felt – defined Mary. Her optimism, refusal to give in no matter the challenge, and willingness to always lead with a smile inspired me, millions of her fans, and countless children with diabetes and their families. She worked tirelessly for the cause of finding cures, all while suffering greatly from diabetes’ many ravages. This included the near blindness that robbed her of the ability to dance, read, and maintain her independence, and ultimately stole her joy. Yet, when others might have given in, Mary always said, “I’ve looked at the alternative, and I choose to push on.”

At her memorial, I had etched into the stone covering her resting place this tribute:

Her spirit a beacon

Her smile eternal

She made us better

Her strength, resilience, refusal to give up, and urgency in completing the work she started – doing what she could to help find cures for diabetes and its complications – motivated me to found the Mary Tyler Moore Vision Initiative as a way to make her dream of a world without vision loss from diabetes a reality. ●