



Transformations

From Concepts to Cures

2022 Annual Report

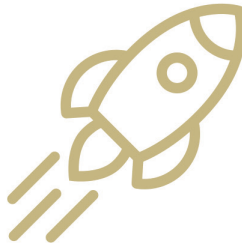


Gates Institute

UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

WHO WE ARE

Gates Institute is a world-class translational research institute with biomanufacturing capabilities. Based at University of Colorado Anschutz Medical Campus, we are part of a rich biomedical ecosystem, enabling the development of life-saving treatments for a host of diseases at unmatched speed and scope. We bring together and support researchers and clinicians who specialize in regenerative, cell and gene therapies, accelerating their discoveries from concept to cures.



VISION

To become a recognized leader in transforming patient care by advancing breakthrough regenerative, cell and gene therapies.



Gates Institute

UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

MISSION

To facilitate the acceleration of novel therapies that will have meaningful benefit for patients with life-threatening and life-altering diseases. Our success will be measured by the number of patients that we serve, the science we advance, and the creation of a sustainable future.

VALUES

“Set the bar high; clear it; and raise it further.”
– Charles C. Gates

“No one does their best work alone.”
– Charles C. Gates

Be relentless in the pursuit of improving outcomes for patients.

Stay curious about the ideas of others.

Innovate, embrace change, and be nimble.

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ABOUT THE COVER

Gates Institute researchers from a spectrum of disciplines made strides in the development of lab-grown stem cells in 2022. The top left image is a human skin organoid developed in the laboratory of Ganna (Anya) Bilousova, PhD, and the image at the bottom right is a lab-grown retinal organoid developed in the *CellSight* laboratory of Valeria Canto-Soler, PhD.



LETTERS FROM OUR DIRECTORS



Dennis Roop, PhD
Associate Director, Gates Institute

When the University of Colorado Anschutz Medical Campus and Gates Frontiers Fund leadership announced a historic commitment to transform the Gates Center for Regenerative Medicine into the Gates Institute on May 11, 2022, it marked the beginning of a new chapter. It also represented the end of the first chapter in an epic story conceived by Charles C. Gates, who dreamed of the enormous potential of stem cell research and regenerative medicine to treat and cure patients.

For six years, outgoing CU Dermatology Chair David Norris, MD, worked to recruit me from the Baylor College of Medicine to CU Anschutz, a fledgling campus that bore no resemblance to the world-class campus we enjoy today. His efforts came to fruition when Charles Gates' children, Diane Gates Wallach and the late John Gates, made a generous gift honoring their father's memory and vision of translating scientific breakthroughs into clinical practice as quickly as possible. I arrived at CU Anschutz in January 2007 to construct the foundation for a program that became the Gates Center, and as of January 2023, the Gates Institute—all of which constitutes the highlight of my career.

Following Charles Gates' adage that "no one does their best work alone," I want to thank all those who bound together over the last 16 years to help establish the foundation from which the Gates Institute will grow. Numerous partnerships, community friends, Gates Center members and staff have enabled us to recruit outstanding talent, launch the Gates Summer Internship Program, establish the Ehlers-Danlos Center of Excellence, and much more. Significantly, there was our collaboration with Diane and John, CU Anschutz, our hospitals, and community supporters to establish the Gates Biomanufacturing Facility in 2015, laying the groundwork for projects that now go from concept to cures, allowing promising new products to move forward into clinical trials and patient benefit at CU Anschutz and beyond.

As the Gates Institute officially launches in May 2023, I look forward with great confidence and enthusiasm in Terry Fry, MD, who will now lead this audacious effort. Having grown up on a farm in the mountains of Southwest Virginia, this journey of progress has been beyond my wildest dreams.

With great appreciation,

A handwritten signature in black ink, appearing to read "Dennis R. Roop".

Dennis R. Roop
Associate Director, Gates Institute
John S. Gates Endowed Chair in Stem Cell Biology

As I assume the leadership of the Gates Institute, I have the privilege of having watched the field of cell and gene therapy evolve and the optimism that the Anschutz Medical Campus is positioned to be a major contributor to the next chapter.

The FDA's first approval of a gene therapy product in 2017 for pediatric leukemia represented a remarkable milestone. It has been followed by an acceleration of approvals and advancements in cell and gene therapy, resulting in meaningful differences in the lives of patients in 2022.

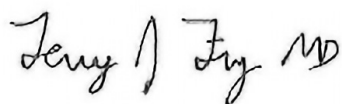
Recent therapeutic advances have been developed based upon innovative science with early human proof of concept at academic institutions, followed by commercialization in industry. I believe that the transformative early development will continue to occur at a few leading academic institutions. I also feel strongly that the University of Colorado Anschutz Medical Campus is poised to be one of those institutions and that our region is positioned to be the next major biotech hub.

I am thrilled about my new role and the opportunity to work with the many talented individuals on the campus and in the region to help realize the potential made possible by Charlie Gates' vision and the generosity of Diane Gates Wallach and her late brother John Gates.

We made significant progress in planning for the Institute in 2022, which would not have been possible without a team led by Chief Operating Officer Laura Borgelt, PharmD, MBA, in partnership with Gates Center staff and numerous individuals across the campus. With this groundwork, talent, and the commitment of members of the new and expanded Gates Institute Advisory Board, we are building capabilities to accelerate the translation of the innovative science taking place at our regional academic institutions into life-changing medicines for patients.

Our key advantage as we embark on this journey will have been the success of the Gates Center, which has demonstrated the potential in cell and gene therapy on this campus, and the Gates Biomanufacturing Facility, which is already producing medicines that are treating patients at our hospitals. This has all happened under the leadership of Dennis Roop, PhD. I can't thank Dennis enough for the unbelievably strong foundation upon which we build our aspirations for the future. I look forward to leading the tremendous team at the Gates Institute as we move onto the next chapter.

Gratefully,



Terry Fry, MD
Executive Director, Gates Institute
Charles C. Gates Endowed Chair in Regenerative Medicine



Terry Fry, MD
Executive Director, Gates Institute

REFLECTING ON A TRANSFORMATIVE YEAR



Diane Gates Wallach

What a year! If you appreciate the value of stirring the pot, engaging with top talent and embracing robust challenges, then you will also be excited about happenings at the Gates Institute.

After months of work, planning and increased funding, the Charles C. Gates Center for Regenerative Medicine evolved into the Gates Institute. The change became quietly official on January 1, 2023, but it was a transition based on positive momentum, built on years of great foundational work under the leadership of Dennis Roop, PhD, continuing the strong financial and strategic partnership with the University of Colorado, and inspired by doing things a bit differently. The Gates Institute intends to blend the best of the academic world with a responsive targeted business model—all designed to get cures to patients as quickly and safely as possible. Positive outcomes are always driven by the right people who share the same vision and set of values, and the Gates Institute is packed with talent at all levels. Add great leadership at the top as Terry Fry, MD, takes the reins, and the future is bright indeed.

Sadly, not all changes are happy ones. John Gates, my brother and co-trustee of the Gates Frontiers Fund and ardent Gates supporter from the beginning, passed away peacefully at home in March 2023, after a long illness. To the end, he was excited about the potential for regenerative medicine and cell therapies, delighted with Dennis Roop's assumption of the John S. Gates Endowed Chair in Stem Cell Biology, and always positive that good science and entrepreneurial spirit can solve many of the problems facing society today.

Sadly, we also lost Tim Gardner this winter after his own valiant two-year battle with cancer. But the work at Gates and elsewhere to crack the code on terrible diseases is what we do. We will be relentless pursuing what we do best—not trying to do everything—but targeting high potential research and clinical trials in our areas of strength. The tipping point is here for the Gates Institute, and the future is promising.

Thank you for your support and interest
as the adventure continues,

Diane Gates Wallach

Diane Gates Wallach
Gates Frontiers Fund

GATES INSTITUTE MEMBER BENEFITS

Gates Institute aspires to move cell and gene therapy research and regenerative medicine forward. We provide the following benefits in conjunction with our partners to support our diverse members as they navigate each stage of the continuum from basic science to patient benefit.

CORE LABS

These labs provide equipment and leading-edge scientific services at a cost that would not otherwise be available or affordable to cell and gene therapy researchers.

- Flow Cytometry Core
- Genomics Core
- Human Immune Monitoring Core
- Histology (Morphology and Phenotyping) Core
- Organoid Core
- Stem Cell Biobank & Disease Modeling Core

GATES BIOMANUFACTURING FACILITY (GBF)

The GBF features expertise in process development, manufacturing of cell- and protein-based therapeutics, and FDA Phase 1 clinical trial quality and control regulations to ensure that on- and off-campus research can progress into clinical trials as efficiently and cost effectively as possible.

EDUCATION & OUTREACH

Through the Gates Summer Internship Program for undergraduates and Gates Institute's support of the graduate program in Cell Biology, Stem Cells and Development, we are committed to moving the field of regenerative medicine forward by developing a pipeline of highly skilled future scientists and physicians. The Gates Institute Seminar Series and community outreach highlight advances in stem cell biology and regenerative medicine.

RESEARCH FUNDING

Financial support is available at critical stages for projects/teams affiliated with Gates Institute through direct grants and endowment distributions. The Gates Grubstake Fund provides support for the translational development of research projects into patented, clinic-ready products.

BUSINESS DEVELOPMENT AND COMMERCIALIZATION SUPPORT

Gates Institute collaborates with CU Innovations to bring together investigators and industry partners or investors to translate novel biomedical technology into patient impact. As an example, Startup Toolbox provides crucial funding to bring promising regenerative discoveries to the clinic and access to regulatory and business formation support.

A MICROGRANT PROGRAM LOWERING BARRIERS TO COMMERCIALIZATION

Developing a cutting-edge therapeutic or novel healthcare technology is challenging and requires a different skillset from academic research. To address this need, the Startup Toolbox was conceived to support Grubstake awardees and encourage entrepreneurship.

The Startup Toolbox is jointly managed by Gates Institute and its partners at CU Innovations to provide guidance, services and resources to help entrepreneurs develop their discoveries and improve patients' lives.

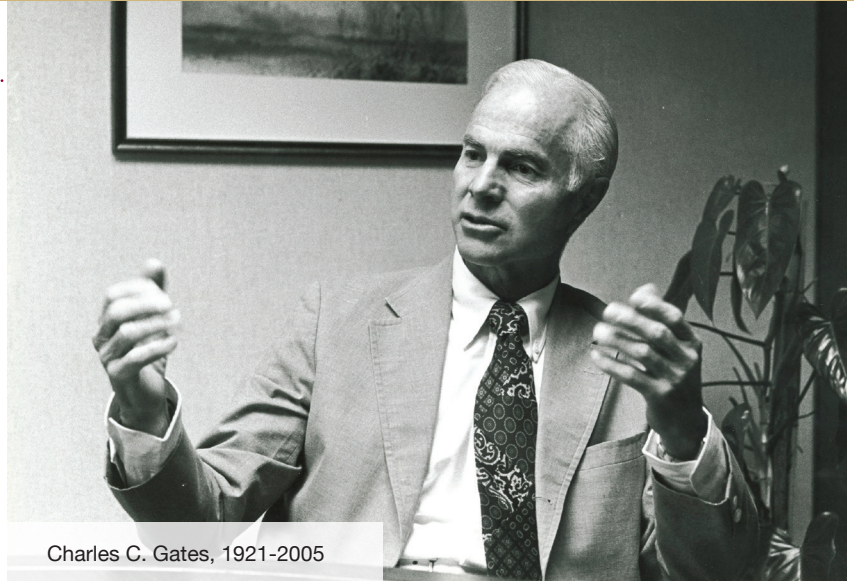
Click or scan the QR code to view a complete list of preferred service providers or seek staff guidance online at cuanschutz.edu/cu-innovations/startup-toolbox.



HISTORY OF SUCCESS PAVED WAY FOR GATES INSTITUTE AND ITS PROGRAMS

2007

Gates Program for Stem Cell Research established in honor of entrepreneur and philanthropist, Charles C. Gates. Dennis Roop, PhD, named founding director.



2010

Gates Program becomes Gates Center for Regenerative Medicine.

2015

Opening of the Gates Bio-manufacturing Facility, an FDA Good Manufacturing Practices (GMP) compliant facility.

Launch of the Gates Grubstake Fund to finance promising research discoveries.

Creation of the Gates Summer Internship Program in regenerative medicine (GSIP) for college undergraduates.



2016

Gates Center partners with CU Department of Ophthalmology to establish *CellSight* ocular stem cell and regeneration program. Valeria Canto Soler, PhD, named director.





2017

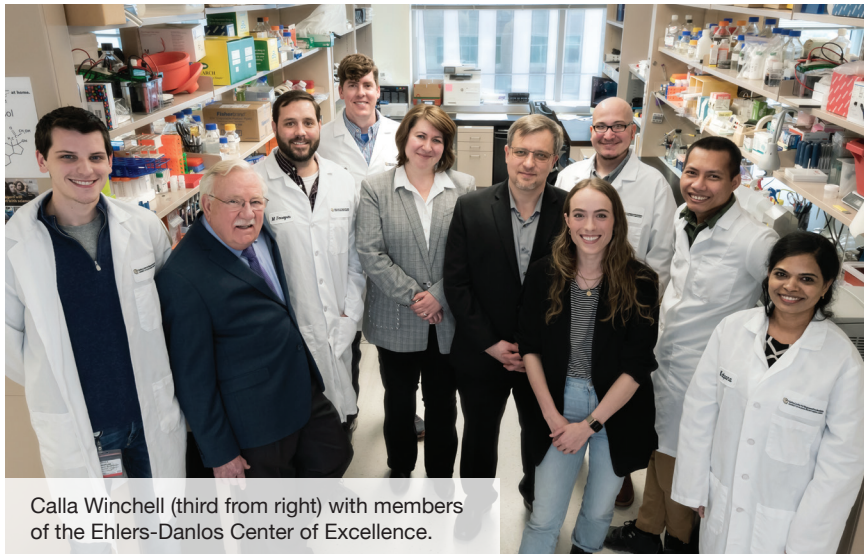
Startup Toolbox established to provide entrepreneurial support to researchers.

2018

GBF achieves its first GMP run and readies its first shipment of clinical trial cancer treatments.

2019

Establishment of the Ehlers-Danlos Center of Excellence in partnership with Children's Hospital Colorado and the CU School of Medicine.



Calla Winchell (third from right) with members of the Ehlers-Danlos Center of Excellence.

2020

Launch of human clinical trials using CAR T cells developed at the CU School of Medicine and created at the Gates Biomanufacturing Facility—the first cellular immunotherapy project where the developmental science, the regulatory filing and approvals, the manufacturing process, and the infusion of patients in clinical trials were all performed at the CU Anschutz.



2022

Historic \$200 million commitment announced to form Gates Institute. Terry Fry, MD, named inaugural director of the new organization, with Dennis Roop, PhD, remaining as associate director.

From left: CU Anschutz Chancellor Donald Elliman, Terry Fry, Dennis Roop, and Diane Gates Wallach

ENVISIONING MACULAR REGENERATION

CellSight, an ocular stem cell and regeneration research program, marked its fifth anniversary by clinching the top two prizes in a National Eye Institute challenge in recognition of its groundbreaking work.

By Toni Lapp

The success story of *CellSight* surely would have gratified Charles C. Gates, who suffered from macular degeneration. Prior to his death in 2005, Gates told his family of his belief in the potential of stem cell-based therapies and the promise of future scientific breakthroughs. The family's bequest led to the founding of Gates Center for Regenerative Medicine.

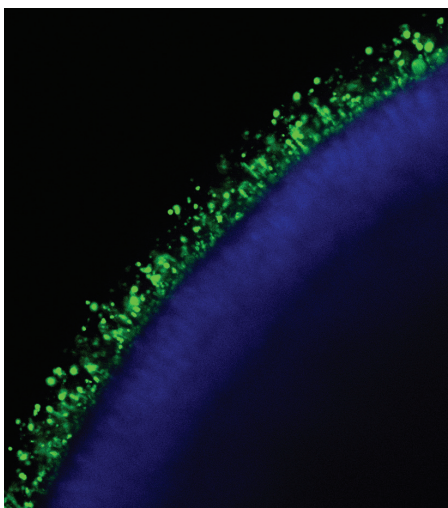
Curing blinding diseases might have seemed like a dream in the early days of the Gates Center, but *CellSight*, launched in 2017 in partnership with the Department

of Ophthalmology at University of Colorado School of Medicine, is making that dream a reality.

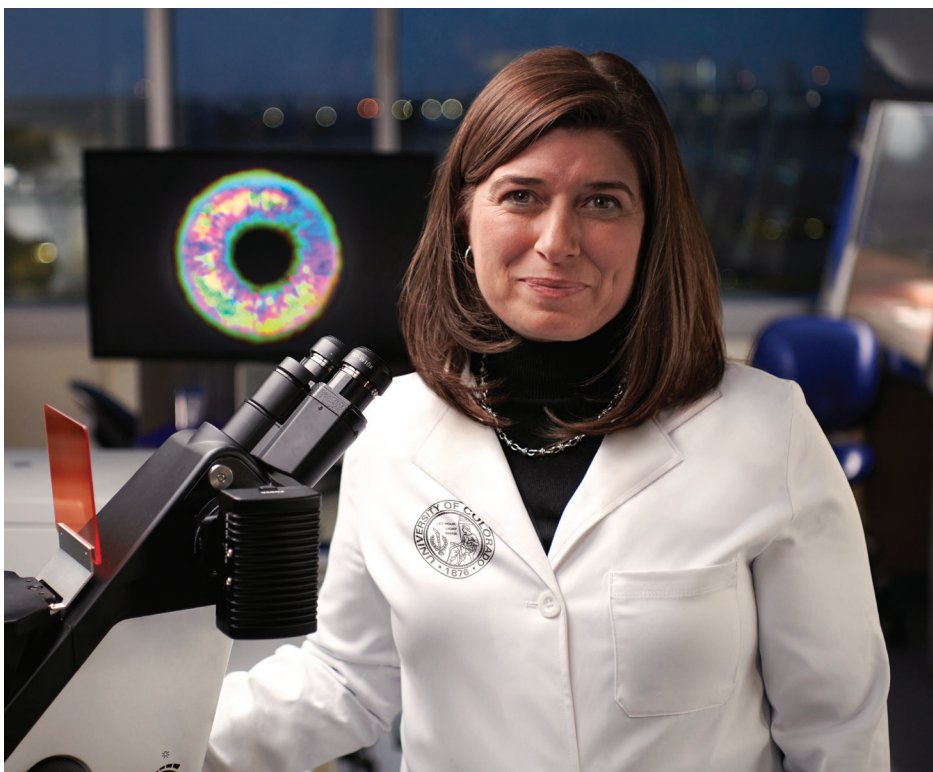
In the five years since its inception, the ocular stem cell program has become a global leader in regenerative research. Financed with a \$5 million matching grant from the Gates Frontiers Fund, *CellSight* exemplifies the partnership between Gates Institute and the Department of Ophthalmology. In 2022, *CellSight* teams clinched the top two places in the National Eye Institute's 3D Retinal Organoid Challenge, earning a combined \$750,000 in

prize money. "The successful outcome of the challenge was the result of a team effort including *CellSight* investigators and members of their respective labs," said *CellSight* Director Valeria Canto-Soler, PhD.

One *CellSight* team took top honors for its disease-modeling research with a lab-grown retinal model that re-creates pathological features of age-related macular degeneration. And a second team was recognized for its work evaluating the effects of drug toxicities on the retina.



CellSight Director Valeria Canto-Soler, PhD, led a team that was recognized by the National Eye Institute for its disease-modeling research with a lab-grown retinal organoid.



‘NOBODY DOES THEIR BEST WORK ALONE.’

In 2014, Canto-Soler had led a team of researchers at Johns Hopkins Wilmer Eye Institute that grew light-sensitive retinas from stem cells in a lab for the first time. She was the ideal candidate to lead *CellSight*, recalled J. Mark Petrash, PhD, CU professor and vice chair for research in ophthalmology, then associate director of the Gates Center.

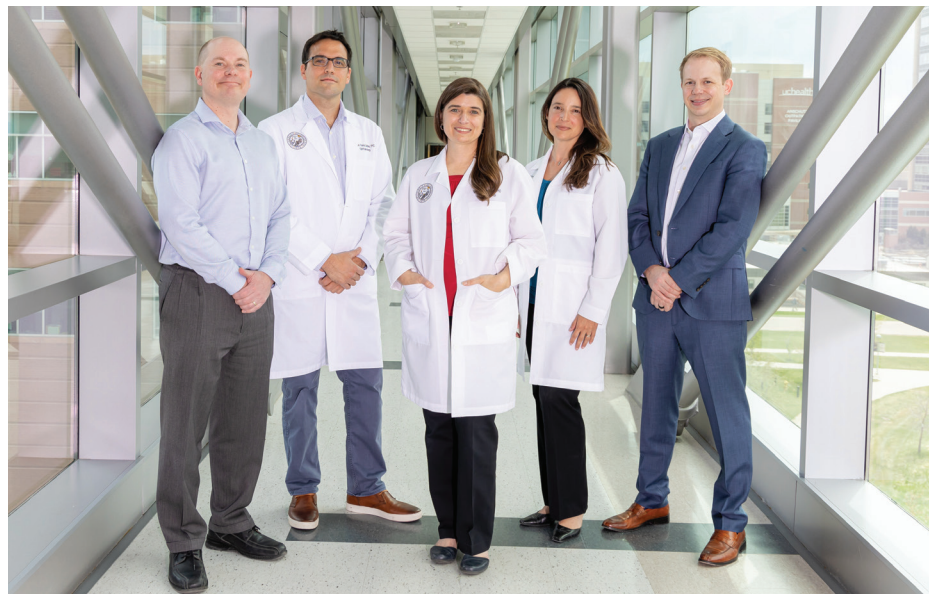
“Her commitment to build collaborations needed to succeed in transformational research reflected the guiding principle of Charles C. Gates, who famously said, ‘Nobody does their best work alone,’ which is a core value of Gates Institute,” Petrash said.

Canto-Soler quickly built a cross-disciplinary team of six researchers, which has grown to include 25 faculty, staff and trainees. The program comprises five complementary research groups, led by Canto-Soler, Natalia Vergara, PhD, Joseph Brzezinski, PhD, Miguel Flores-Bellver, PhD, and Marc Mathias, MD.

“The team that we dreamt about years ago was nothing but a profile I wrote out on a piece of paper,” Canto-Soler said. “That team exists today and surpasses my own expectations.”

GROUNDBREAKING RETINAL TECHNOLOGY

Top-notch research requires sophisticated laboratories. Engineering and architectural teams worked around the clock to design and build a space capable of meeting demanding environmental conditions, complex workflows, long-term cell culturing, and strict anti-contamination protocols. The facility meets exacting standards for lighting and air flow, with automatic opening doors, training



CellSight investigators, from left: Joseph Brzezinski, Miguel Flores-Bellver, Valeria Canto-Soler, Natalia Vergara, and Marc Mathias.

and quarantine spaces, as well as experimental rooms, a transgenic suite, and ample temperature-controlled storage.

The facility can accommodate up to 60 cell culture incubators, which researchers use to transform cells—derived from the skin, blood or even urine—into pluripotent stem cells, ultimately used to grow miniature retinas in petri dishes.

The *CellSight* team is working to develop a retinal transplant derived from retinal organoid technology to treat macular degeneration. They are also collaborating with industry partners to develop tools for retinal transplantation.

“The nature of the transplant that we are developing is unique, so we had to go from zero,” said Canto-Soler.

“You have to solve all the problems of a new technology that no one else has tried to develop before. There were no surgical instruments to manipulate and deliver this type of transplant. We had to design the right tools to use and adapt the surgical procedures to suit the clinical product that we are working toward.”

“In macular degeneration, you have retinal pigment epithelium (RPE) behind the retina which becomes damaged, and you have photoreceptor cells that are juxtaposed to it that are injured or lost. But initially, the rest of the retina is not degenerated,” Vergara said. “We were able to develop a technology to specifically injure the RPE and the photoreceptor cells in animal models, leaving the rest of the retina uncompromised, creating a model that is better suited to our purpose.”

With the new model, *CellSight* performs surgeries by inserting the transplant in the area of the retina that has been damaged by a laser. The transplant is then tracked to assess whether it maintains its structure and remains functional.

“This is hard work. We are committed to finding a cure for blindness, which was a goal of Charles Gates, and we’re aiming to do it in a way that has not been done before,” Canto-Soler said. “At *CellSight*, we are dreamers and believers, and without the support from our donors and friends, *CellSight* would still be just a dream.”

A VISIONARY WHO TOOK A CHANCE

Gates Institute is poised to become a world leader in moving discoveries from the laboratory to the clinic, thanks to the groundwork laid by Dennis Roop, PhD, inaugural director of the Gates Center for Regenerative Medicine.

By Chris Casey

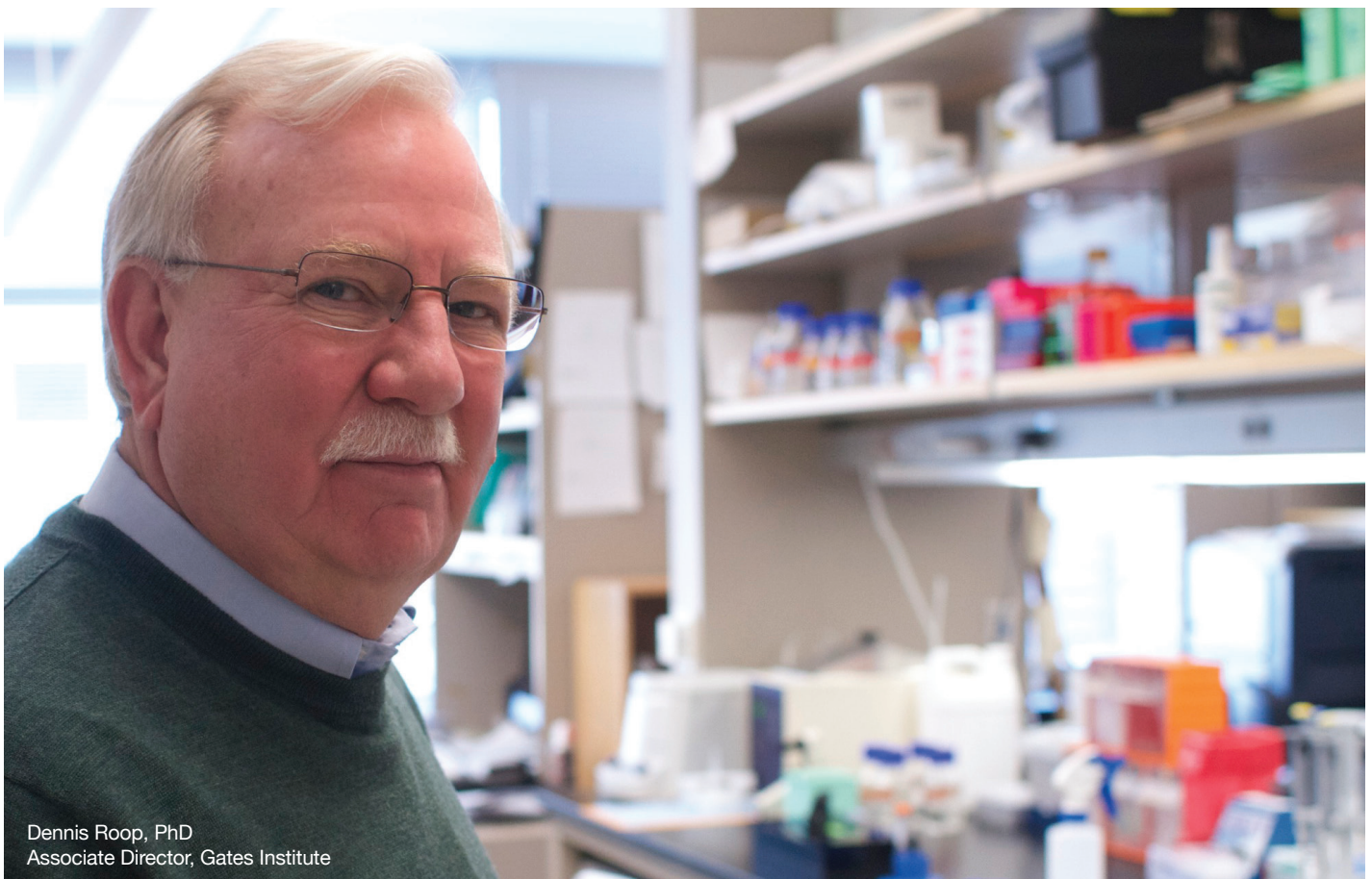
Stem cell therapy, which takes diseased cells and genetically reprograms them to exploit the body's ability to heal itself, was a relatively new area of medicine when the Gates Stem Cell Program was established in 2007. The endeavor has relied on the knowledge, collaboration and investment of scores of visionaries—from philanthropists and hospital administrators to scientists and campus leaders. Dennis

Roop, PhD, recruited to lead the nascent program, shaped this enterprise from a program to Gates Center for Regenerative Medicine, and laid the groundwork for it to become Gates Institute.

Roop's leadership and enthusiasm guided the organization through regulatory hoops, lab-space problems, budgetary issues and other challenges. He was also helped by the steadfast support of CU

Anschutz Chancellor Don Elliman and John J. Reilly Jr., dean of the CU School of Medicine and vice chancellor for health affairs.

With the announcement in May 2022 of an expanded \$200 million partnership between the Gates Frontiers Fund and CU Anschutz, the operation is positioned to become a world leader in moving discoveries from the laboratory to the clinic.



Dennis Roop, PhD
Associate Director, Gates Institute

Roop, who will remain as associate director, is handing over the reins to Terry Fry, MD, a pediatric oncologist and renowned expert in CAR (chimeric antigen receptor) T-cell therapy.

RECRUITING TALENT, PIONEERING DISCOVERIES

Colleagues describe Roop, a man with a touch of a Southern drawl (he put in two stints in molecular biology labs at Baylor College of Medicine in Houston), as visionary, tenacious, risk-taking, enthusiastic and charismatic.

David Norris, MD, professor and chairman of the Department of Dermatology at the University of Colorado School of Medicine, was on the team that recruited Roop to CU Anschutz. Norris had tried to recruit Roop to various positions over the years, but nothing was a fit until the launch of the stem cell program.

“Dennis tapped resources at the NIH (National Institutes of Health), the NCI (National Cancer Institute) and foundations, including the University of Colorado Foundation, and gave a good example of how you can raise funds to support translational research—even in the so-called valley of death in the life of a translational research project where it’s difficult to translate basic research findings into clinical practice,” Norris said. “His first big accomplishment was great recruitments, building his own research program, and then getting others to be involved in various programs at the Gates Center—the Gates Grubstake Fund, the Graduate Program (in Cell Biology, Stem Cells and Development), the Gates Summer Internship Program and other programs.”

“It’s simply remarkable” what has happened at Gates under Roop’s tenure. “It went from nothing to a \$200 million state-of-the-art pioneering institute that will shape medical therapy and research for decades.”

—Stuart Yuspa, MD, National Institutes of Health Scientist Emeritus

Stuart Yuspa, MD, a mentor of Roop’s at the NIH, where Roop ascended from post-doc to tenured faculty over eight years, said Roop was a personable and upbeat colleague as well as a pioneer in molecular skin biology. “It wasn’t just the science he brought to the lab; he brought a charisma that changed everybody’s behavior,” Yuspa said. “He generated a lot of excitement every day.”

“It’s simply remarkable” what has happened at Gates under Roop’s tenure, Yuspa said. “It went from nothing to a \$200 million state-of-the-art pioneering institute that will shape medical therapy and research for decades.” Roop arrived at CU Anschutz from the Baylor College of Medicine, which had a GMP (Good Manufacturing Practices) facility that manufactured cellular and gene therapies. He knew CU Anschutz would need an in-house facility as well, especially as pioneering discoveries, such as Fry’s CAR T-cell therapy, were emerging and required the GMP clean-room technology.

Roop’s recruits included Valeria Canto-Soler, PhD, whose research aims to develop cell-based treatments for patients suffering from vision loss, and the dermatological research team of Ganna Bilousova,

PhD, and Igor Kogut, PhD, who developed a more efficient approach to reprogramming a patient’s diseased skin cells into stem cells.

Roop’s indefatigable enthusiasm fueled the innovative programs and ultimately the linchpin milestone—development of the Gates Biomanufacturing Facility (GBF). The creation of the GBF was necessary to attract a scientist of Fry’s caliber—and it’s a story unto itself.

GETTING ON THE MAP

In 2013, when a company located in a new wing of the Bioscience 1 Building in the Fitzsimons Innovation Community suddenly was unable to obtain next-round funding and had to vacate the newly renovated space, Roop saw a window. Roop called Diane Gates Wallach, co-trustee of the Gates Frontiers Fund, and said, “We now have the space (for a GMP).” Wallach knew the GMP was essential.

“We can’t be on the map without one, but we never thought we had the resources to do it sooner instead of later,” she said. “And then this whole opportunity opened up, and Dennis said, ‘We have to do this. I know it’s risky, we’re going to stumble, it’s going to be messy, but we have to do this.’ And so, we did it.”

It began a six-year process, including the securing of key on-campus investment partners: UCHealth University of Colorado Hospital, Children's Hospital Colorado and the University of Colorado School of Medicine. The Gates Center secured a 15-year lease and \$8.8 million in commitments from donors, foundations and campus partners to renovate, equip, retain and operate the GBF through 2018. Today, the GBF is cost-neutral, covering operations

turned out to be right: (outside entities) didn't have quite the capabilities that we needed, and now Dr. Fry bringing his lab here was a big part of validating that."

Roop provided his usual balance of scientist, business director and medical liaison during the negotiations, Gaines said. "He has a unique blend of skills and an ability to talk face to face with donors and understand their needs."

machine that you just slot into. You'll have the people with the expertise to help draft the FDA (Food and Drug Administration) documents you need to get approval for a clinical trial."

Fry is excited about the substantial groundwork that's been laid by Roop and his team. "We're not starting from scratch," he said. "What we're really doing is connecting all of these strengths to launch an institute that is going to be amongst the leading programs in the world."

"We're now looking at a future of energized leadership, the continuity with the leadership of Dennis Roop, and a facility that will service multiple investigators and programs on campus."

—David Norris, MD, Department of Dermatology Chair

through contracts with nonprofits and for-profit industry (made possible through its Fitzsimons Innovation Community location) and producing both cell-based therapies and protein-based therapies (biologics). Exhaustive rounds of number crunching, strategic planning and negotiation undergirded the facility, the only one of its kind within a 500-mile radius. Patrick Gaines, former executive director of the Gates Center, recalled the process as being a pivotal juncture in the center's history.

"Dr. Roop relied on us to do market studies and research, and it's proven to be accurate," Gaines said. "In the early stages, around 2015, there were some competing voices out there saying, 'We can do this (for you). We can do it cheaper.' And after running due diligence, we

MAKING A DIFFERENCE

The key donor was the Gates Frontiers Fund, but other community leaders also stepped up, expanding the sources of support.

"It was very difficult to get the GBF launched and certified, but now you look at it, and it's just essential, and they're doing a great job," Wallach said. "They're making a difference—contributing to clinical trials and Terry's work. It's worked out well."

Gates Institute offers a robust regulatory team that "removes friction from the system" and allows the safe and efficient practice of translational science, Roop said. "There is no reason beyond appropriate safety and scientific protocols that investigators at the Gates Institute should have to wait to get their potential therapy into clinic. It should be a well-oiled

A PROMISING FUTURE, REACHING THE NEXT LEVEL

"We're now looking at a future of energized leadership, the continuity with the leadership of Dennis Roop, and a facility that will service multiple investigators and programs on campus," Norris said.

Wallach is likewise thrilled to see cutting-edge clinical trials rolling out in her home state and the promise of beating the most serious and stubborn diseases—macular degeneration and various cancers among them—with these discoveries. Gates Institute is envisioned to further break down silos and operate in an integrated and entrepreneurial environment that's needed to take stem cell therapy to the next level.

"Everything we saw in Dennis suggested he would be great—and he has been great. Anytime you start something, you can't anticipate all the roadblocks that are going to come your way."

Wallach is certain her father would be ecstatic to see the fruits of his vision. "I just know he'd be tickled seeing that this endeavor is still going, and we're really dipping into the things that he wanted to see happen in big ways."

BRINGING CLINICAL TRIALS TO LIFE

The **C**linical Inv**E**stigation and Regu**L**atory **S**ciences (**CELLS**) team has been an integral part of connecting discoveries from Gates Center members, and products manufactured at the Gates Biomanufacturing Facility, to patients at the UCHealth University of Colorado Hospital and Children's Hospital Colorado. This team of clinical trial and regulatory experts was previously housed in the Office of the Vice Chancellor for Research (oVCR), and was formed in 2020 to serve as a hub for CU Anschutz-sponsored investigational new drug (IND) applications and break down barriers that exist in the complicated regulatory landscape of cell and gene therapy. They successfully developed, submitted, and cleared two INDs and collaborated with campus and hospital partners to operationalize

four separate clinical investigations under those INDs. Twenty patients were treated by the end of 2022.

SAME TEAM. NEW NAME. BIGGER GOALS.

The CELLS team, formerly known as the Cell Therapy Operations Program (CTOP), moved from the oVCR into the Gates Institute, where they will build on their previous successes bringing to life Phase I cellular therapy clinical trials. They will continue to develop, operationalize, and oversee clinical trial protocols, while expanding their scope of services to include regulatory support much earlier in the product lifecycle. The team is small but mighty. Cheri Adams, MSHS, RN, RAC, has been instrumental in developing a critical patient safety oversight program and establishing a positive rela-

tionship and reputation with FDA project managers. Andrew Roth, PhD, collaborates with site principal investigators and staff to develop robust clinical trial protocols, databases, and obtain the necessary local regulatory approvals. Chanel Mansfield, MPH, CCRP, leads the team administratively, while Michael Verneris, MD, provides medical and scientific oversight.

As the team looks toward a bright future with the Gates Institute, they will continue to foster partnerships including, but not limited to the Hematology Clinical Trials Unit, the Blood and Marrow Transplant team at Children's Colorado, the Clinical Research Support Team (CReST), and the newly formed IND/IDE office within the oVCR. After all, no one does their best work alone.



A patient at UCHealth University of Colorado Hospital enrolled in a clinical trial receives chimeric antigen receptor (CAR) T-cell therapy manufactured at Gates Biomanufacturing Facility. The CELLS team provides support to these clinical trials, which are key to moving research from concepts to cures.

PIONEER IN CAR T-CELL THERAPY TAKES THE LEAD

Q&A with Terry Fry, MD, who will help steer the Rocky Mountain region toward leader status in cell and gene therapy with recent funding commitment.

By Debra Melani

Q What do you find most exciting about the transformation of Gates Institute?

A It's pretty clear that cell and gene therapies are going to ultimately change the face of medicine. I think it's going to take time, but there's been tremendous progress. The technologies will require close partnerships between academic institutions and biotechnology companies. This is the type of investment that has the potential to put CU Anschutz on the map in this space—and, actually, I would say, the University of Colorado more broadly. This is really about leveraging the scientific excellence in the region to develop medicines that will benefit patients.

Q What makes the institute status so important?

A It's really a heavy lift taking something that is more than a scientific idea, something that's really promising in pre-clinical trials, and turning that into a medicine—

something that goes into humans. That's where something like the institute really becomes important. The goal is to build out the infrastructure within the institute to be able to facilitate translation of those ideas that are coming from scientists across the region and get them into patients on the CU Anschutz Medical Campus.

Q What is Gates Institute's value proposition to campus researchers?

A The reason this transformation is possible at CU Anschutz is because many of the elements that are necessary to put this together are already on the campus. We have the excellence in science. We have strong hospital partners and clinical programs. The Charles C. Gates Biomanufacturing Facility is already manufacturing cells that are going into patients with cancer. We're connecting all of these strengths to launch an institute that is going to be amongst the leading programs in the world.

Gates Center might have been the best-kept secret on campus, but I hope that will change as we transform into Gates Institute. Our core labs provide equipment and leading-edge scientific services at cost to our affiliated researchers. We have regulatory specialists who can help researchers get their discoveries into clinical trials. We provide funding opportunities and commercialization support. Gates Institute is filling a much-needed role in translational research.

Q How did you end up focused on CAR T-cell therapy?

A I was interested in using the immune system to fight cancer. The history of that approach goes back over a hundred years. In many ways, I feel like my opportunity in CAR T cells was serendipitous and a bit of a privilege. I was fortunate to be in the field at a time when a lot of work done by a lot of other people sort of came together.

The other element of it is that the enthusiasm for cell and gene therapy more broadly really has been enabled by the success of CAR-T cells. CAR T-cell therapy has been just remarkable. It really has substantially changed the landscape of therapeutic options for kids with leukemia. And it was subsequently followed by approval for CAR T-cell therapy in adult cancers.

Terry Fry, MD, developed two CAR T-cell constructs being tested on campus.



Q How have you remained dedicated to CAR T-cell therapy through all of the hard times, particularly when your young patients did not see success?

A There's a really important component of humility. When you go into these early phase clinical trials, if it's your therapy that you are passionate about, you are taking it into the clinic because you really think it has the potential to help patients. But, if we're honest with ourselves, when we go into that first clinical experience, we really don't know what's going to happen.

The bravest person in all of this is the patient who chooses to be among the first patients that are enrolled in a trial of a novel therapy. If I'm doing my job, I'm talking to those patients and families about what I know and don't know and that I'm not sure if it's going to help. So this is a partnership between a physician and a patient. In honesty, in many ways, that partnership is why I do it.

There are times where that partnership absolutely results in heartbreak. And there have been times where I've been very lucky, where there's a lot of success with patients who had no other options. That is unbelievably powerful and what keeps me going. But it's as much, in kind of a strange way, the experiences that don't go well that drive you to do better.

Q How do you envision Gates Institute 10 years from now, and is there anything else you would like to add about this venture ahead?

A I would envision that when people think about which academic institutions are at the forefront of transformative therapies for patients in this cell and gene therapy space, that CU Anschutz is considered amongst the leading institutions. I'm delighted to have this opportunity that has been enabled by a number of people who have believed in this vision for CU Anschutz since before I arrived on campus. None of this would have been possible without campus and hospital leadership and, obviously, the Gates family support.

"The bravest person in all of this is the patient who chooses to be among the first patients that are enrolled in a trial of a novel therapy." — Terry Fry, MD





Before coming to CU Anschutz, Terry Fry, MD, led efforts in cellular immunotherapy for pediatric leukemia at the National Institutes of Health (NIH). Photo courtesy of NIH.

GATES INSTITUTE ANCHORS A THRIVING CELL AND GENE THERAPY HUB IN COLORADO

By Elyse Blazeovich, President & CEO, **Colorado BioScience Association**
April Giles, Vice President, Business Development, **Fitzsimons Innovation Community**

Gates Institute solidifies Colorado’s reputation as a rising leader in cell and gene therapy, with more than 30 Colorado companies focused on variations of the novel, life-saving technologies. This ecosystem is supported by the state’s convergence of leading-edge research, clinical collaborations, and specialized infrastructure that includes manufacturing capabilities.

CELL AND GENE THERAPY GROWING IN COLORADO		
30+	1,000	\$230M
Companies in State	Jobs Created in Five Years	Being Raised in Current Funding Rounds
 COLORADO BIOSCIENCE ASSOCIATION	Source: Colorado BioScience Association. Data represents projections at the low end of each range for jobs and fundraising.	
		fitzsimons Innovation Community

Gates Institute Executive Director, Terry Fry, MD, is a pediatric oncologist and a pioneer in the development of chimeric antigen receptor (CAR) T-cell therapies. When the Colorado BioScience Association held its first-ever biotech symposium focused on cell and gene therapy in early 2023, Fry’s keynote presentation—an update on Gates Institute, the \$200 million investment that expands on the Gates Center for Regenerative Medicine and Gates Biomanufacturing Facility (GBF)—drew a standing-room-only audience. Cell and gene therapies are already saving and changing lives around the world, said Fry. “You’re going to see cell and gene therapy begin to expand into a large number of diseases with an almost unbelievable potential to cure those patients.”

INNOVATION FOR PATIENT IMPACT

Cell and gene therapy serves as a broad term for two crucial tools in the disease-fighting workbench. Cellular therapy is “the transplantation of human cells to replace or repair damaged tissue and/or

cells,” according to the Association for the Advancement of Blood and Biotherapies. The U.S. Food & Drug Administration (FDA) indicates “gene therapy modifies a person’s genes to treat or cure disease.”

In the last decade, research breakthroughs and government approvals advanced these game-changing treatments for a variety of illnesses, including cancer. Forward-thinking academic institutions, collaborative hospitals, and innovative companies are working to translate discoveries into treatments for patients, creating hubs for cell and gene therapy. The first FDA approval of a CAR T-cell therapy in 2017 “really paved the way for cell and gene therapy going beyond a phase 1, fully academic enterprise into something that has the potential to be commercialized with success,” says Fry.

COLORADO’S LEADERSHIP

Colorado’s culture of collaboration and convergence of leading researchers and clinicians, top academic and research institutions, and 30 companies focused on commercializing cell and gene

therapy position the state to become a leading cell and gene therapy hub. The 30 companies working on cell and gene therapy innovations foresee fast growth and anticipate hiring more than 1,000 people in the next few years.

While late-stage development and manufacturing are key elements of the commercial phase of cell and gene therapy advancements, Fry explains that the initial phases of research are often purely an academic endeavor.

“This research all starts as an idea in a lab, an idea that goes through many iterations of trial and error and many failed starts,” he says. “Almost all those activities happen at academic institutions, where there is patience for the iterative work and the ability to build on failures. But development eventually needs to be done in the context of industry, too. It’s partnerships between academia, industry, and manufacturing that allow this field to evolve.”

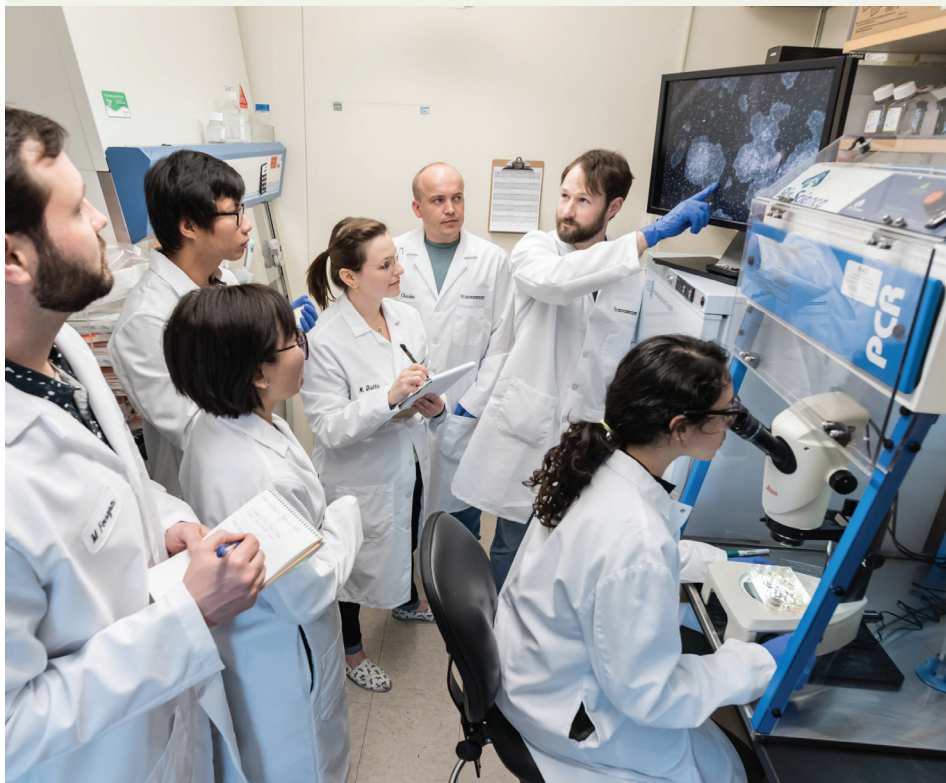
Fry explains that these partnerships were some of the most important considerations taken when building the CU Anschutz Medical Campus and each individual facility. “The model we’re exploring is one where the CU Anschutz Medical Campus becomes a one-stop place where we’re able to take the biotechnology companies here and partner them with our clinical entities on campus. We can then identify the patient population, open the clinical trial, generate the data, and, on the back end, transfer it back to the biotech company so they can then use that data for subsequent development and eventual manufacturing.”

The CU Anschutz Medical Campus makes this model extremely viable. Across the street, the GBF occupies 21,000 square feet in the Bioscience 1 building, where it focuses on phase 1 trials; the recently completed Bioscience 5 building at Fitzsimons Innovation Community offers full-scale commercial manufacturing for cell and gene therapy. The 90,000-square-foot facility is designed to optimize advancements in the ecosystem and support its member companies’ overall development.

Gates Institute was designed to fill in gaps in traditional academic infrastructure, to become a place where first-class ideas are generated with the ability to turn those ideas into cures for patients. According to Fry, that’s already happening. “We’ve already demonstrated that we can manufacture genetically modified cellular products, get them to patients, and achieve very favorable outcomes for those patients, including patients with refractory cancers that are now in remission. We’re doing that right now through manufacturing these products on campus. We’ve succeeded in the first important steps and now we’re ready to build on that.”

TRACK RECORD OF SUCCESS

Gates Institute was born from two entities—the Gates Biomanufacturing Facility, which is housed within Fitzsimons Innovation Community, and the Gates Center for Regenerative Medicine. The institute will build on the success of both organizations, which have conducted groundbreaking stem cell research for cancer and rare diseases, pioneering new therapies in recent years. Funding from Colorado’s Advanced Industries Accelerator Grant Program supported Gates Biomanufacturing Facility’s work to qualify as a current Good Manufacturing Practice (cGMP) facility.



GATES BIOMANUFACTURING FACILITY

A pillar of Gates Institute, the GBF serves a pivotal role in translational research under the leadership of Matthew Seefeldt, PhD.

By Toni Lapp

Like many start-ups, the [Gates Biomanufacturing Facility's](#) path to becoming sustainable has been full of twists and turns. The facility, known internally as the GBF, was launched in 2015 with no customers and no jobs in the pipeline, but many capital needs. The visionaries at University of Colorado Anschutz Medical Campus and the Gates Frontiers Fund saw biomanufacturing capabilities as being key to the success of the nascent Gates Center for Regenerative Medicine, and took a leap of faith.

'EMPLOYEE NO. 3'

Just as cells are the building blocks of life, people are the building blocks of an organization.

Meet Matthew Seefeldt, PhD.

"I was employee No. 3 when I joined the GBF," said Seefeldt, who earned his doctorate in chemical engineering at University of Colorado Boulder. His career path was also full of twists and turns.

He had worked his way through college, even doing a stint between semesters as an undergraduate at Colorado School of Mines at Gates Rubber Co. in Denver, where he applied his chemical engineering skills to improve processes at the plant. He went on to launch a biologics firm that manufactured a protein for treating multiple sclerosis with his then-academic adviser Ted Randolph, PhD, at CU

Boulder in the early 2000s, and had gained a reputation for his expertise in protein "folding," a technique required to ensure the protein would function properly when manufactured at a large scale.

But that start-up venture ended after taking a molecule through phase 3 clinical trials, and in 2014, he was sought out as a consultant for protein manufacturing at the GBF. The facility had just secured funding and a space in the Biosciences 1 building at the Fitzsimons Innovation Complex.

"All that existed here were the office spaces and cubicles," Seefeldt said. "The rest of the space was a concrete slab. The job initially was to manage the construction site for six months."

Dennis Roop, PhD, inaugural director of the Gates Center, recalled that Seefeldt demonstrated his versatility early on, designing and overseeing the buildout of the laboratory suites, selecting equipment, and negotiating contracts. Seefeldt already had experience with investigational new drug (IND) filings and had become an authority on the Food and Drug Administration's current Good Manufacturing Practices (cGMPs), a requirement for manufacturing pharmaceutical products. Seefeldt quickly advanced from a consultant to director of protein manufacturing



Matt Seefeldt, PhD

at GBF. Within a couple of years, he had become knowledgeable about all aspects of the operation.

"As the GBF evolved, it was really Matt who had gained experience in running the whole operation, not only the protein manufacturing side, but also the cell therapy side," said Roop. "He really proved to be an unbelievably good manager at a time when we needed someone with his expertise."

In addition, Seefeldt was instrumental in getting external clients in the door, said Roop. "The reality was that with these (external) companies, the technology that they brought in wasn't turnkey. It really had to be developed by Matt and his team."

In short, Seefeldt was able to sell the value proposition of an academic GMP facility. “We can tell them, ‘We’re willing to work with you and help you,’” said Roop. “We are the experts that can help optimize this technology.”

Being able to serve external clients has enabled the GBF to ramp up its infrastructure to benefit internal clients—researchers affiliated with Gates Institute—and to initiate new clinical trials that the University of Colorado sponsors.

NAVIGATING HIGHS AND LOWS OF A START-UP

Although Seefeldt likes to say he saw the opportunity at the GBF as being like a “start-up without the start-up drama,” there were some dramatic moments.

The facility operated at a loss in its first few years, due to the massive investment required for a GMP facility to get up and running. The

facility could absorb this cost due to the support from the Gates Frontiers Fund, CU Anschutz Medical Campus, Children’s Hospital Colorado and UCHealth University of Colorado Hospital, who together supported operating costs. As the GBF waited for academic researchers to bring in work, Seefeldt courted external clients.

“Nobody wanted to be the first customer of a new facility,” Seefeldt recalled. In 2016, the GBF onboarded its first external customer, a client with a protein product that was unable to be successfully manufactured by another company.

The next turning point came in 2018, when Gates Biomanufacturing Facility created chimeric antigen receptor (CAR) T cells for another private client. That was followed by CAR T-cell therapy production in collaboration with faculty in the CU School of Medicine for the first-in-human clinical trials at UCHealth

University of Colorado Hospital and Children’s Colorado in 2020. It was the first cellular immunotherapy project where the developmental science, the regulatory filing and approvals, the manufacturing process, and the infusion of patients in clinical trials were all performed at the CU Anschutz campus.

In 2020, the year the GBF first achieved breakeven financials, Seefeldt was promoted to executive director of the GBF.

When Seefeldt reflects on the ups and downs he navigated at the GBF, he credits his resiliency for seeing him through the challenges. “It’s a lot like science,” he muses. “Anyone who does a lot of bench work knows, a majority of your experiments won’t work. There are a lot of iterations in early-stage process development. I apply those same strategies to running a business. Eventually the dice roll the right way.”



THE GATES BIOMANUFACTURING FACILITY LEADERSHIP TEAM

From left: Matt Seefeldt, Russell Marians, Terri Foote, Gana Batt, Charles Hickey, Chris Freedman, and Chandresh Undhad

A PACKAGE DEAL

Husband-and-wife research team Ganna Bilousova, PhD, and Igor Kogut, PhD, recently patented two complementary technologies to develop stem-cell created skin grafts, which could translate to cures for those with devastating skin diseases.

By Carie Behounek

When Dennis Roop, PhD, joined the University of Colorado School of Medicine to lead the Gates Program for Stem Cell Research in 2007, the first postdoc he recruited was Ganna (Any) Bilousova, PhD, a Ukrainian researcher who had recently completed graduate training in biochemistry at CU.

Only a year before, Japanese researcher Shinya Yamanaka, MD, PhD, had created a sensation in the scientific community when he reported that he could reprogram adult skin cells into embryonic-like cells, introducing the world to induced pluripotent stem cell (iPSC) technology. When stem cells are pluripotent, they can develop into any number of cell types in the body.

But early iPSC technology wasn't simple. The process was time-consuming and resulted in very few viable cells, as the efficiency of gene editing is less than 5%.

One of Bilousova's first projects in Roop's lab in the Department of Dermatology was to determine whether Yamanaka's iPSC research was reproducible, and if so, whether it could be improved upon. The answers were yes and yes.

'WE NEED A MOLECULAR BIOLOGIST'

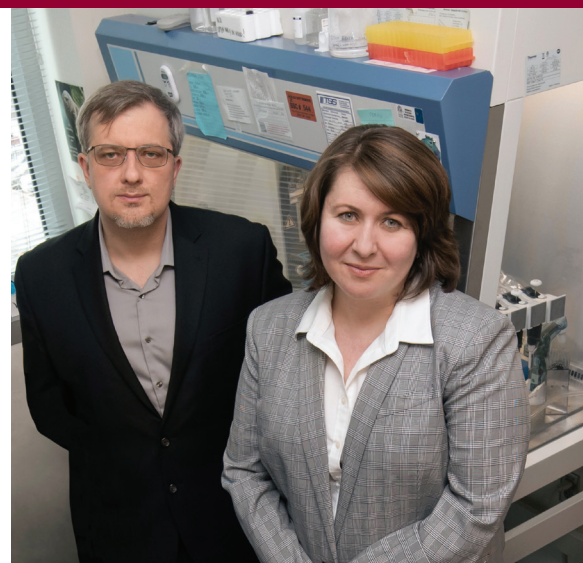
Although Bilousova was new to dermatology and inexperienced with keratinocytes—the primary cells of the epidermis—she quickly impressed Roop with her creative problem solving in the lab.

"I call Anya a cell whisperer because she has this innate ability to look at cells when they're growing in a petri dish and just knows what they need to be happy," Roop quipped, and he's only half-joking.

Having established that Yamanaka's research was robust, Bilousova turned her focus to improving the iPSC technology to yield real-world applications in dermatology.

"Anya came to me and said, 'You know, we need a molecular biologist, and I just happen to know somebody,' " Roop recalled.

That somebody was Bilousova's husband, Igor Kogut, PhD, who had also emigrated from Ukraine to obtain his PhD at CU in biochemistry and molecular genetics. With Bilousova's expertise in cell biology



Igor Kogut, PhD, and Ganna "Any" Bilousova, PhD

and Kogut's background in molecular genetics, they made a formidable team. Roop provided guidance throughout as well as support navigating grant applications.

Since then, Bilousova and Kogut established their own independent research laboratories but continued their close collaboration with Dr. Roop on developing therapies using iPSCs. Kogut is now assistant professor of dermatology and Bilousova is associate professor of dermatology.

FROM CONCEPT TO CURES

Growing genetically modified human skin in a lab may have sounded like science fiction a few years ago, but recent strides are making iPSC technology a reality. Bilousova's and Kogut's work in collaboration with Roop could offer hope for a better quality of life for patients with devastating skin-blistering diseases, such as epidermolysis bullosa (EB). Not only that, it could open the door to cures for other diseases.

“These embryonic cells can be expanded upon indefinitely,” said Bilousova. “And as a result, we can do a lot of things with them.”

Including *precise* gene editing to correct the mutation that causes EB.

With the assistance of their laboratory members, Bilousova and Kogut found ways to speed up the process and make more cells viable. In late 2022 and early 2023, they patented two new technologies—the result of more than a decade of work. “One is a high-efficiency RNA-based reprogramming, which is a protocol that allows us to reprogram at least 80% of the cells we plate,” said Bilousova. “The second patent allows us to combine this high-efficiency reprogramming method with gene editing. And that allows us to shorten the procedure for the generation of genetically corrected iPS cells that we can use for the treatment of inherited skin-blistering diseases.”

The higher success rate makes the process more practical for clinical applications. Because skin has been generated “in a dish” for many years now, techniques are already available that allow for functional skin to be transplanted back to patients. In addition, the researchers are

investigating a promising alternative involving a form of “spray-on skin” that could improve upon current skin graft techniques.

The numerous grants they’ve received, from entities like the National Institutes of Health and Department of Defense, are testament to the potential real-world applications of their work.

MOVING FROM LAB TO CLINICAL TRIALS

Roop, Bilousova and Kogut were recently awarded funding from the Epidermolysis Bullosa iPS Cell Consortium to manufacture their stem-cell created skin grafts. They’ve begun moving their technologies into the Gates Biomanufacturing Facility (GBF) to launch the production of their modified mRNA protocol.

“It seems like they were able to successfully produce the molecules,” Bilousova said. “We recently tested them in our lab and they performed as expected, so we believe it’s going to work.”

Their next step is to move the combined gene editing and reprogramming to the GBF, which will produce clinically relevant, genetically corrected, patient-specific iPS cells, ready for differentiation.

Once the cells are differentiated into skin organoids, they are ready to use on patients for clinical trials. Which is again where the GBF comes in.

“The Gates Biomanufacturing Facility will help us make the whole complex protocol suitable for clinical manufacturing,” said Bilousova. “And once we accomplish that, we can go to the FDA and ask permission to initiate a clinical trial to treat the patients.”

The researchers are cautiously optimistic, recognizing there’s still a lot of work to be done.

“It’s pretty cool to be at the forefront of the whole technology and make a difference for the quality of life of these patients,” said Bilousova.

Kogut says many diseases could benefit from this technology, including inherited hematological diseases like Fanconi anemia.

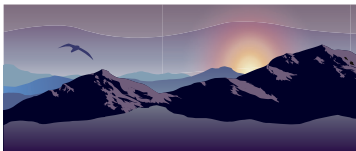
“We could be providing a cure for currently incurable diseases,” he said. “We’re really in the position to help people.”

Note: Toni Lapp contributed to this article.



Igor Kogut and Anya Bilousova, front and center, surrounded by their respective lab teams.

GATES INSTITUTE'S GRUBSTAKE FUND AWARDS OVER \$1.5 MILLION TO CAMPUS RESEARCHERS



GATES GRUBSTAKE FUND

The Gates Grubstake Fund invokes the memory of Gold Rush prospectors who received seed money, “grubstakes,” for food and supplies so they could search for treasure. Gates Grubstake Fund provides funding to modern-day prospectors—translational researchers affiliated with Gates Institute—whose work could make a difference in human lives. In 2022, four awardees received \$350,000 each to support their work. In addition, second-tranche awards were made to two previous Grubstake recipients who demonstrated success in developing technology toward a clinical trial. Since its inception, the Grubstake Fund has made 29 awards, totaling \$9.7 million.

2022 GRUBSTAKE AWARDEES



GANNA BILOUSOVA, PhD

Somatic Cell Rejuvenation for Skin Transplantation and Wound Healing

With a steady increase in the aging population, the care of acute and chronic wounds in the elderly has become a priority topic for clinicians.

Many options to treat wounds are currently available. However, none of them restores the functionality of aged skin cells, hence low success rate in the elderly. Ganna Bilousova, PhD, associate professor of dermatology, and Igor Kogut, PhD, assistant professor of dermatology, are developing a permanent corrective therapy for acute and chronic wounds in the elderly by rejuvenating the patient's own skin cells using a patent-pending RNA cocktail of factors. The Grubstake Award will allow their teams to finalize their therapeutic product and compare its efficacy with the competition to accelerate development toward pre-investigational new drug (IND) filing with the Food & Drug Administration.

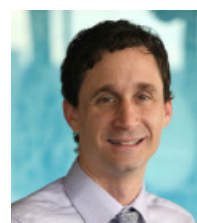


MI-HYUN NAM, PhD

Restoration of Vision in Glaucoma through Cell Therapy

Principal investigator Mi-Hyun Nam, PhD, research instructor in ophthalmology, and her co-PI, Natalia Vergara, PhD, assistant professor

of ophthalmology, are developing a human stem cell-based therapy for treating glaucoma, the second-leading cause of blindness worldwide. Current medical therapies are limited to lowering intraocular pressure, which may prevent further vision loss, but no treatment to date can restore vision once it has been lost. The Grubstake funding will enable them to perform preclinical studies to determine the feasibility and efficacy of their therapy.



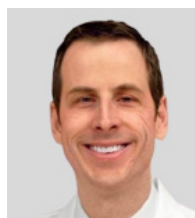
MARK (ERIC) KOHLER, MD, PhD

Adjunctive LAT-Activating Chimeric Antigen Receptor T cells (ALA-CART) Strengths

CAR-T cells have revolutionized the treatment of leukemia and lymphoma, inducing responses

against cancers that no longer respond to traditional therapies. However, current CAR-T cell strategies are unable to induce long-term remissions in the majority of patients, owing to limitations in their persistence,

potency and sensitivity. By studying CAR-T cell signaling, the lab of Eric Kohler, MD, PhD, assistant professor in the Department of Pediatrics, identified that inefficient activation of the molecule LAT was responsible for many of the limitations in current CAR-T cell therapies. Using this finding, they rationally designed a new Adjunctive LAT-Activating CAR-T cell (ALA-CART) that restores LAT signaling and demonstrates enhanced potency and persistence in preclinical models. Furthermore, ALA-CART cells demonstrated increased sensitivity to tumor cells with low levels of the targeted antigen, allowing for eradication of leukemia that would otherwise not be "seen" by current CAR-T cell therapies. These advancements hold the potential to close many of the vulnerabilities of CAR-T cell therapies and improve their long-term effectiveness for patients. Grubstake funding will be used to generate safety data and establish manufacturing workflows at the Gates Biomanufacturing Facility to transition this work to clinical trials



DANIEL SHERBENOU, MD, PhD

Response Prediction for T Cell Engaging Bispecific Antibodies in Multiple Myeloma

Daniel Sherbenou, MD, PhD, associate professor in hematology, Department of Medicine, received

a Gates Grubstake Award to commercialize the new myeloma drug sensitivity testing (My-DST) assay for profiling responses to T cell engaging bispecific antibodies for patients with multiple myeloma, an incurable blood cancer afflicting more than 150,000 Americans. Bispecific antibodies are a promising new class of therapy that redirect a patient's own T cells to kill the cancerous myeloma cells. To improve the clinical application of these drugs, My-DST has potential as a new laboratory test for measuring responses of an individual patient's tumor cells from biopsy specimens. In this project, Sherbenou's team will pursue regulatory approvals and scale up efforts to establish My-DST as a personalized medicine approach for the various bispecific antibodies in clinical use or in clinical trials.

Continued on next page.

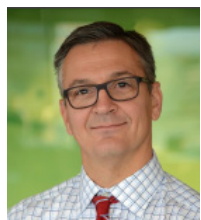
SECOND-TRANCHE RECIPIENTS



EDUARDO DAVILA, PhD

Manufacturing of Genetically Engineered Tumor Infiltrating Lymphocyte Therapy

Eduardo Davila, PhD, professor in the Division of Medical Oncology, was awarded \$50,000 in second-tranche funds. This funding will accelerate development toward pre-IND filing with the FDA by completing studies related to (1) specificity and potency assays to test TIL function; investigate changes in the T cell repertoire; and confirm that TILs do not become leukemic.



MICHAEL VERNERIS, MD

Multi-omic Approach to Establish Mechanisms of Efficacy of Stem Cell-Derived Innate Lymphoid Cells in Gastrointestinal Tract Repair

Michael Verneris, MD, professor in the Department of Pediatrics, received a second-tranche award of \$100,000. Innate lymphoid cells are tissue resident lymphocytes that can be restorative to injured mucosal tissues. In Crohn's disease (CD), a subpopulation of ILCs (ILC3's) are depleted and the loss of these cells is thought to be part of the pathogenesis of CD. Replacement of ILC3's in CD may be therapeutic. Verneris' laboratory has developed methods to generate ILC3's from hematopoietic stem cells and has found that adoptive transfer of these cells can improve the intestinal dysfunction in TNFdARE mice, which is a model of CD. With this funding they will perform CITE-SEQ and Xenium in situ analysis on ILC3 treated (and untreated) mice to better understand the impact of ILC3's adoptive transfer at single cell resolution. Additionally, they will continue to perform scale-up experiments with the goal of transferring this technology to the Gates Biomanufacturing Facility.

ACKNOWLEDGEMENTS

The Gates Grubstake Fund is a testament to the collaborative nature of Gates Institute. The awards are made possible through private philanthropy and facilitated by a committee of talented volunteers. The program has been a major success, providing hope that through research, philanthropy and team-work, cellular and genetic therapies will provide effective treatments for the most challenging afflictions facing patients today.

Recipients of Grubstake Awards are selected by the Scientific Investment Advisory Committee, which reviews applications through a competitive process. We would like to thank the members of the committee:

Mark Brunvand, MD	Kimberly Muller, JD
Sibylle Hauser	Mark Petrash, PhD
Ryan Kirkpatrick	Matt Seefeldt, PhD
David L. Lacey, MD	Duffy Solich
Mark Lupa, PhD	Ann Sperling
Mani Mohindru, PhD	Robert Traver, PhD

IMPORTANT DATES

SEPTEMBER 2023: Investigators whose applications are selected for presentation will be notified

NOVEMBER 2023: Presentations made to investment committee

DECEMBER 2023: Awardees notified

For more information about the Grubstake Fund, click or scan the QR Code



GATES CENTER LENDS ITS SUPPORT TO CSD GRADUATE PROGRAM

For the seventh consecutive year, Gates Center provided support for the graduate program in Cell Biology, Stem Cells and Development (CSD) in 2022.

by Jeff Moore

CSD, one of 12 biomedical PhD programs on the University of Colorado Anschutz Medical Campus, is distinguished by training that integrates foundational knowledge in cell and developmental biology with a focus on applying that knowledge to better understand disease and develop regenerative therapies.

Six CSD students completed their PhD training in 2022. Among them was Madison Rogers, who first trained on campus in 2015 in the Gates Summer Internship Program in the labs of David Norris, MD, and Yiqun Shellman, PhD. Madison joined CSD in fall 2017 and for her thesis studied platelet-derived growth factor receptor signaling in the lab of Katie Fantauzzo, PhD, publishing three papers as first author. Madison was a valued leader in the CSD program, serving on the Graduate Advising Committee, chairing the Student Executive Committee, and helping to start the Advanced Writing Workshop where students develop writing skills for different types of scientific communication. Armed with her PhD, Rogers now pursues her passion for science communication as a medical writer at Real Chemistry.

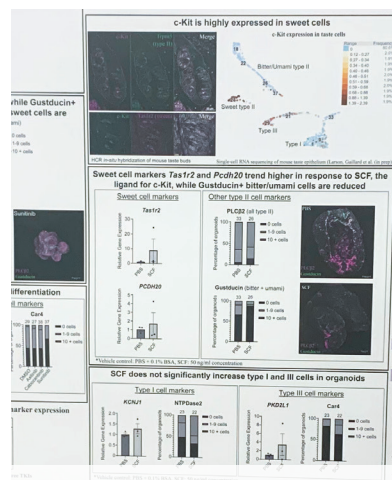
Gates' support was particularly impactful in creating opportunities for students to travel to scientific conferences, after a two-year hiatus due to the pandemic. Conferences

are a major component of student training—they are forums for students to present and discuss their thesis work and to build professional relationships with experts in their fields. Conference attendance also helps build the reputation of CSD and attract talented applicants, since students are our best ambassadors for the program. In 2022, the Gates Center awarded \$500 to each of 13 CSD students. Destinations included the Society for Developmental Biology meeting in Vancouver, Canada; the International Symposium on Pediatric Oncology in Hamburg, Germany; the Military Health System Research Symposium in Kissimmee, Florida; and the Embryology Course in Woods Hole, Massachusetts. At the Association for Chemoreception Sciences meeting, CSD student Tina

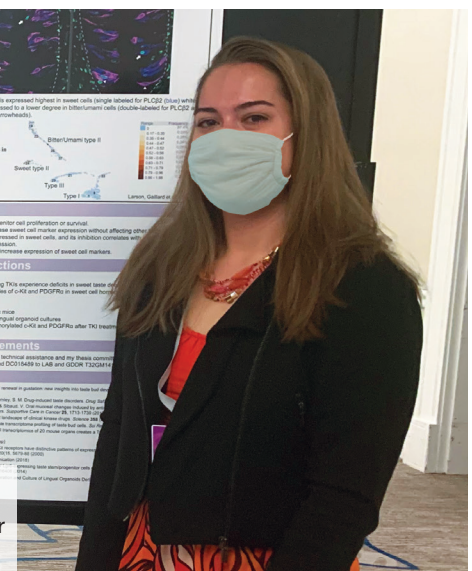
Piarowski (lab of Gates member Linda Barlow, PhD) won the award for best graduate student presentation. These experiences are an essential part of training to become the next generation of leaders in biomedical research.



Madison Rogers, PhD, CSD graduate



CSD student Tina Piarowski, Best Graduate Student Presentation 2022 at the Association for Chemoreception Sciences meeting.



CELEBRATING THE CLASS OF 2022 GATES SUMMER INTERNSHIP PROGRAM

The Gates Summer Internship Program (GSIP) marked its eighth year in 2022, immersing 21 extraordinary undergraduates in the transformative science taking place at the University of Colorado Anschutz Medical Campus.

Since its inception, the program has done much to transform the lives of 162 college undergraduates.

GSIP was initiated by Gates Center members Neil Box, PhD, Tamara Terzian, PhD, and Enrique Torchia, PhD, who had noted the great potential of the summer interns they regularly hosted in their labs. Captivated by the hope

that Gates could play a formative role in creating a pipeline of researchers and clinicians in the regenerative medicine space, others jumped in to make that dream possible. A gift from the late Peter Grant and his wife, Rhondda, enabled the program's planning to begin in 2014, and GSIP continues to enjoy philanthropic support from Grant and others whose names are acknowledged within this report.

Students from four continents were represented in GSIP Class of 2022, including two students who attended through an ongoing arrangement with Berea College in Kentucky—a tuition-free college that was the first racially integrated college in the South.

Each intern was assigned to a Gates member mentor's lab for 11 weeks to pursue an individual



GSIP CLASS OF 2022

FRONT ROW From left: Sarah Loew, Lucy Egan, Jeny Lahamer, Citlali Aguilera-Rico, Ore Ladele, Lindsey Smith, Jay-Ho Chung, Medrine Kihanga, Yifei Chen, Nhan Huynh, Brett Li, Vrushali Patel

BACK ROW From left: Reeya Callychurn, Tony Salcido-Alcántar, Kendall Harrington, Jack Bozik, Corey Tesdahl, Madelyn Jaeger, Ethan Beltrand, Francisca Rocha, Blake Neiderlander, Shalika Deviredy, Enkhy Enkhbayar



Corey Tesdahl explains his summer research to guests during the Final Day Poster Session.

project that culminated in a poster presentation on the final day of the program. Interns' lab duties were supplemented by bi-weekly seminars on a myriad of scientific, medical, and professional development topics along with social events. Guest speakers included newly appointed Gates Institute Executive Director Terry Fry, MD, and Gates Advisory Board member Wagner Schorr, MD, who described their disparate career paths, and

CU School of Medicine student Ella Annest (GSIP '20 and '21) who participated in a medical school Q&A. Additionally, students were exposed to cellular therapy and protein biologics manufacturing at the Gates Biomanufacturing Facility and to clinical research with board member Marc Bonaca, MD, PhD, and his colleagues at CPC Clinical Research. Rhondra Grant and her daughter Liza generously treated the students to a hike and picnic at their family cabin in the gorgeous heights of Rocky Mountain National Park.

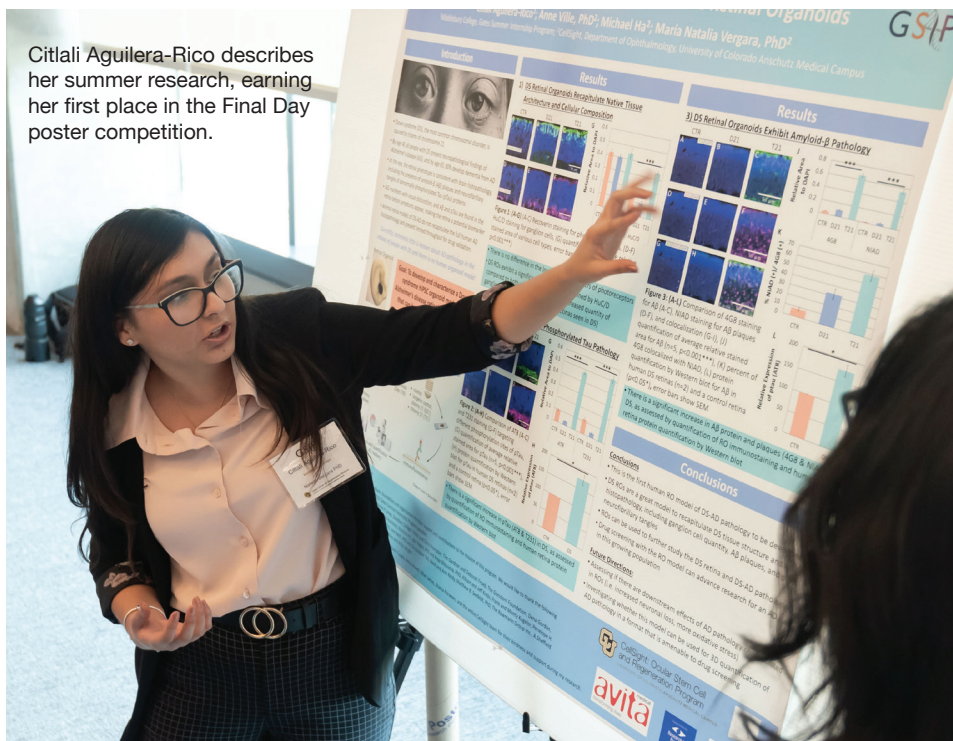
Over the years, the Gates Center for Regenerative Medicine has recognized the Gates Summer Internship Program as one of its most important educational offerings. It has given us an opportunity to inspire the next generation of investigators and clinicians as well as to cultivate a growing number of extraordinary young people who are aware of and intrigued by the amenities and resources on the CU Anschutz campus. We are also proud to have enabled our Gates

members to benefit at no cost from the talent, energy and ideas that come with welcoming these talented interns into their labs.

"Our interns are bright and highly committed to their research projects, performing at the level of PhD students," said M. Valeria Canto-Soler, PhD, who directs *CellSight*, a team working to develop novel stem cell-based therapeutics to save and restore sight in patients with blinding diseases.

As we prepare for the program's return under the new Gates Institute's umbrella, we are grateful for the donors, board members, mentors, lab staff, speakers, and others who make this comprehensive program possible, leaving a profound impact on young people's lives.

Continued on next page.



Citlali Aguilera-Rico describes her summer research, earning her first place in the Final Day poster competition.

Thank you to the GSIP program for making this summer truly memorable. There's a quote by Emerson that's always stuck with me: *Treat a man as he is, and he will remain as he is. Treat a man as he could be, and he will become what he should be.*

—Jay-Ho Chung,
Middlebury College



Intern Francisca Rocha questions Terry Fry, MD, following his GSIP seminar, "Gene-modified Cells as Living Drugs."

Working at GSIP 2022 is one of the remarkable milestones of my undergraduate years, and it is meaningful in my scientific career path.

—Nhan Huynh, Wabash College

The program opened my eyes to endless possibilities within the field of medicine and showed me that the sky is the limit in what I can do.

—Blake Neiderlander
Allegheny College



From left: Interns Medrine Kihanga, Jeny Lahamer, Shalika Devireddy, Ore Ladele and Reeya Callychurn



The Class of 2022 reached new heights hiking together in Rocky Mountain National Park as the guests of GSIP's founding donor, Rhondha Grant (in the stars and stripes) her daughter Liza (on the far left).

Working in Dr. Verneris' lab was such a great environment and one that was very supportive and pushed me to develop many new skills and helped me learn how to be a better scientist.

—Lucy Egan, CU Boulder

GSIP STUDENTS & MENTORS

CITLALI AGUILERA-RICO

Middlebury College
Mentor: Maria Natalia Vergara, PhD
Poster title: *Signs of Alzheimer's Disease in Down Syndrome Retinal Organoids*

ETHAN BELTRAND

St. Olaf College
Mentor: Karin Payne, PhD
Poster title: *Characterization of the Immune Response after Growth Plate Injury*

JACK BOZIK

Bellarmino University
Mentor: Sujatha Jagannathan, PhD
Poster title: *Understanding the Effect of the Myotoxic Gene DUX4 on the Centrosome*

REEYA CALLYCHURN

Caldwell University
Mentor: Xiying Fan, PhD
Poster title: *Using CRISPR-Cas9 to Knock-out TGFB3 Gene in Skin Tumor Cell Lines*

YIFEI CHEN

Johns Hopkins University
Mentor: Ronald Vagnozzi, PhD
Poster title: *Defining the Role of Fibroblast cGAS and MyD88 in Shaping the Cardiac Inflammatory Response*

JAY-HO CHUNG

Middlebury College
Mentor: Lori Sussel, PhD
Poster title: *Characterization of Potential Interactors with CHD4 in Pancreatic Beta Cells*

SHALIKA DEVIREDDY

Johns Hopkins University
Mentor: Tania Reis, PhD
Poster title: *Determining the Role of Fl(2)d in the Mushroom Body on Lipid Storage and Metabolism in Drosophila*

LUCILLE EGAN

University of Colorado Boulder
Mentor: Michael Verneris, MD
Poster title: *Small Molecule Inhibitors in Hematopoietic Stem Cell Expansion and Differentiation*

ENKHSANAA ENKHBAYAR

Stevens Institute of Technology
Mentor: Nicholas Jacobson, Mdes
Poster title: *Morphology of the Pulmonary Tract with Tetralogy of Fallot*

KENDALL HARRINGTON

University of California Berkeley
Mentor: Jeffrey Jacot PhD
Poster title: *Exploring the Characteristics of Exosomes Extracted from Cardiomyocytes from Patients with Down Syndrome*

NHAN HUYNH

Wabash College
Mentor: Yiqun Shellman, PhD
Poster title: *SASH1's function in proliferation and differentiation of melanocytes*

MADELYN JAEGER

Colorado School of Mines
Mentor: Gana Batt, PhD
Poster title: *Protein purification of Indigo-2 (P1105-02) for Formulation Studies*

MEDRINE KIHANGA

Earlham College
Mentor: Kristen Boyle, PhD
Poster title: *The Susceptibility and Development of Insulin Resistance in Umbilical Cord MSCs Exposed to High Sugar/Fat Cell Media*

OREOLUWA LADELE

Berea College
Mentor: Xiying Fan, PhD
Poster title: *Investigating the Role of Endoglin (ENG) in Cutaneous Squamous Cell Carcinoma Progression*

JENNAN LAHAMER

Berea College
Mentor: Igor Kogut, PhD
Poster title: *Constructing a Fluorescent Plasmid for Tagging Endogenous ITGa5 Locus in Skin Organoid Dermal Papilla Cells*

BRETT LI

University of Colorado Boulder
Mentor: Kunhua Song, PhD
Poster title: *Development of a Novel Dual-Reporter Human iPSC Line to Identify Factors that Facilitate Direct Reprogramming of Cardiac Fibroblasts to Cardiomyocytes*

SARAH LOEW

Georgetown University
Mentor: Santos Franco, PhD
Poster title: *Notch Signaling Directs Cell Fate Decisions in Dorsal Forebrain Progenitor Cells*

BLAKE NEIDERLANDER

Allegheny College
Mentor: Chelsea Magin, PhD
Poster title: *Investigating the Influence of Sex- and Age-Related Biochemical Cues on Pulmonary Arterial Adventitial Fibroblast Activation*

VRUSHALI PATEL

University of Colorado Boulder
Mentor: Holger Russ, PhD
Poster title: *Protecting Stem Cell Derived Beta Like Cells with PD-L1 Expression and CAR Treg Technology for Type 1 Diabetes Cell Replacement Therapy*

MARIA FRANCISCA ROCHA

Bates College
Mentor: Maria Valeria Canto-Soler, PhD
Poster title: *Characterization of Human iPSC-derived 3D Retinal Complex*

ANTONIO SALCIDO-ALCANTAR

University of Colorado Boulder
Mentor: Russell Marians, PhD
Poster title: *Developing a Potency Assay for Chimeric Antigen Receptor (CAR) T Cells*

LINDSEY SMITH

Colorado College
Mentor: Patricia Ernst, PhD
Poster title: *Designing Peptides to Interfere with Specific KMT2 Family Proteins for AML Killing*

COREY TESDAHL

University of Colorado Boulder
Mentor: Joseph Brzezinski, PhD, MS
Poster title: *Characterizing the Complex Regulation of Otx2*

MEMBER HIGHLIGHTS



CU Anschutz Chancellor Donald Elliman and Joseph Brzezinski, PhD

RECOGNITIONS

In October, Vice Chancellor for Research Thomas Flaig, MD, celebrated the second-annual University of Colorado Anschutz Medical Campus [Research Awards](#). The following Gates Institute members were honored:

■ **ULLI BAYER, PhD**, received the Research Collaboration Team Award.

■ **PACO HERSON, PhD**, received the Research Mentor Award and the Research Collaboration Team Award.

■ **JAY HESSELBERTH, PhD**, received the Research Faculty Collaborator Award.

■ **NIDIA QUILLINAN, PhD**, received the Research Collaborator Team Award.

ANNA BRUCKNER, MD, MSCS, started a two-year term as president of the Pediatric Dermatology Research Alliance.

JUSTIN BRUMBAUGH, PhD, was selected as an International Society for Stem Cell Research (ISSCR) Goldstein Fellow.

JOSEPH BRZEZINSKI, PhD, was selected by a committee of students, faculty and administrators for the Graduate School to receive the CU Anschutz Chancellor's Teaching Recognition Award.

ANGELO D'ALESSANDRO, PhD, was promoted to full professor in the Department of Biochemistry and Molecular Genetics. He also received the International Society for Blood Transfusion's Jean Julliard Award and the Research Innovation in Scientific Excellence (RISE) award recognizing an original research article from the Association for the Advancement of Blood & Biotherapies Transfusion Journal.

National Eye Institute's 3D Retinal Organoid Challenge (see related story on pages 8–9):

■ **VALERIA CANTO-SOLER, PhD**, led the team that won in the disease-modeling category, earning \$500,000.

■ **NATALIA VERGARA, PhD**, led the team that won the National Eye Institute's 3D Retinal Organoid Challenge in the drug-screening category, earning \$250,000.

EDUARDO DAVILA, PhD, was highlighted in the [Chancellor's State of the Campus](#) address for his work in mentoring [underrepresented students](#) to pursue post-baccalaureate research.

IGOR KOGUT, PHD, DENNIS ROOP, PHD, GANNA BILOUSOVA, PhD, had two patents issued on technologies currently used to develop an iPSC-based therapy for inherited skin blistering diseases. These patents describe their high-efficiency reprogramming approach and their combined gene editing and reprogramming approach (PCT Application No. PCT/US2016/063258).

TRACI LYONS, PhD, was named American Cancer Society 2022 Medical Honoree.

CHRISTIAN MOSIMANN, PhD, was elected to Board of Directors, International Zebrafish Society, US/Canada Representative.

JENNIFER RICHER, PhD, was named dean of the Graduate School at the CU Anschutz Medical Campus.

MICHAEL VERNERIS, MD, was elected chair of the Pediatric Transplantation and Cellular Therapy Consortium.

GRANTS

KUNHUA SONG, PhD

Mechanisms for Cell Signaling
in the Control of Cardiomyogenesis
Sponsor: National Institute
of Health
\$2,027,109

KUNHUA SONG, PhD, AND THOMAS VONDRISKA, PhD

Regulation of Gene Transcription
and Alternative Splicing by a
Long Non-Coding RNA
Sponsor: National Institute of
Health
\$2,199,199

RAM NAGARAJ, PhD

Lens Capsule and
Secondary Cataract
Sponsor: National Institutes
of Health
\$1,468,098

CATHERINE MUSSELMAN, PhD, AND CHRISTIAN MOSIMANN, PhD

Regulation of Histone
Readers Through Functional
Disordered Regions
Sponsor: National Science
Foundation
\$1,300,000

Researchers know that serendipity often plays a role in science. For Gates Institute members Catherine Musselman, PhD, and Christian Mosimann, PhD, serendipity came in the form of a misdelivered package containing zebrafish embryos. After an introductory meeting, they began to collaborate on research that was funded with a \$1.3 million grant from the National Science Foundation in 2022.

Click or scan
the QR Code
to read
the story



PAUL W. BUEHLER, ANGELO D'ALESSANDRO, DAVID IRWIN

The Paradoxical Response to Iron
in Pulmonary Hypertension of
Sickle Cell Disease
Sponsor: National Heart, Lung,
and Blood Institute
\$2,496,355

CHRISTIAN MOSIMANN, PhD; ALEXA BURGER, PhD; CLAUDIO CANTU, PhD; DANIELA PANAKOVA, PhD

Gene-Regulatory Impact of Wnt
Signaling in Ventricle Formation
Sponsor: Additional Ventures
\$500,000

TRACI LYONS, PhD

SEMA7A in Postpartum
Mammary Gland Development and
Cellular Transformation
Sponsor: National Institute of Health/
National Cancer Institute
\$2,290,220

KRISTEN BOYLE, PhD; SONJA ENTRINGER, PhD; PATHIK WADHWA, PhD

Stress and Human Stem/Progenitor
Cells: Biobehavioral Mechanisms
Sponsor: National Institute of Health/
National Institute of Child Health and
Human Development
\$3,300,212

KRISTEN BOYLE, PhD; SONJA ENTRINGER, PhD; PATHIK WADHWA, PhD

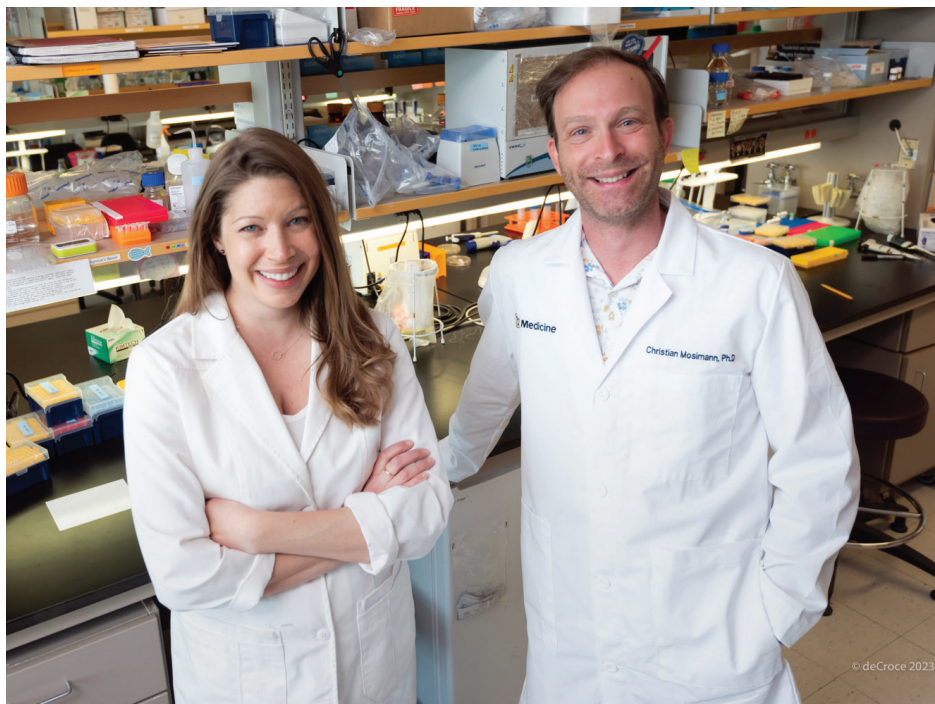
Biological Embedding of Social
Disadvantage in Human Stem Cells:
Implications for Health Disparities
Sponsor: National Institute of Health/
National Institute on Minority Health
and Health Disparities
\$3,092,789

MIHYUN NAM, PhD

Saving Vision after Traumatic
Brain Injury
Sponsor: Colorado Clinical
and Translational Sciences
Institute
\$30,000

DENNIS ROOP, PHD; XIYING FAN, PHD; ANDRII ROZHOK, PHD; XIAO-JING WANG, MD, PHD; AND IGOR KOGUT, PHD

Defining the Role of Innate Immune
Cells in the Early Stages of Immune
Surveillance of Skin Cancer by
Using a Novel Model that
Allows in vivo Imaging of the
Immunoediting Process
Sponsor: National Institute
of Arthritis and Musculoskeletal
and Skin Diseases
\$2,543,280



SELECT MEMBER PUBLICATIONS



Conserved and Divergent Features of Neuronal CaMKII Holoenzyme Structure, Function, and High-order Assembly **K. ULLRICH “ULLI” BAYER, PHD, PROFESSOR, DEPARTMENT OF PHARMACOLOGY**

In this *Cell Reports* manuscript, Buonarati, et al, perform a comparative analysis of neuronal CaMKII holoenzymes (α - and β -isoforms), which enable neuronal signal computation underlying learning and memory. They find evidence for kinase domain dimers within the holoenzyme, which enable a cooperative activation mechanism in both isoforms, and inter-holoenzyme interactions that enable high-order aggregate formation under ischemic conditions. The artwork (above) by Steve L. Reichow depicts CaMKII holoenzymes, which mainly assemble as 12-mers.

CaMKII T286 Phosphorylation has Distinct Essential Functions in Three Forms of Long-term Plasticity

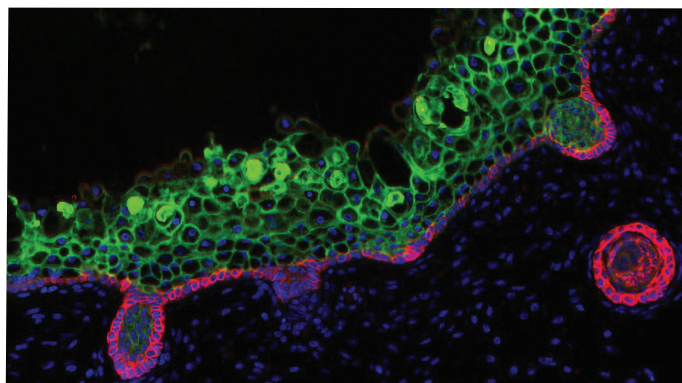
K. ULLRICH “ULLI” BAYER, PHD, PROFESSOR, DEPARTMENT OF PHARMACOLOGY

CaMKII is a central regulator of synaptic plasticity and well established to mediate both N-methyl-D-aspartate receptor (NMDAR)-dependent long-term potentiation (LTP) and long-term depression (LTD), two opposing

forms of synaptic plasticity thought to mediate higher brain functions such as learning, memory, and cognition. In this *Journal of Biological Chemistry* manuscript, Dr. Bayer and his colleagues demonstrate an additional requirement for CaMKII also in mGluR-LTD. Like NMDAR-LTP, but in contrast to NMDAR-LTD, this mGluR-LTD is robustly induced not only in young but also in mature animals.

Induced Pluripotent Stem Cells: Advances and Applications in Regenerative Medicine **GANNA BILOUSOVA, PHD, ASSOCIATE PROFESSOR, DEPARTMENT OF DERMATOLOGY**

Reprogramming adult somatic cells into induced pluripotent stem cells (iPSCs) through the ectopic expression of reprogramming factors offers truly personalized cell-based therapy options for numerous human diseases. The iPSC technology also provides a platform for disease modeling and new drug discoveries. Similar to embryonic stem cells, iPSCs can give rise to any cell type in the body and are amenable to genetic correction. These properties of iPSCs allow for the development of permanent corrective therapies for many currently incurable disorders. In this review chapter for *Possibilities and Limitations in Current Translational Stem Cell Research*, Dr. Bilousova provides an overview of the status of iPSC-based therapies in the clinic and research, with a focus on potential clinical applications of these cells. (Skin organoid, below.)



Courtesy of Shennea McGarvey, MS; Maryna Pavlova, PhD; Jocelyn Castillo Flores, BS; Sean Vieau, BS; and Ganna Bilousova, PhD.

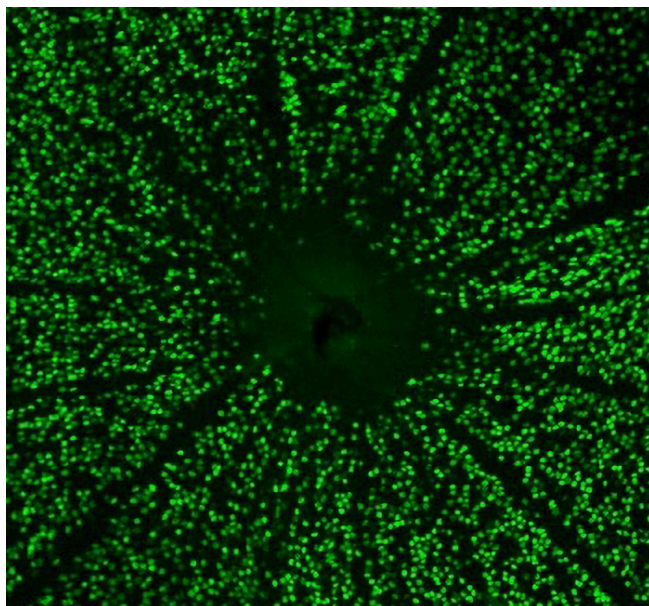
Hand2 Delineates Mesothelium Progenitors and is Reactivated in Mesothelioma **CHRISTIAN MOSIMANN, PHD, ASSOCIATE PROFESSOR, DEPARTMENT OF PEDIATRICS**

In this *Nature Communications* manuscript, Dr. Mosimann's team and collaborators identify the earliest developmental origin of mesothelium, the supporting tissue that surrounds our internal

organs and body cavities. Their work further linked reactivation of a developmental gene program to the injury response that leads to mesothelioma tumors, providing new insights into this deadly cancer and how mesothelium responds during regeneration.

Peptains Block Retinal Ganglion Cell Death in Animal Models of Ocular Hypertension: Implications for Neuroprotection in Glaucoma
RAM NAGARAJ, PHD, PROFESSOR, DEPARTMENT OF OPHTHALMOLOGY

In this *Cell Death & Disease* manuscript, Dr. Nagaraj demonstrates that anti-apoptotic peptides of HSPB5 and HSPB6 injected intravitreally can inhibit retinal ganglion cells death in animal models of glaucoma (below). They propose that those peptides could be developed as neuroprotective agents to prevent vision loss in glaucoma.



Courtesy of Ram Nagaraj, PhD

AAV2-Mediated Expression of HspB1 in RGCs Prevents Somal Damage and Axonal Transport Deficits in a Mouse Model of Ocular Hypertension
MIHYUN NAM, PHD, RESEARCH INSTRUCTOR, DEPARTMENT OF OPHTHALMOLOGY

In this article for *Translational Vision Science & Technology*, Dr. Nam determines the neuroprotective ability of the gene, small heat shock protein B1, on retinal ganglion cells against ocular hypertension in mice. A single injection of this gene therapy shows sustained beneficial effects on retinal ganglion cell survival. This gene therapy may be developed to prevent vision loss on a long-term basis in glaucoma patients.

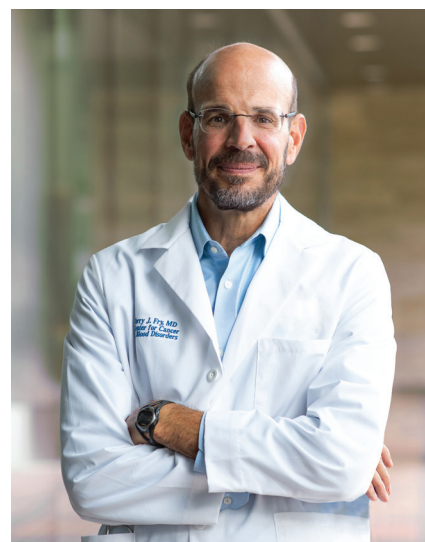
Cardiomyocyte-Specific Long Noncoding RNA Regulates Alternative Splicing of the Triadin Gene in the Heart
KUNHUA SONG, PHD, ASSOCIATE PROFESSOR, DEPARTMENT OF CARDIOLOGY

Dr. Song and his colleagues reveal a new mechanism for controlling cardiac arrhythmias by a long noncoding RNA. This study published in *Circulation* indicates potential therapeutics for heart disease by targeting the long noncoding RNA or pathways regulating alternative splicing.

GATES INSTITUTE IN THE NEWS

COLORADO INSTITUTE PITS WORLD-CLASS CAR T-CELL EXPERTISE AGAINST AGGRESSIVE LYMPHOMAS

In October, a feature in the journal *Nature* described how Gates Institute researchers at the University of Colorado Anschutz Medical Campus are spearheading clinical trials of cutting-edge cellular therapies to improve survival rates for aggressive cancers: Cell therapy is especially effective against leukaemia and lymphoma. About half of patients with these cancers who don't respond to chemotherapy and stem cell transplants enter remission after receiving an immune treatment known as chimeric antigen receptor (CAR) T-cell therapy. CAR-T cells are made by taking white blood cells from a patient and genetically modifying them to attach to and eliminate malignant cells.



Terry Fry leads the new Gates Institute at the University of Colorado Anschutz Medical Campus, where his team is rapidly advancing CAR T-cell research from basic science to human clinical trials.

“People thought it was a crazy idea, but it completely changed the treatment landscape,” says Terry Fry, clinical professor of pediatric oncology at the University of Colorado School of Medicine. “The field figured out how to turn this process into an FDA-approved drug in just five years.”

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National Jewish Health

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National Jewish Health

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Inworks Innovation Initiative

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The Sandy Wolf Chair in Maternal Fetal Surgery
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Professor, Cardiology
CU Anschutz

SHI-LONG LU, MD, PhD

Associate Professor, Otolaryngology
CU Anschutz

TRACI LYONS, PhD

Associate Professor, Medical Oncology
CU Anschutz

***New member**

CHELSEA MAGIN, PhD

Assistant Professor, Bioengineering,
Pediatrics
CU Denver
CU Anschutz

SUSAN MAJKA, PhD

Professor, Medicine
National Jewish Health
CU Anschutz

NARESH MANDAVA, MD

Professor, Ophthalmology
Sue Anschutz-Rodgers Endowed Chair
in Retinal Diseases
CU Anschutz

JOANNE MASTERSON, PhD

Assistant Professor, Pediatrics
CU Anschutz

XIANZHONG MENG, MD, PhD

Professor, Cardiology
CU Anschutz

CHRISTIAN MOSIMANN, PhD

Associate Professor, Pediatrics,
Section of Developmental Biology
The Helen and Arthur E. Johnson Chair
for Cardiac Research Director
CU Anschutz

RAM NAGARAJ, PhD

Professor, Ophthalmology
School of Pharmacy
CU Anschutz

DEVATHA NAIR, PhD

Assistant Professor, School of
Dental Medicine
CU Anschutz
CU Boulder

MI-HYUN NAM, PhD*

Research Instructor, Ophthalmology
CU Anschutz

COREY NEU, PhD

Associate Professor, Mechanical
Engineering
Donnelly Family Endowed
Professor
CU Boulder

LEE NISWANDER, PhD

Professor, Molecular, Cellular
and Developmental Biology
CU Boulder

DAVID NORRIS, MD

Professor, Dermatology
CU Anschutz

JEFFREY OLSON, MD

Associate Professor, Ophthalmology
CU Anschutz

BRADLEY OLWIN, PhD

Professor, Molecular, Cellular
and Developmental Biology
CU Boulder

DAVID RYAN ORMOND, MD, PhD

Assistant Professor, Neurosurgery,
Translational Clinical Research
CU Anschutz
VA Medical Center

VIKAS PATEL, MD

Professor, Orthopedics
Endowed Chair in Orthopedic Spinal
Innovation, Executive Vice Chair, Surgery
CU Anschutz
CU Denver

KARIN PAYNE, PhD

Associate Professor, Orthopedics
CU Anschutz

MARK PETRASH, PhD

Professor, Ophthalmology
School of Pharmacy and
Pharmaceutical Science
CU Anschutz

CHRISTOPHER PHIEL, PhD

Associate Professor, Integrative Biology,
Pharmacology
CU Denver

ERIC PIETRAS, PhD

Associate Professor, Hematology
Cleo Meador and George Ryland Scott
Endowed Chair in Hematology
CU Anschutz

ROBERT PLENTER

Senior Professional Research Assistant,
Division of Pulmonary Sciences
CU Anschutz

CHRISTOPHER PORTER, MD

Associate Professor, Pediatrics,
Hematology/Oncology and Bone Mar-
row Transplantation
CU Anschutz
VA Medical Center

HUNTINGTON POTTER, PhD

Professor, Neurology
Director, CU Alzheimer's and
Cognition Center
CU Anschutz

CHAITANYA PURANIK, BDS, MS, MDENTSCI, PhD

Assistant Professor, School of
Dental Medicine
Children's Hospital Colorado
CU Anschutz

NIDIA QUILLINAN, PhD

Associate Professor, Anesthesiology
CU Anschutz

YOSEF REFAELI, PhD

Associate Professor,
Dermatology
CU Anschutz

TANIA REIS, PhD

Associate Professor, Endocrinology/
Metabolism Diabetes
CU Anschutz

MARY REYLAND, PhD

Professor, Craniofacial Biology,
Cell Developmental Biology, Pathology
CU Anschutz

JENNIFER RICHER, PhD

Professor, Pathology
Dean, Graduate School
CU Anschutz

JAMES ROEDE, PhD

Associate Professor, Pharmaceutical
Sciences
CU Anschutz

DENNIS ROOP, PhD

Professor, Dermatology
John S. Gates Endowed Chair in Stem
Cell Biology
CU Anschutz

PAUL ROZANCE, MD

Professor, Pediatrics and Integrative
Physiology
CU Anschutz

ANDRII ROZHOK, PhD

Research Instructor, Dermatology
CU Anschutz

***New member**

HOLGER ANDREAS RUSS, PhD

Assistant Professor, Microbiology
and Immunology Department
Barbara Davis Center for Diabetes
CU Anschutz

BRANDEN SALINAS, PhD

Senior Director, Manufacturing Science
and Technology
Umoja Biopharma

CAROL SARTORIUS, PhD

Associate Professor, Pathology
CU Anschutz

MATTHEW SEEFELDT, PhD

Executive Director, Gates
Biomanufacturing Facility
CU Anschutz

KARINA SERBAN, MD

Assistant Professor, Division of
Pulmonary and Critical Care Medicine
National Jewish Health

KARTIK SHANKAR, PhD

Professor, Pediatrics, Section
of Nutrition
CU Anschutz

YIQUN SHELLMAN, PhD

Associate Professor, Dermatology
CU Anschutz

**DANIEL SHERBENOU,
MD, PhD**

Associate Professor, Medicine
CU Anschutz

VANESSA SHERK, PhD

Instructor, Endocrinology
CU Anschutz

KUNHUA SONG, PhD

Associate Professor, Cardiology
CU Anschutz

DANIELLE SORANNO, MD

Assistant Professor, Pediatrics
CU Anschutz

BALAJI SRIDHAR, MD, PhD

Resident
CU Anschutz
CU Boulder

KURT STENMARK, MD

Professor, Pediatrics, Critical Care
La Cache Endowed Chair in Pediatric
Critical Care
CU Anschutz

LORI SUSSEL, PhD

Professor, Pediatrics, Cell and
Developmental Biology
Sissel and Findlow Family Chair
Barbara Davis Center for Diabetes
CU Anschutz

TAMARA TERZIAN, PhD

Assistant Professor, Dermatology
CU Anschutz

DOUGLAS THAMM, VMD

Assistant Professor, Clinical Sciences
Colorado State University

ENRIQUE TORCHIA, PhD

Assistant Professor, Dermatology
CU Anschutz

RONALD VAGNOZZI, PhD

Assistant Professor, Cardiology
Consortium for Fibrosis Research
and Translation (CFReT)
CU Anschutz

MARIA NATALIA VERGARA, PhD

Assistant Professor, Ophthalmology
CU Anschutz

MICHAEL VERNERIS, MD

Professor, Pediatrics,
Hematology/Oncology and
Bone Marrow Transplantation
The Barton Endowed Chair of
Pediatric Bone Marrow Transplant
CU Anschutz
Children's Hospital Colorado

ESZTER VLADAR, PhD

Assistant Professor, Cell and
Developmental Biology, Division
of Pulmonary Sciences
CU Anschutz

DAVID WAGNER, PhD

Associate Professor, Neurology
CU Anschutz

LORI WALKER, PhD

Associate Professor, Cardiology
CU Anschutz

XIAO-JING WANG, MD, PhD

Professor, Pathology, Dermatology
CU Anschutz
VA Medical Center

ZHIJIE WANG, PhD

Assistant Professor, Mechanical
Engineering
Colorado State University

MARY WEISER-EVANS, PhD*

Professor, Medicine, Renal Diseases
and Hypertension
CU Anschutz

TREVOR WILLIAMS, PhD

Professor, Craniofacial Biology, Cell
and Developmental Biology
Timpfe/Brownie Endowed Chair in
Craniofacial/Molecular Biology
School of Dental Medicine
CU Anschutz

CAROL WILUSZ, PhD

Professor, Microbiology, Immunology
and Pathology
Colorado State University

JEFF WILUSZ, PhD

Professor, Microbiology, Immunology
and Pathology
Colorado State University

RUI YI, PhD

Associate Professor, Molecular, Cellular
and Developmental Biology
CU Boulder

MARTIN ZAMORA, MD

Professor, Division of Pulmonary, Critical
Care Medicine
CU Anschutz

MICHAEL ZARETSKY, MD

Associate Professor, Obstetrics and
Gynecology, Maternal Fetal Medicine
Medical Director Colorado Fetal
Care Center
CU Anschutz
Children's Hospital Colorado

WENBO ZHOU, PhD

Associate Professor, Clinical
Pharmacology and Toxicology
CU Anschutz

MICHAEL ZUSCIK, PhD

Professor and Vice Chair of
Research, Orthopedics
Mack L. Clayton Endowed Chair
in Orthopaedics
CU Anschutz

***New member**

ACKNOWLEDGEMENTS

2022 FINANCIAL HIGHLIGHTS

\$10 million in Grubstake Funds awarded across 29 projects since inception

\$60 million in follow-on funding from Grubstake Awards

\$5 million in hospital support for cellular therapy — pediatrics to adults

\$25 million invested in manufacturing innovation

\$5 million invested in campus infrastructure



In 2022, the Gates Center for Regenerative Medicine began its transformation to the Gates Institute. The name is new, but our focus remains on moving bold ideas through the basic, clinical and translational research continuum. New, highly targeted cell and gene therapies (CGTs) for cancers and other rare diseases are being developed, manufactured and tested, thanks to the infrastructure we have built. But work remains to be done; Gates Institute recognizes the challenges investigators encounter in advancing CGTs, and is investing into building capabilities to address these issues that will drive innovation and accelerate the path for new therapies.

The exciting announcement of \$200 million in funding from the Gates Frontiers Fund and University of Colorado Anschutz Medical Campus will accelerate the creation of new programs, additional funding opportunities, and ongoing support of key programs that had been established at the Gates Center. Our investments and programs span across all areas of the product life cycle from education internships, early-stage funding for translational science, resources for regulatory and clinical support, and innovation in manufacturing. The financial impact has been tremendous since the inception of these programs.



DONORS

We gratefully acknowledge the following individuals, foundations and organizations for supporting our research and mission during 2022.

Anonymous	Jill & Roger Giller, MD	Betty & Dennis Roop, PhD
Avita Medical	Glendorn Foundation	Walter S. Rosenberry, III Charitable Trust
Mary & Bob Bearman	Dana Gordon	Morris Schertz
Alice & John Benitez	Sally & Daniel Graham	Annalee & Wagner Schorr, MD
The Berenice Gates Hopper Family Fund	Barbara Hopper	Ann Sperling
Anya Bilousova, PhD & Igor Kogut, PhD	Joyce & Wayne Hutchens	Michael Tortoro
Janelle & Buck Blessing	Shelly Kilgas	Sheffield Tulp
Lauren & Marc Bonaca, MD	Allison & Jeffrey Krebs	UCHealth
Laura Borgelt, PharmD & Brendan Lundy	Montjoy & Frank Kugeler	University of Colorado Anschutz Medical Campus, Office of the Chancellor
Kathy & Michael Chevalier	Jeannette & Charles Kurtz	University of Colorado Anschutz Medical Campus, School of Medicine
Children's Hospital Colorado	Mary Lanius	Diane & Marshall Wallach
Beverly & Dennis Christine	Barbara Larkin	Susan & Matthew Warta
Marilyn & Pete Coors	Penelope Lewis	Christina & Willis Wright, Jr.
Phyllis M. Coors Foundation / Scott Coors	LGA Family Foundation	
Jill Cowperthwaite & Charles Jones	Gretchen Lobitz, PhD & Charles Lobitz	
Marguerite & Thomas Detmer, Jr.	Daniel Mallatt	
Paula & John Crowley	Margaret & Gerald Martinez	
Cathey & Dick Finlon	John Moyski	
Yvette & Christopher Frampton	The New L Family Fund	
Susan & Woodrow Gandy	Dennis O'Hanlon	
John Gates	Kelly & Mark Petrash, PhD	
Gates Frontiers Fund	The Poha Fund	
	Jane Rech, PhD & Christopher Toll	
	Ann & Kevin Reidy	

CHARLIE'S PICNIC

This annual tradition brings the Gates community together in a celebration of its mission to advance cell and gene research in a quest to deliver cures to patients.



Dennis Roop delivers heartfelt comments at his last Charlie's Picnic as director of the Gates Center.



Xiao-Jing Wang and Antonio Jimeno



Calla Winchell and Annalee and Wag Schorr



Chanel Mansfield, Laura Borgelt and Jordan Krause



Ryan Crisman, Jill Cowperthwaite, Janelle Blessing, Michael Tortoro



Gretchen and Charles Lobitz



Gates Institute Advisory Board member Yvette Frampton takes the stage with Ted Parks, MD, and his band.



Lia Gore and Frank Haluska



John Reilly, Naresh and Donna Mandava, and Lise Woodward



Diane Gates Wallach



Gates Institute Advisory Board members Cathey Finlon and Ann Sperling, and Dick Finlon (center)



Saumya De Silva and Gana Batt



Gates Summer Internship Program (GSIP) interns show their affection for GSIP sponsor Rhondda Grant (center).

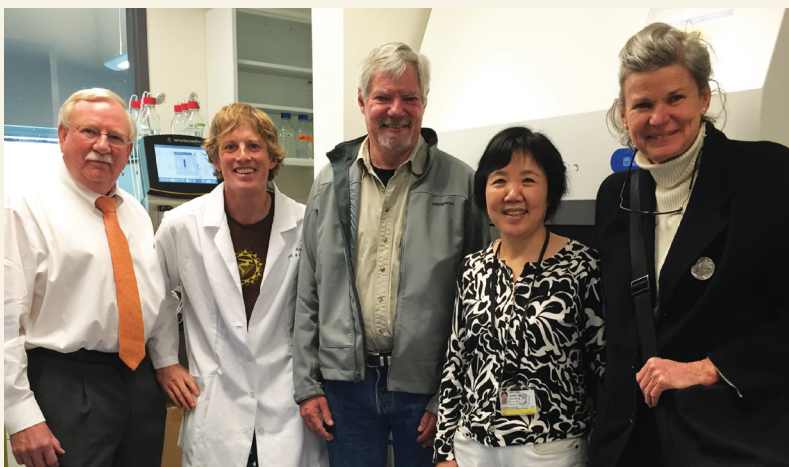


Annette and Bill Peltzman



Kristin Ecklund Weber, Spike and Nan Ecklund

TRIBUTES The Gates community lost two of its luminaries in early 2023 – John S. Gates, who shared his father Charles Gates' passion for finding cures through cell and gene therapy research, and Tim Gardner, who as chief financial officer of the Gates Center helped build the infrastructure for its success.



From left: Dennis Roop, Matt Seefeldt, John Gates, Xiao-Jing Wang and Julia Gates



Tim Gardner

GATES INSTITUTE ADVISORY BOARD

The Gates Center Advisory Board held its final meeting on May 10, 2022, at which the announcement was made of the historic gift to establish the Gates Institute, with Terry Fry, MD, as executive director. Fry serves as chair of the newly formed Gates Institute Advisory Board, which added four new members (pictured at right). We are deeply grateful to Daniel Ritchie, MD, who retired from the board after nine years of leadership and service.

Janelle Blessing	Dennis Roop, PhD
Marc Bonaca, MD, MPH	Wagner Schorr, MD
Marilyn Coors, PhD	Geoff “Duffy” Solich
Donald Elliman	Ann Sperling
Cathey Finlon	Rick Stoddard
Yvette Pita Frampton	Raphe Schwartz*
Terry Fry, MD, Chair	Diane Gates Wallach
Tom Gronow*	Daniel Welch*
Kevin Reidy	*New Member
John Reilly, MD*	



Marilyn Coors



Cathey Finlon



Tom Gronow*



John Reilly, MD*



Raphe Schwartz*



Daniel Welch*



FRONT ROW From left: Don Elliman, Rick Stoddard, Diane Gates Wallach, Ann Sperling, Dennis Roop, Terry Fry
BACK ROW From left: Marc Bonaca, Yvette Frampton, Kevin Reidy, Geoff “Duffy” Solich, Janelle Blessing, Tim Gardner, Wag Schorr
Marilyn Coors and Cathey Finlon pictured above.

OUR PEOPLE

The Gates Institute team is a collaborative group representing a variety of disciplines, dedicated to advancing research in cell and gene therapy to accelerate discoveries from concepts to cures.



“No one does their best work alone.”

– Charles C. Gates



ANSCHUTZ HEALTH SCIENCES BUILDING

GATES INSTITUTE

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FOR INQUIRIES about the Gates Biomanufacturing Facility, please visit www.gatesbiomanufacturing.com or contact Matthew Seefeldt at 303.808.8436 or email matthew.seefeldt@cuanschutz.edu.

FOR GIVING OPPORTUNITIES, contact Allison Krebs, Office of Advancement, at 303.724.5704 or email allison.krebs@cuanschutz.edu.



Gates Institute

UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

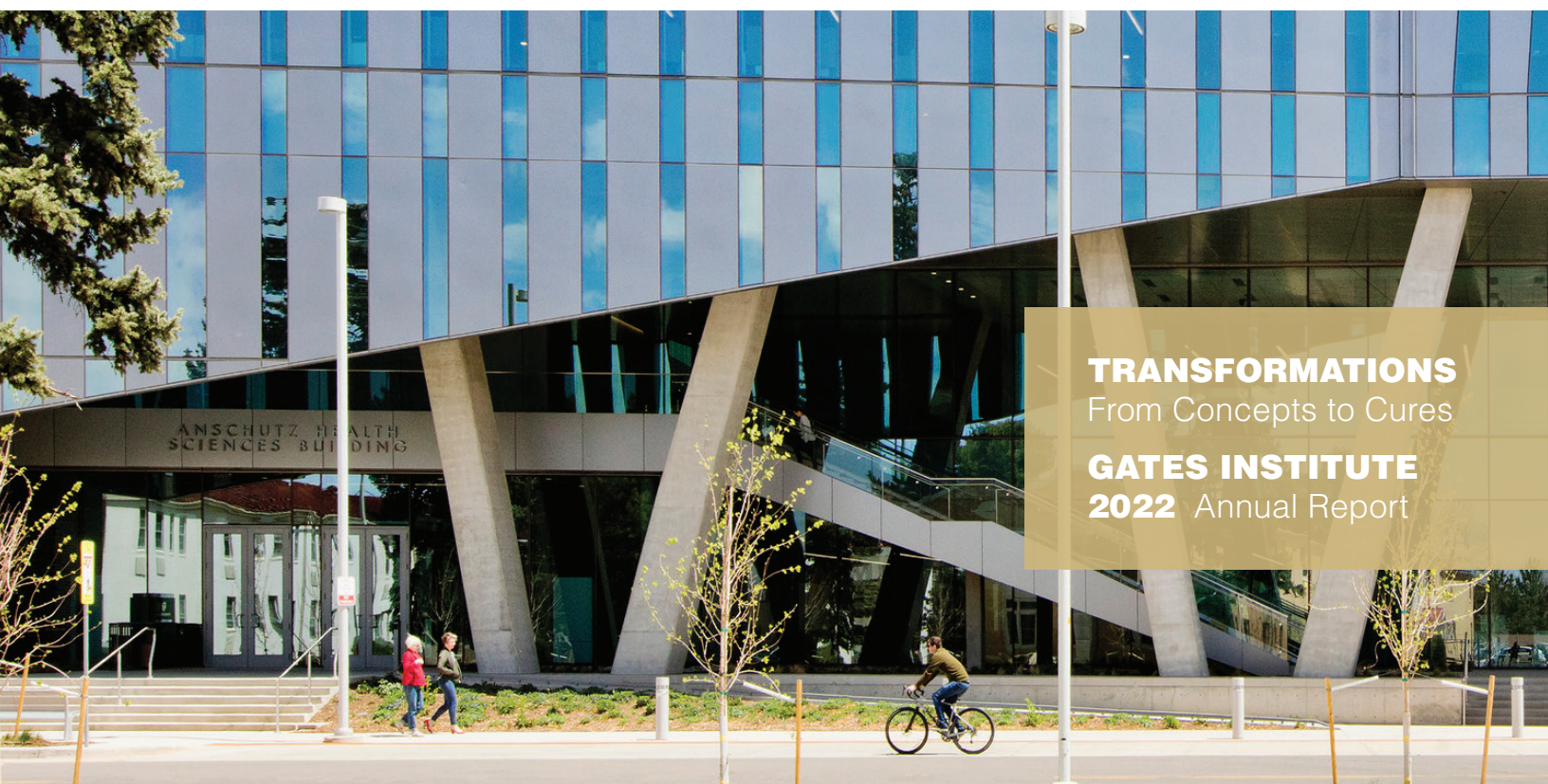


University of Colorado
Anschutz Medical Campus

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TRANSFORMATIONS
From Concepts to Cures

GATES INSTITUTE
2022 Annual Report