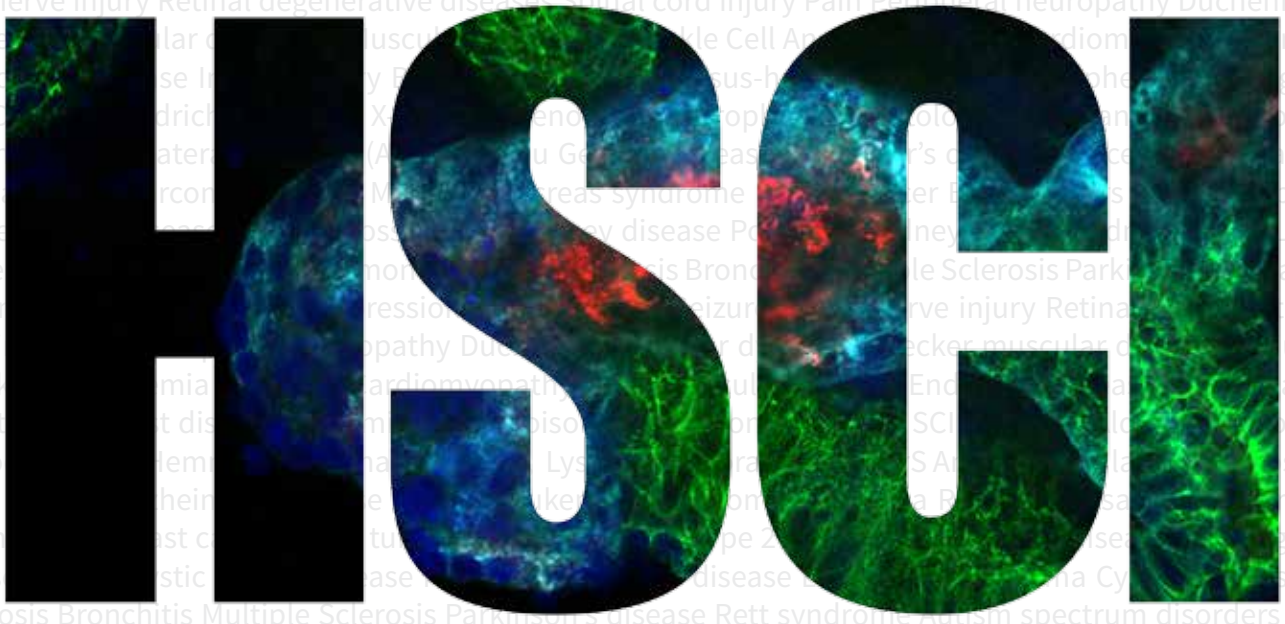


THE HARVARD STEM CELL INSTITUTE 2015

DEAR FRIENDS AND SUPPORTERS OF HSCI

For most of its first decade, the efforts of the Harvard Stem Cell Institute were focused on advancing the understanding of stem cells and their regenerative powers. As that work was underway, we also were building the platforms and core facilities that were essential to our being able to take advantage of what was being learned by our 1,200 scientists in more than 100 laboratories spread across the Boston/Cambridge biomedical ecosystem. Perhaps most important, bringing together academic researchers seeking to answer fundamental questions about human biology and disease, physicians/scientists in Harvard's affiliated hospitals, and partners in the biotech, pharmaceutical, and venture capital arenas, we have created new models for advancing basic discoveries through the pipeline to the patients who will benefit from them. Having more than accomplished our goals for the last decade, we would like to tell you what comes next:

We are now moving forward with a primary goal of bringing stem cell-derived treatments and cures to patients as quickly as possible. While we are, of course, still investing money and intellectual power in advancing basic discovery – for that is the engine that powers all other efforts — we are focusing on four specific areas, which you will read about in this report:

- **Diseases of aging,** which include everything from heart disease, to muscle wasting, to many cancers, to the decline of function throughout the body;
- **Diseases of the blood,** with a primary focus on improving blood stem cell transplantations that are so essential to the success of numerous cancer therapies, but also with efforts focused on conditions from sickle cell anemia to HIV/AIDS;
- **Diseases of metabolism,** where we are making enormous strides toward developing a cure for type 1 diabetes, and in finding ways to successfully treat obesity, which is at epidemic levels around the globe;
- **Diseases of the nervous system,** from ALS, to Parkinson's, to Alzheimer's, and beyond. Utilizing the "disease in a dish" model, which we pioneered, the latest in gene editing technologies, and working with bioengineers and computational specialists, we have created new models for drug discovery that promise to reduce both the time of moving new treatments from bench to bedside, and the cost of getting there. The past decade has been a difficult political and financial time for biomedical research. But as NIH funding has steadily declined and grants have become more difficult to obtain, HSCI has excelled in using philanthropic funds to leverage federal funding and to develop the results needed to convince federal funders of the validity of our ideas.

You have had faith in our mission. As we do, you believe that stem cell biology is the basis of a New Medicine, the foundation of an age in which cellular-based and -derived treatments, informed by the enormous strides in understanding the genetic instructions that control those cells are going to change the face of disease, of aging, and of the ways in which we are able to live out our life spans.

We hope you will join us on the next phase of our journey, that you share with us the excitement we are generating as we transmute what were only dreams into very real treatments for the diseases that plague us, our loved ones, and all of humanity. We hope that you will be with us as we deliver on our earlier promises. For that is what comes next – and next is right around the corner.

David Scadden, MD, Founding Co-Director

Doug Melton, PhD, Founding Co-Director

Brock Reeve, MPhil, MBA, Executive Director

DISEASES OF AGING RESEARCH GROUP

We as a people are in the age of the aging. By **2030,** an estimated 45 percent of the US population will be 65 years or older. Thanks to the availability of clean water, improvement in **nutrition,** and the development of antibiotics, **life** expectancy has increased markedly — from about 47 years in 1900, to an average of just about 80 years today. What has not **improved** nearly as much, however, is the **quality** of those additional years as muscles weaken, hearts and kidneys begin to fail, joints stiffen, **memory** declines, and chances of developing **cancer** increase. Of the 74 million Americans over the age of 65, about half experience at least one physical or sensory **disability,** such as the loss of eye-sight, hearing, taste, balance; and a quarter experience two. Biological processes of repair and **regeneration** working earlier in life fail to function in our later years. That is why reducing the burdens of aging is one of the major **focuses** of HSCI **researchers.** That focus is not on increasing life span, but rather is on increasing "health span," **finding** ways to slow, or even reverse, the declines in function associated with aging — and we have been making very real **progress.**

Richard Lee, MD, a practicing cardiologist and stem cell researcher, and Amy Wagers, PhD, a stem cell biologist, are two of the leaders in the field of aging research.

Together, they explain how this nascent scientific field has changed some researchers' approach to studying diseases and conditions of aging.

DISEASES OF AGING

Amy Wagers: Aging is an area that really wasn't in the forefront of scientists' thinking in past generations, and now it affects one of the largest growing demographics of people and is causing a huge change in the way the practice of medicine approaches disease.

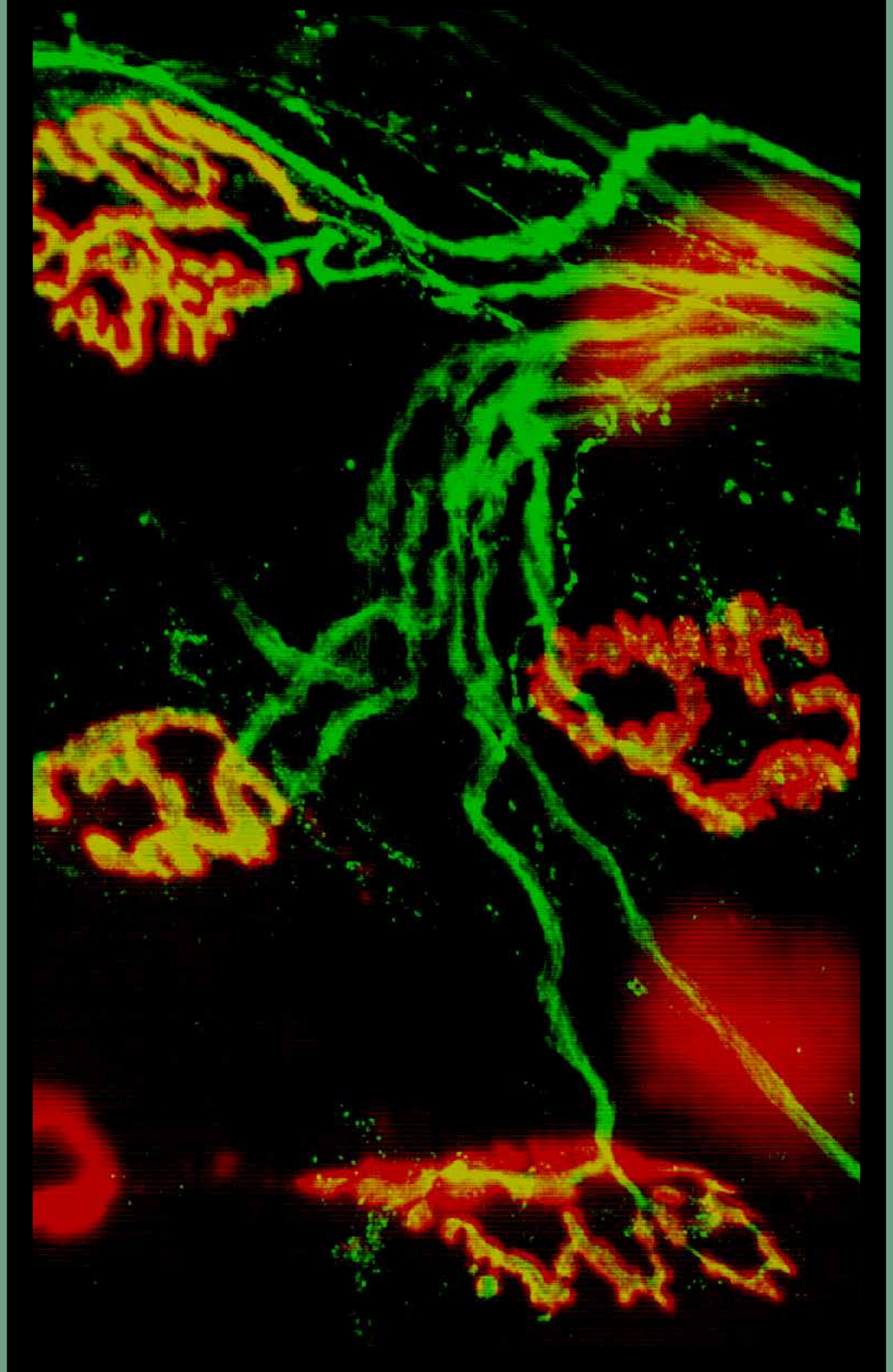
Rich Lee: Most of the patients I see wouldn't be alive if they had been born in an earlier generation and hadn't seen the benefits of what we can do now. With people in the second half of life, much of what we're dealing with is brand new biology that the world's never seen before.

AW: Our research group is very interested in understanding this biology and how it leads to the increase in incidence of disease in elderly individuals. We began by searching for signals that might be shared among different types of aging cells, and in so doing we focused on the blood system.

The concept that something in the blood is having an effect on aging and might even reverse pathologies that arise with age was the jumping off point. We discovered that one molecule could be coordinating processes across tissues, including those that are the targets of what I would argue are the most feared consequences of aging – cognitive decline, heart failure, and loss of independent mobility. The possible existence of such a coordinating molecule is really exciting.

RL: The molecule, GDF11, is actually quite remarkable because it seems to affect several organs at the same time.

AW: But, GDF11 is one of many factors, and this system is clearly a complicated network of interactions. As we build out the molecular blueprint of how this works, we will likely discover other interventions that will work as well.



RL: We believe that GDF11 has opened up an avenue of investigation that has the potential to reveal important things about aging, and there's a lot of work for the scientific community to do.

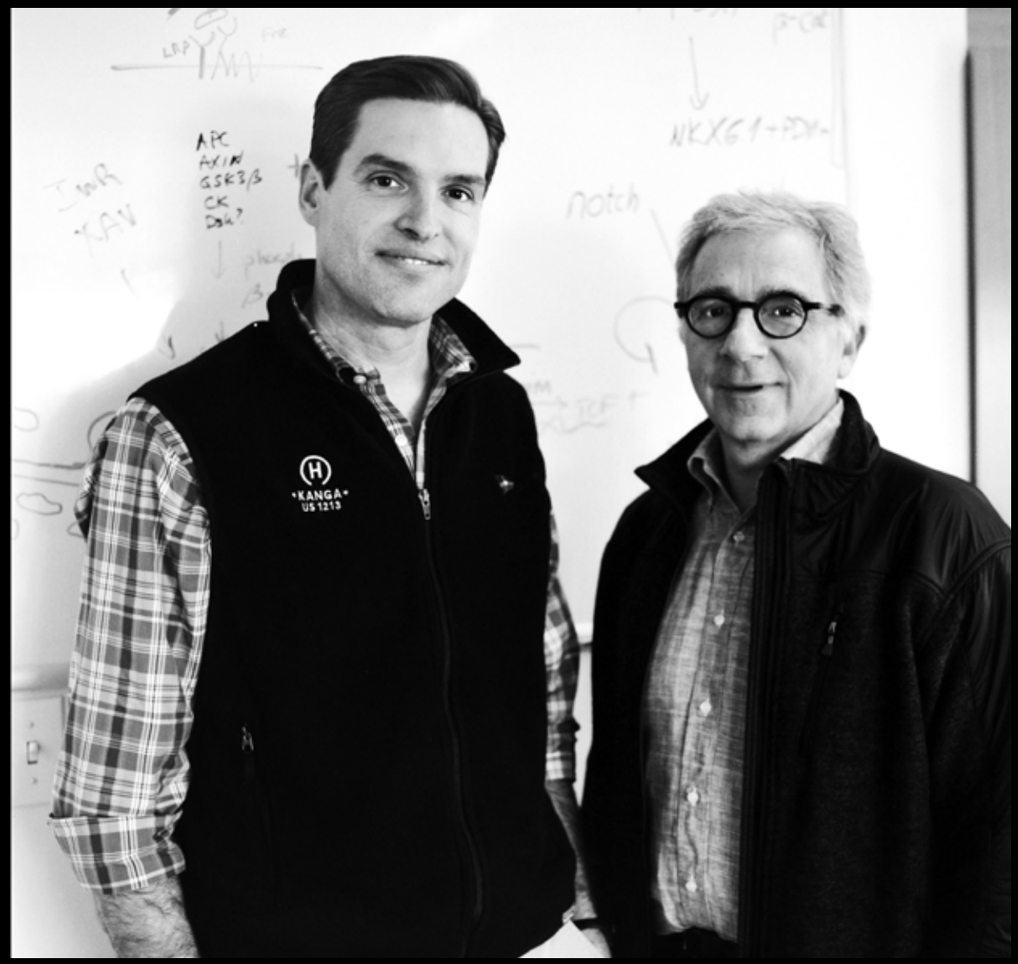
AW: When you age, there is a natural process of decline in cell repair and regeneration. The strategies that we might develop to enhance these processes in older individuals could have potential applications in other contexts. In other words, the mechanisms that deregulate organ function in older individuals might prematurely be activated in individuals with congenital diseases. Aging impacts all aspects of biology, and therefore aging research intersects with research in other HSCI research groups. I would argue that a strength of HSCI is its focus on multiple areas: neuroscience, blood, metabolism, and others.

RL: Additionally, HSCI has been enormously influential to me. It's brought new ideas into my head that I know I wouldn't have thought of myself. It has been the environment of the other investigators and the philosophy about trying to do something about problems that we normally think of as unsolvable. So it has been a big factor in my career.

AW: Likewise. I wouldn't be where I am today without HSCI. It's why I wanted to start my lab here in Boston. The ability to approach the question of aging from an integrated viewpoint, looking at all of these different organ systems and how they talk to one another and respond to signals, no one lab has the expertise to do that. HSCI fosters this collaborative community that makes the big questions now addressable.

METABOLIC DISEASES RESEARCH GROUP

Metabolic diseases, which include type 1 and type 2 **diabetes** and obesity, are some of the biggest health **challenges** we face. With more than one third of its **adult** population obese, the US is spending in excess of **$200** billion every year on obesity-related illnesses and **healthcare** costs. Though diabetes may affect a smaller portion of the population, about 10 percent, its consequences are just as **devastating** and just as deadly. One of the Harvard Stem Cell Institute's greatest successes has been in making the **insulin-producing** beta cells that are typically faulty or **attacked** and destroyed by a diabetic's own body, and our **scientists** are now collaborating with bioengineers to develop devices that could be implanted in the body and **protect** new beta cells from immune attack. **Never before** have scientists been so close to finding a **solution** for these deadly diseases, and the researchers in HSCI's Metabolic Diseases Research Group are **committed** to using stem cells to continue to **understand** the diseases and develop treatments.



Chad Cowan, PhD, and colleague Doug Melton, PhD, co-founder and co-director of HSCI, are two stem cell scientists leading our efforts.

METABOLIC DISEASES

Chad Cowan: HSCI's approach is to do what's in our wheelhouse; since we can study human biology with human cells, we have the ability to look at the genetic contributions to these diseases, the cellular biology, and the cellular mechanisms at play. The two cell types that we put a lot of attention on are the fat cell, and the beta cell in diabetes type 1 and type 2.

Doug Melton: In the next year, we're looking to improve on the process of making beta cells and to work more closely with pharma and biotech in order to move faster to transplantation. As that train is now set and going, it leaves behind big questions: What starts the autoimmune attack? Does everyone get the disease in the same way? What is the key initiating event?

Here we are informed by decades of research in the mouse, but that unfortunately has not lead to any useful clinical applications. So we've decided to focus on humans and start a major program on trying to figure out why in type 1 diabetes in humans the immune system attacks beta cells.

CC: With the goal of preventing that attack with transplantation and new beta cells.

DM: Our focus in type 2 diabetes is more on learning how the development of insulin resistance relates to obesity and fat cells. If there has been any change in our approach it has been to connect those two diseases more tightly, rather than studying them separately.

Now that we can make human fat cells from iPS cells, we are initiating a study using both genetics and modern cell biology to figure out what's different about fat cells in people who are obese and people who are not.

CC: One exciting finding in the last decade is the discovery that adults have this type of fat known as brown fat. Most of us know fat as the cells that store energy, and in terms of modern America, store too much energy so we get obese. Brown fat's job is exactly the opposite; it's designed to burn energy in the form of heat to keep your body temperature normal. It's a process called non-shivering thermogenesis.

The real root cause of why people get fat and how fat cells are involved is still a basic research problem we'll be focusing on in the next five to seven years. In the short term, we'll likely use our cells in collaboration with pharmaceutical companies to develop new and better drugs for controlling blood lipid and blood glucose problems associated with obesity.

DM: Also, we've more fully embraced our bioengineering colleagues to help us think of how we can transplant and protect cells, and also how to make organs on a chip to understand how systems connect to each other. Chad is working on what amounts to a gym on a chip.

CC: Exercising muscle next to fat, hopefully connecting fat to the cells in the brain that are thought to control appetite. We want to see how they all talk to each other.

DM: We also need to revisit or redouble our efforts on engaging two other groups of people: one is the bioengineers I referred to; the other is transplantation immunologists, the people who help us think about how you get fully functional cells back into a person's body so that they work. The science of transplanting whole organs is established, but in terms of transplanting cells, it's really new biology.

BLOOD DISEASES RESEARCH GROUP

Blood stem cell **transplantation**, much better known to the general public as bone marrow transplantation, is one of the few time-tested, **effective** stem cell **therapies** available. For the 50,000 individuals a year who receive a transplant, it is both their one chance at **survival** and a savage assault on their bodies. Patients first undergo **chemotherapy** and/or radiation to kill cancer or other **genetically** defective cells and to wipe out their bone marrow. Since the first transplant took place more than 50 years ago, **physicians** have been working to make the procedure more effective, but it is still far from ideal. This is why **researchers** of the HSCI's Blood Diseases Research Group are **dedicated** to making stem cell transplants **safer**, more effective, and more widely available.

HSCI co-founder and co-director David Scadden, MD, is one trailblazing hematologist, and his colleague Leonard Zon, MD, is another.

BLOOD DISEASES

David Scadden: For me, the whole draw of stem cells is what we saw when we were in medical training; people on death's door, with no other options but to get a stem cell transplant, would walk out alive and gradually regain vigorous health. They could and did enjoy decades of life without the agonies of their underlying disease.

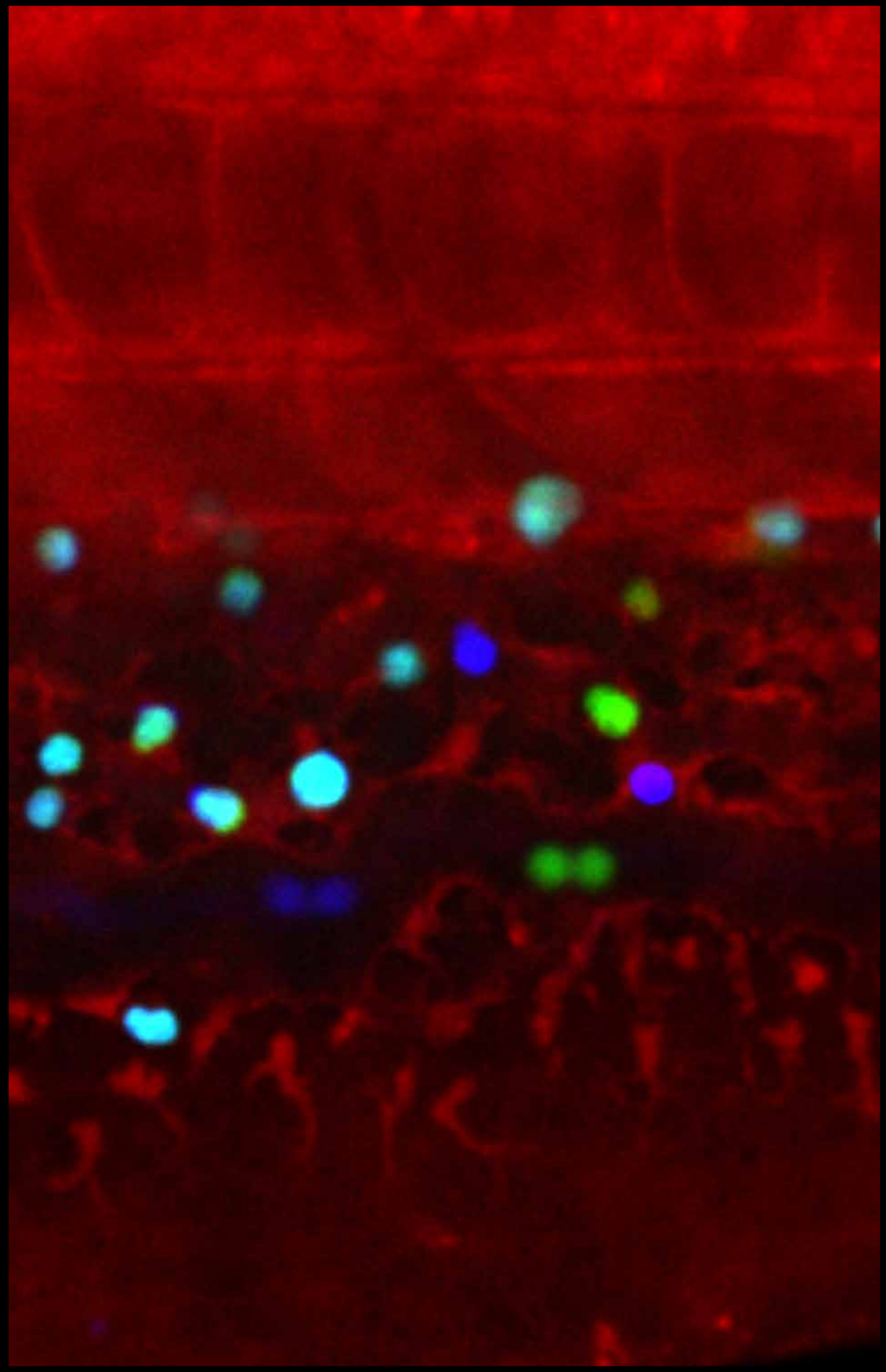
Leonard Zon: I went out to dinner recently with a friend from residency. He was diagnosed with acute myeloid leukemia, had a transplant about 13 months ago, and looks great. He was cured of his disease. It's quite remarkable when you see it and particularly when it touches someone you know. But he was among the lucky 25% with AML who survive.

DS: The ability to have an impact on patients, and sometimes our loved ones, through things we've done here at HSCI — studying how chemicals can modulate how stem cells interact with the niche, or the place in which they settle and thrive; how they amplify their number; how they maximize their function — it' s a very powerful thing.

LZ: However, there is still a 25% death rate associated with a marrow transplant procedure in most populations, and that's sad because it is a curative therapy. Over the next years, we will be working to make these transplants safer.

DS: Safer and more effective, absolutely. And more widely available. Only one third of the people known to be able to benefit from a bone marrow transplant actually get it.

LZ: Sometimes patients have a brother or sister who is a match, but if they don't we try to look for alternative sources in public registries for cord blood and other marrows. Often people are left without a chance of being cured.



One of the new things on the horizon here at HSCI is to reprogram a patient's own cells into a blood stem cell, which could then be transplanted back into the patient with little fear of rejection. If we can succeed in that task it will really be game changing.

DS: By learning more about how stem cells function at the level of basic biology, there is now this opportunity to see stem cell transplant as something that can be applied to people not just with cancers, the way it's been mostly used, but also with genetic diseases including the very widespread, enormously complicated problems of sickle cell anemia, thalassemia, and HIV. Combining gene-editing technology with stem cell science is extremely powerful.

And HSCI is really at the epicenter of this. For example, three of the leading start-up companies that focus on using CRISPR gene-editing technologies to develop therapies for genetic diseases are in the greater Boston area, and HSCI connects with all of them.

LZ: Additionally, HSCI faculty have been instrumental in the formation of seven separate companies, five of which are established and two of which are incubating, that will provide therapies for diseases of the blood.

DS: As the technology matures and eventually becomes therapeutically viable, we are in a position to help move those therapies quickly to patients.


D2
D1
D3
TR

NEUROLOGICAL DISEASES RESEARCH GROUP

The physical **costs of diseases** affecting the nervous system are staggering. As they progress, these diseases rob their victims of their **mobility** and use of **their hands,** of control of their bodily functions, of their minds, and of their lives. Not only are the most common of those conditions — autism spectrum disorders, schizophrenia, **Alzheimer's**, Parkinson's, ALS, and multiple sclerosis — medically and socially devastating, they also are on track to **bankrupt** the country's **healthcare** system. The costs for treating the **5.2 million Americans** estimated to have Alzheimer's disease — to say nothing of all the others — is about **$214 billion** annually. By 2050, when today's teenagers are getting ready to retire, it is predicted there will be about 14 million cases of Alzheimer's, at a **cost** to the nation's healthcare system and economy of **$1.2 trillion** per year. That is almost twice today's entire budget for **Medicare.** Other neurological diseases, such as eye disease and trauma, hearing loss, and spinal cord injury, leave scores of patients **permanently debilitated** and/or in pain. Which is why the neurobiologists and neurologists of HSCI's Neurological Diseases Research Group are so **committed** to increasing understanding of the causes and courses of these diseases and conditions, and to developing new effective **treatments** for them without disabling side effects.

HSCI's Paola Arlotta, PhD, is one such neurobiologist, and her colleague, Clifford Woolf, MD, is another. Together, they explain where HSCI neurological research is now and where it can go in the future.

NEUROLOGICAL DISEASES

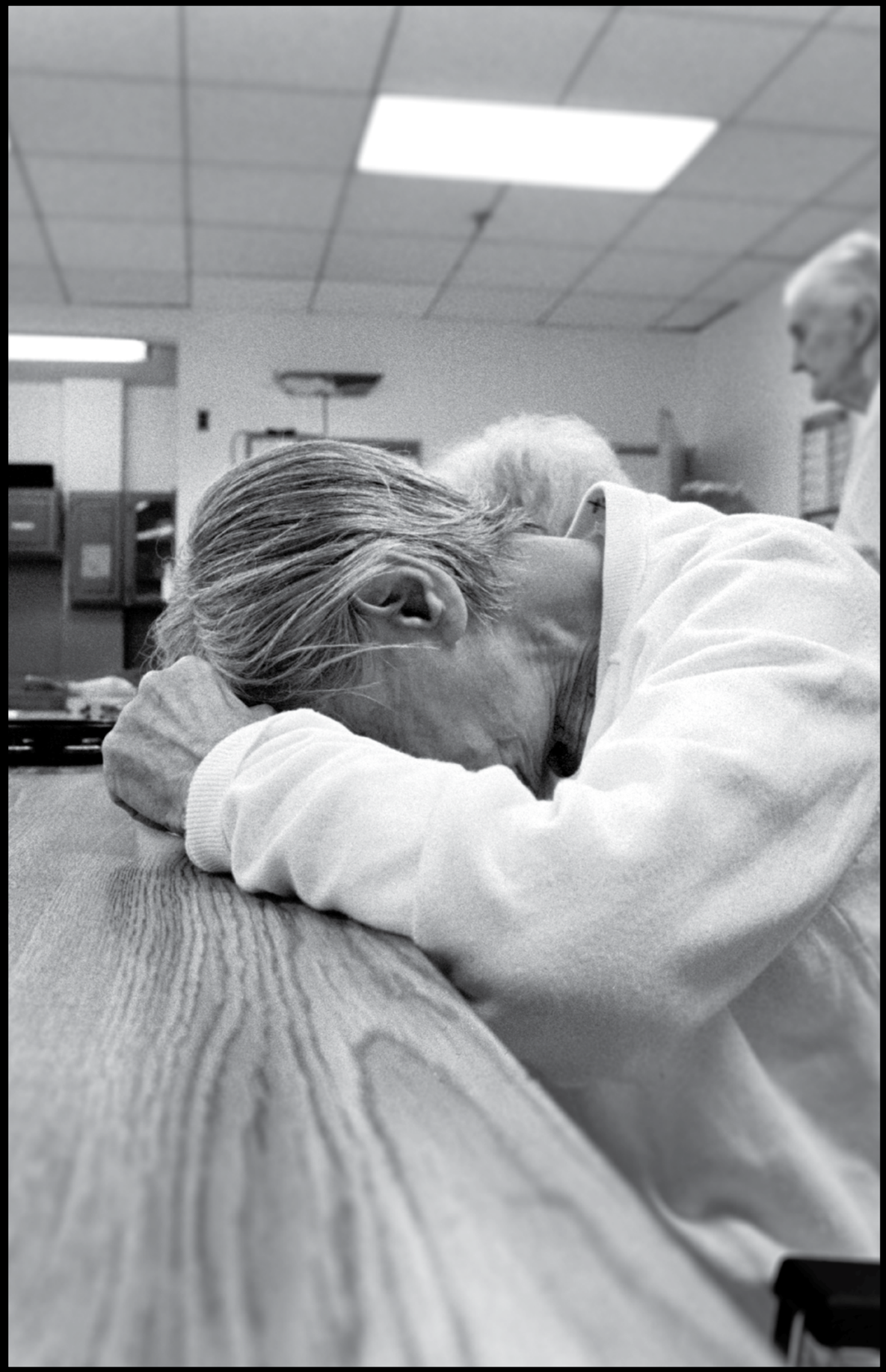
Clifford Woolf: In collaboration with the ALS Association, GlaxoSmithKline, and physicians at Massachusetts General Hospital, HSCI researchers are testing whether retigabine, a drug already approved for use in epilepsy and that we've shown calms hyperexcitable motor neurons derived from stem cells of patients affected by ALS, is also beneficial to the patients. Many major ALS treatment centers around the US are participating. There's enormous interest from the field because it goes beyond ALS and beyond neuroscience: this is really two trials combined – one in patients and one in neurons in a dish in the lab, asking the fundamental question of whether or not we can use human stem cells as a way of characterizing disease and predicting patient response.

Paola Arlotta: This work is also extremely important for diseases that affect complex networks in the human central nervous system and are difficult to model in mice. Being able to model disease in a dish with patient iPS cells will set a completely new way to study human neurobiology and test treatments.

We've never been able to really study human brain or human brain diseases at the tissue or cellular level; we've only been able to study symptoms and use non-invasive analysis. This is the time when basic stem cell discovery can lead us to really do *human* neurobiology in *human* neurological and neurodegenerative disease.

CW: The initial focus for the potential application of stem cell biology to patients was regenerative medicine, the idea of replacing diseased tissue. But in the case of the nervous system, that is very difficult and expensive. Someday, we may well be able to inject stem cell-derived brain cells and get some repair or replacement, but it's not likely to be a widespread approach.

PA: And it's certainly not generalizable nor applicable to every disease. You can imagine some disease such as Parkinson's disease, for example, where there might be benefit in having transplanted midbrain-like tissue that would produce dopamine and ameliorate symptoms.



But if you think about autism, schizophrenia, depression, it is more difficult to predict what benefit the transplantation of neurons would carry. They're very complex diseases, where multiple cell types and the communication among cells are affected. We think that modeling in vitro, screening for drugs, and trying to understand the genetics is the way to go.

CW: And now industrial scale technologies are providing us with new, exciting opportunities to study and understand those diseases. Not only do we now have the capacity to make and study diseased neurons starting from patients' stem cells in the dish, but we also can analyze thousands of cells there and see how different or how similar they are, how some are affected by a given disease and some are not, and if they can be rescued by correcting genetic defects.

PA: With these new tools, we'll be able to tell what every single cell in a dish is doing. How affecting one cell can affect other cells you would never think are involved in a disease.

CW: It's about embracing complexity. When we started off training as scientists we were taught to control everything – to study one thing at a time. That's not the way the brain works. We're getting to be more respectful of what the brain may be in terms of how we approach the study of this dynamic, plastic, complex organ.

PA: At HSCI, another major goal of ours has been to bridge together everybody from basic neurobiology to stem cell biology and disease, from academia to pharma, so that we can build on the collective power of this large community to achieve something that has never been achieved before. Now is the time to look at disease. We have all the tools we need: the technology— to go from the patient to iPS cells, to complex neuronal networks in dishes, and even to mini-organs; the analytics— from studying the single cell to high-throughput analysis of neuronal networks; and the scientists— in multiple disciplines, from neurobiology, to physiology, to genetics. We have ways to genetically engineer the cells, to fix mutations. We have the many patients out there and the scientists who can do the work. The pieces are all here.

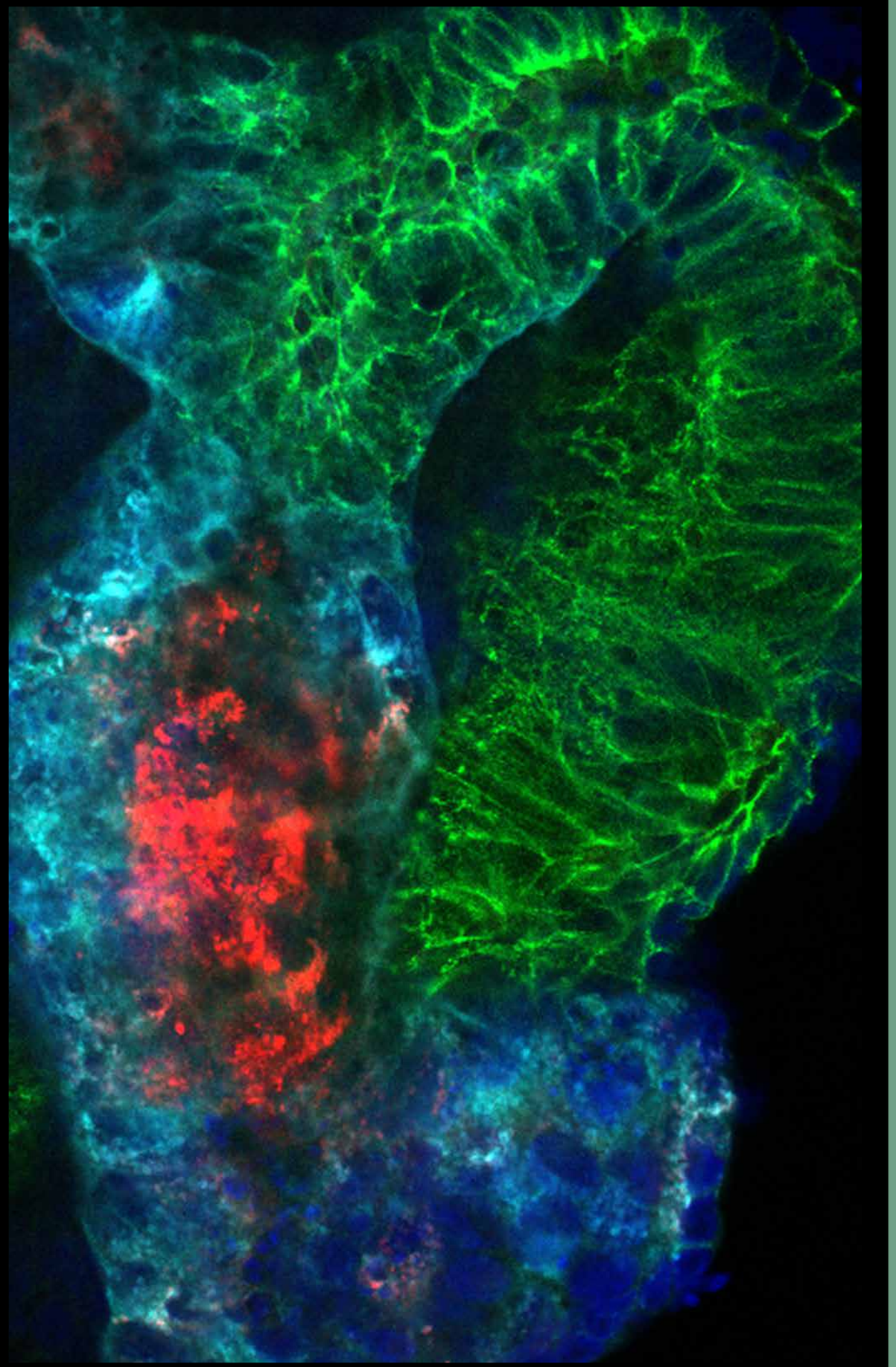
DISCOVERY

Thanks to advances in stem cell biology, scientists now have tools with which to model the processes of the human body that sustain life. They can recreate in real time in the laboratory not just the organs and the cells that make up those organs, but their development and their interactions. And they can do it on a variety of scales; from the individual cell level and 3D networks of cells, to mini-organs and regenerated organs. HSCI scientists are creating and taking advantage of these new platforms to study diseases and human development at a depth never before possible.

Our scientists are studying the precise synchronicity of events that determine whether a single cell will become a skin cell, rather than a blood cell, a liver cell, or a kidney cell. They are working to develop protocols that push stem cells to develop into the specific cell types that become the fundamental building blocks for studying diseases. And with advances in high-throughput screening technology, researchers are also able to use these cells for drug discovery, testing how the same type of cells respond to hundreds of different compounds with a single screen.

Some diseases, such as ALS and Parkinson's, target only one cell type, and research can accelerate once scientists determine how to create the affected cell types from patient cells. Other diseases are more complex, involving multiple cell types and interactions. By creating 3D networks of cells, HSCI researchers can now model these diseases, such as depression and schizophrenia, and visualize cell-to-cell interactions in a setting that more closely resembles an in vivo environment. Pinpointing how interactions vary in healthy and diseased networks could lead to the identification of new drug targets.

Mini-organs, called organoids, offer another platform for studying diseases and screening potential drugs. HSCI's Joseph Bonventre, MD, PhD, for example, has created kidney organoids from the cells of patients with genetic diseases in order to observe how the diseases affect kidney development and function. Using these mini-organoids, researchers will also be able to screen for and test the toxicity of potential drugs.



HSCI scientists have combined organ-on-a-chip and stem cell technologies to model hereditary diseases. HSCI's Kevin Kit Parker, PhD, has used patient stem cells to create heart tissue-on-a-chip to study inherited cardiovascular diseases.

HSCI's Harald Ott, MD, has pioneered a technique to regenerate organs that involves populating a de-cellularized scaffold with stem cells and pushing them to become the cells that make up the organ tissues. So far he's regenerated the tissues for lungs, heart, and kidneys, and these regenerated organs could prove beneficial for studying diseases and could provide a novel source for organ transplants without the need of immunosuppressive drugs.

Shaping the conversation:

Not only are HSCI scientists making and taking advantage of basic stem cell discoveries, but they are also shaping the conversations around various advances both in the stem cell world and in the larger scientific community. For example, HSCI co-founder David Scadden, MD, has become the "go-to" stem cell scientist for reporters with questions about stem cell tourism and unregulated clinics selling untested stem cell therapies, while HSCI co-founder Doug Melton, PhD, has become a trusted voice commenting on advances in diabetes research. Furthermore, George Daley, MD, PhD, HSCI Executive Committee member, is shaping the ongoing conversation about, and public understanding of, recent gene-editing technologies.

Framing the ethical discussion not only for the general public, but also for his fellow scientists, Daley participated in the recent Napa Valley retreat which brought together stem cell scientists, lawyers, and bioethicists and propelled this issue to the forefront of scientific and public awareness last year, and also helped organize a global summit convened by the National Academy of Sciences in Washington, D.C. Both meetings concluded that it would be irresponsible to attempt any gene-editing in embryos, sperm, or eggs at this time — until all the implications and ramifications can be explored. "While scientific evidence may one day convince us that altering human heredity is safe," Daley said, "we should cross this Rubicon only after thoughtful consideration of the social and ethical consequences."

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