The SECRET WORLD of STEM CELL THERAPY

What YOU Need to Know about the Health, Beauty, and Anti-Aging Breakthrough

Prof. Dr. Ernst von Schwarz
Praise for
The Secret World of Stem Cell Therapy

This book by Dr. von Schwarz explains whatever one needs to know about stem cell therapy, easy to understand and scientifically sound.

Frank Stallone, Musician, Los Angeles, USA

Great read for those who want to learn more about stem cells or regenerative medicine.

Fabio, Model, Los Angeles, USA

Refreshing, informative, scientific, and very helpful. Finally, a useful tool helpful from an expert in the field for all of us prospective patients on everything one needs to know on stem cell therapy.

Drea de Matteo, Actress, New York, USA

Dr. Schwarz book on stem cells is a long-awaited insiders perspective based on years of clinical and research experience. This text will replace hours of internet research as well as initial discussion with less informed medical professionals. Highly recommended.

Prof. Laurent Cleenewerck, Theologian, Washington DC, USA

As a patient of Dr. Schwarz, I found his book highly informative. Additionally, I received stem cell therapy and I experienced what I would consider to be truly miraculous results.

Pete Angelus, Music Producer, Phoenix, USA

A reliable source of the untold truths about a revolutionary topic in medicine by one of the most qualified experts. Thank you for all you do.

Liliana Mattaeus, Model, Munich, Germany

I have known Dr. Ernst Schwarz for many years as an exceptional Cardiologist. His research on Stem Cell Therapy is worth reading for those who are considering its use.

Frank G. Mancuso, Studio Executive, Los Angeles, USA

A great guide to navigate the science, regulations, and pitfalls of one of the most promising medical breakthroughs of our time.

Dr. Parag Bharadwai, Physician, Irvine, USA
The SECRET WORLD of STEM CELL THERAPY

What YOU Need to Know about the Health, Beauty, and Anti-Aging Breakthrough

Prof. Dr. Ernst von Schwarz

NEW YORK LONDON • NASHVILLE • MELBOURNE • VANCOUVER
The Secret World of Stem Cell Therapy
What YOU Need to Know about the Health, Beauty, and Anti-Aging Breakthrough

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Dr. Ernst von Schwarz is President and Owner of “Ernst Schwarz, MD A Professional Medical Corporation,” Los Angeles, California, President and Owner of “Pacific Heart Medical Group,” Murrieta, California, and Chief Medical Officer of “HeartStem, Inc.,” Beverly Hills, California.

Medicine and medical science are in constant flux. The statements made in this book represent the personal opinion of Dr. Ernst von Schwarz but do not replace any recommendations or prescriptions from any healthcare professional to any patient. In addition, the statements do not represent a complete review of the current scientific data on stem cell therapy but an overview to the best of the Dr. Ernst von Schwarz’s knowledge at the time of writing.

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Dedicated to

Aubriana D’Ivana Angel, Lujain Vanessa, Cecilia Florence Magdalena, Nathaniel Ferdinand Valentino, and Rafferty Atticus Kip von Schwarz
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Acknowledgments

This book is a synopsis of more than twenty-two years of work in basic research as well as clinical studies using stem cell therapy for different conditions. Research is always made possible by teamwork, which includes extensive brainstorming, idea development, formulation of study protocols, many hours day and night of study conduction, as well as analysis interpretation and preparation of scientific manuscripts.

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Preface

Stem cell therapy is considered to be the most important discovery in modern medicine, likely bigger than the discovery of penicillin or the detection of the tuberculous bacteria. It is the path to rethinking the traditional dogmas of several pathophysiologic concepts. It also made us reconsider the definitions and meaning of cell death, processes of aging and degeneration, and the natural course of diseases. Tons of scientific data is published about the benefits of stem cell therapy; however, its widespread practical use is intentionally prohibited by government regulators like the FDA to protect patients from unapproved therapies with a lack of large-scale clinical and scientific data. On the other hand, thousands of businesses currently make big money from desperate patients who believe an internet ad for stem cell therapy as the “cure of diseases” like heart disease and cancer. These ads are often provided by nonscientific individuals and even some healthcare providers.

In order to understand the dilemma of modern stem cell therapy, we must acknowledge the “squatting the circle” challenge. That is the almost-impossible problem of translating reliable basic research into daily clinical practice without accepting business-driven delays introduced by regulatory agencies and the health industry and avoiding companies and
providers who sell false promises to patients for thousands of dollars for the cure of diseases without knowing the risks and potential outcomes.

To critically reveal the truth about stem cell therapy apart from overwhelming and false data, we must first evaluate the following five interest groups that are heavily involved in the current practice of stem cell therapy, either directly or indirectly.

**Interest Groups for Stem Cell Therapy:**

- Basic Researchers
- Clinical Researchers
- Healthcare Providers
- Stem Cell Companies
- Regulatory Agencies
- Patients

Group 1(A): **Basic Researchers**, the “academicians.” These are basic researchers who have done tons of work on the pathophysiology of diseases and the efficacy of stem cell injections in experimental (mostly animal) models.

Group 1(B): **Clinical Researchers**, the academic clinicians. These are researchers with a large publication list in their curriculum vitae who know basic research data and some clinical data and are driven by researched funded by the National Institutes of Health (NIH) to establish their working hypotheses. They do not recognize or accept other less-established researchers who might have a lot of clinical experience without the academic reputation.

Group 2: **Healthcare Providers**, doctors, and other advanced care providers. These are providers who use stem cells in their clinical practice for different conditions and who have seen impressive anecdotal successes but have no academic reputation and have never written a scientific paper to publish their observational results. Amongst this group is a subgroup
of providers who claim to cure diseases and charge desperate patients a lot of money per injection but never provide follow-up or further testing (the so-called “black sheep”).

Group 3: Stem Cell Companies and laboratories. These are sometimes created by physicians and researchers without any direct connection to patients and other times created by investors without any ties to medicine, and they sell their stem cell products to physicians for use on their patients. Amongst this group are companies with somewhat shady business ethics and, in several cases, companies that have no doctors or researchers on their teams but consist purely of businesspeople interested in their own financial profit with no regard for patient safety or the cleanliness of their products.

Group 4: Regulatory Agencies, governmental agencies such as the Food and Drug Administration (FDA) and other regulators. These are mainly financed by the healthcare industry with no interest in supporting or approving new therapies since no large entity lobbies for more research if there is no industrial benefit. On the other hand, these regulatory agencies protect consumers—all of us—against unproven or questionable therapies.

Group 5: Patients, consumers, all of us. We are all patients with current or potential diseases and health problems, looking for alternatives or cures when doctors tell us there is none. Consumers often search the internet for answers and are bombarded by an unprecedented amount of uncontrolled, and oftentimes false and misleading, information. We as patients are in the middle of false information and are unable to interpret scientific data or extrapolate shady findings to different populations. We are the ones who need special guidance.

As a physician and scientist, I am going to show you the points of view from these five interest groups. The fact is that I belong to all of these groups, likely more than anyone else in the business. I am a physician and clinical cardiologist, and I take care of very sick patients every
day in my clinics as well as in several hospitals, including large academic centers. I am also a researcher and scientist, and I was among the first in the world to perform basic research stem cell studies by using embryonic heart muscle cells and stem cells in experimental animal models to reduce heart attacks. I was actively involved in NIH-funded stem cell studies in patients with heart diseases. I have published more than 150 scientific articles in international peer-reviewed journals, as well as books and book chapters in medicine. I have been a member of stem cell expert committee groups of academic institutions advising regulatory agencies, but I am also involved in the clinical practice of stem cell therapy for a limited number of patients in the frame of smaller clinical studies.

Based on my experience, I will give you, the reader, insights that many may not want to hear—to unveil the truth, the myths, and the secret world of stem cell therapy.
Introduction

This is the one and only book you need to read if you are interested in stem cell therapy, either for yourself or a loved one as a potential patient, or if you just want to look behind the curtains to see the evidence and the reality of today’s stem cell research and its promising clinical implications.

Many books have been written by individuals who want to promote their services and sell stem cell therapies. There is a wide discrepancy between what has been published in the scientific literature and what is advertised in the media about stem cell therapies. No other topic in medicine has gained more interest from both serious researchers and the public than the promising treatments using stem cells for a wide variety of both acute and chronic illnesses.

This book’s goal is to provide people current knowledge about the secret world of stem cell therapy from the perspective of a researcher and clinician who has a wide array of experience in the basic research lab, clinical studies, and daily clinical practice treating patients with life-threatening conditions.

Even though I personally use stem cells to treat patients with certain conditions, this book is in no way meant to sell my services. In contrast,
I would like to warn you not to blindly believe in unapproved stem cell therapies presented in an overwhelming amount via internet advertising. Most of these lack any scientific evidence and are presented by people without any scientific or appropriate clinical background.

The book is written based on my personal experiences. I may unintentionally throw some practitioners or companies under the bus, but unless something was public knowledge, I avoided using real names.

For the consumers, the patients, all of us, this book should serve as a guide for how to approach promising new treatments without relying on information provided by a single person or advertiser. It is also meant to help readers develop critical thinking before spending lots of money on questionable therapies. It should also make readers realize that the FDA as a regulatory government entity is not infallible and is often guided by lobbyist interests. Unfortunately, many of us do not have the luxury of being able to wait twenty or more years for a regulatory agency to finally approve a therapy that has the potential to save and preserve thousands of lives.

This book reveals the secrets and sorts the scientific facts of current stem cell research and critically demonstrates the basics of published studies, including some shortcomings. I discuss the reasons why “big pharma” has little interest in stem cell therapy and why insurance companies are not going to pay for it—and likely won’t for the next twenty-five years—unless the public and insured customers put pressure on them, which is overdue.

I also explain the current practice of doctors offering indistinguishable stem cell therapies for everyone (It is never true that everything works for everyone, by the way!). I also discuss the myths and truth behind “anti-aging medicine” as a big business and give advice about how to avoid getting caught up in marketing promises. Instead, I try to show readers how to ask the right questions beforehand.

True translational research that leads “from bench to bedside” treatment opportunities is also addressed. These approaches are performed by
several scientific groups worldwide in patients using “regenerative therapies” for acute injuries as well as for chronic degenerative diseases. I also describe some of my group’s own published and unpublished study data with different outcomes over the last twenty years of research and clinical practice using stem cell therapies.

As a result, I hope readers understand the enormous potential of stem cell therapy in modern medicine. Moreover, I sincerely hope that this book can serve as a guide for those who are interested in stem cell therapies but do not know how to find the right sources and avoid being blinded by nonscientific marketing materials. I try to shed some light on the unknowns, the pitfalls, and the risks, list questions to ask physicians offering therapies, and provide an overview of the current knowledge of stem cell therapy and its huge potential in modern medicine now and in the near future.

Medical science is in flux, and there are new developments every day. In no way do I intend to be all-inclusive, neither do I pretend to know everything that has been researched or published on stem cell therapies. My team and I have spent the last twenty-five years participating in basic science and clinical trials using stem cells for different diseases, and we are currently involved in stem cell therapies, scientific analyses of unpublished data, and the preparation of several manuscripts for publication in peer-reviewed scientific journals.

For those who are interested in looking for the scientific reference papers that were used to summarize published data, please see the bibliography.
THE SECRET WORLD
OF STEM CELL THERAPY
IS THE ONLY COMPREHENSIVE
OVERVIEW OF THE SECRETS AND
CURRENTLY KNOWN FACTS
ABOUT STEM CELL THERAPY.

Dr. Ernst R von Schwarz, MD, PhD is a world-renowned researcher and clinical and academic cardiologist, who has published more than 150 scientific articles in international peer-reviewed journals, several book chapters and books in cardiovascular medicine. He is also a sought-after speaker at international scientific conferences worldwide, an expert on stem cell therapy and research, and a public figure in medical media.

From an academic and clinical point of view, stem cell therapy represents one of the most promising advances in modern medicine. While several business entities make unsubstantiated claims without having appropriate scientific evidence, The Secret World of Stem Cell Therapy provides the one and only inside view from a researcher and clinical cardiologist, who has himself participated in countless basic research studies and clinical trials using stem cells for different conditions over the last 25 years. With appropriate advice how to approach the subject, what questions to ask, and how to be alerted to red flags, The Secret World of Stem Cell Therapy is an invaluable resource for anyone interested in stem cell therapy.

Refreshing, informative, scientific, and very helpful. Finally, a useful tool helpful from an expert in the field for all of us prospective patients on everything one needs to know on stem cell therapy. 

Drea de Matteo, Actress, New York, USA

Dr. Schwarz’s book on stem cells is a long-awaited insiders perspective based on years of clinical and research experience. This text will replace hours of internet research as well as initial discussion with less informed medical professionals. Highly recommended.

Prof. Laurent Cleenewerck, Theologian, Washington DC, USA
The Dilemma

- Stem cell therapy might be the biggest breakthrough of our lifetime in modern medicine.
- Large-scale clinical trial data is lacking for broader use of stem cell therapy at this time.

Every single day there are stories published about stem cell therapy. These stories are either in support of it—or harshly against it. There is no middle ground. In fact, there is a current trend that reveals that several groups have no interest in the scientific facts and will not support any form of acceptance by regulators.

Who are these interest groups? Well, they (obviously) include the pharmaceutical industry, parts of the government, the FDA, some insurance companies, some established academic institutions and professional societies, doctors who are not educated about stem cell therapy, some hospitals, nursing homes … the list goes on. Essentially, the groups are comprised of everyone who might benefit from all of us being sick patients, especially if we were suffering from chronic diseases. Why would anyone who profits from sick patients promote a therapy that has the potential to
delay the processes of aging and the progression of chronic diseases? That would be counterproductive to their businesses, wouldn’t it?

On the other hand, one might argue that it is in everyone’s best interest for us to stay younger, healthier, and stronger by natural means using the biologic reserve nature provided—that which is silent and untapped within our bodies. Stem cells are not pharmaceutically engineered; they come from either someone’s own body or from pooled donors (placenta or umbilical cord); thus, they have no artificial chemicals in them.

With that being the case, why are we not jumping on it? Why is the FDA shutting stem cell clinics down? Why aren’t insurance companies paying for therapies that can save lives and reduce costs down the road? Why are academic institutions staying away from practical applications outside clinical trials? Why are primary practitioners not referring patients to (the few) specialists who have seen the benefits and treat patients with stem cells despite lack of FDA approval?

There are several things that answers all of the above questions. Some make sense. Many include fear of economic downfall. In this chapter, I discuss the pros and cons of stem cell therapy, its current practice, its economic abuse, its enormous potential (based on published data from the scientific literature, my team’s research, and clinical data collected over twenty years using stem cells in experimental animal studies, clinical trials, and practical therapies). I will also launch a thorough investigation into the current issues concerning stem cell therapies from a scientific, clinical, regulatory, and qualitative point of view.

Stem cell therapy as a form of modern medicine appears in the news on a daily basis, whether in print, on TV news reports, or on social media. As physicians dealing with very sick patients, especially those with heart and cardiovascular diseases, my colleagues and I are constantly confronted with questions from patients and their caregivers about whether stem cell therapy is an option for them as an additional treatment to the armamentarium of standard therapies.
Simultaneously, we see news reports on stem cells as a “cure” for diseases such as HIV. In the early 2000s, a man named Timothy Ray Brown, first known as the “Berlin patient,” was treated with stem cells and remains free of the HIV virus years later. On March 5, 2019, the journal *Nature* reported a second patient who is now free of HIV after stem cell therapy.

But there are also weekly reports of the closure of stem cell clinics by the federal government, especially the FDA. On January 18, 2019, vox.com stated, “the FDA is going after stem cell clinics that peddle unproven treatments.” Other news outlets have reported serious side effects, such as the hospital admissions of a dozen patients in three states who received stem cell therapies (mainly intravenously) that resulted in infections from the cell products being contaminated with E. coli and other bacteria (article from *The Washington Post*, December 21, 2018).

These reports are in contrast to the widely publicized anecdotal reports of enormous improvements for different conditions after stem cell treatments. For example, you’ve most likely seen the video of a dog unable to walk because of chronic hip degeneration and then that same dog was able to happily jump up and down the stairs after stem cell injections.

At the same time, well-known academic institutions also demonstrate and publicize initial results from successful stem cell therapies. On October 11, 2018, physicians and researchers from the University of Southern California Los Angeles (USC) promoted the case of twenty-year-old Kris Bosen from Bakersfield who had a terrible motor vehicle accident that left him permanently paralyzed from the neck down. However, after receiving stem cell injections in his spine as part of an experimental study, Kris regained the use of his hands and arms as evidenced by pictures of him lifting a barbell.

Without a doubt, results like Kris’s are life-changing and create hope for thousands of patients with similar conditions who have not been lucky enough to benefit from the potential of experimental procedures, so far.
Stem cell use may be the biggest scientific and medical breakthrough for humankind, but the lack of large-scale randomized controlled study data, the undifferentiated and relatively expensive sale and marketing of stem cell therapies by providers outside of the academic world with no scientific background, and the active attempts by the medical industry and regulatory institutions to avoid the broader use of stem cell therapies for the public has led to confusion, misinterpretation, and pseudo-knowledge for many people trying to understand it.

1.1 The Beginning of Stem Cell Therapy
As a faculty member at major academic institutions with well-established scientific reputations, I have been working on stem cell therapies since 1995. Our group was among the first in the world to use embryonic cells to mimic the effects of stem cells in experimental animal models. For example, we removed embryonic hearts from pregnant rats and injected them in recipient animals that had experimentally induced heart attacks weeks earlier. By injecting male embryonic cells into female recipients, we were able to detect the Y chromosome (male chromosome) as proof that the cells came from the cell injections. Not only did our group show that these cells survived several months after the injections, but we also showed that the extent of the scar tissue from the heart attacks was significantly less, and the contractile function of the hearts injected with cells was significantly better than those treated with placebo injections.1

The results of these initial basic research animal studies created hype around the search for the clinical use of stem cells in humans with the design of several clinical trials using different kinds of stem cells for acute and chronic heart diseases as well as other devastating illnesses. Consequently, the first clinical studies using stem cell therapy in patients with heart disease were published in the year 2000 (over twenty years ago). Precursor cells derived from bone marrow were the first types of cells used in clinical studies in humans with the idea that the transplanta-
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Despite the fact that every single published study using stem cells has demonstrated benefits—with very little side effects so far—this medical breakthrough has yet to become mainstream for patients in need worldwide. After twenty years and tons of scientific data on the potential and benefits of stem cell therapies, why is this still not an approved therapy?

1.2 How New Therapies Get Approved

To give you an idea of approval processes in the medical community, let me give an example of a drug approval. The drug *nesiritide*, which is meant to treat patients with heart failure, was approved by the FDA in August of 2001 after the evaluation of ten total trials that included 941 patients, including the so-called VMAC trial that looked at 489 subjects with heart failure.3

Basically, this drug was FDA-approved for the treatment of acute decompensated heart failure after data showed (only) 489 patients experiencing less shortness of breath compared to standard therapy. It took less than 1,000 patients’ data to approve the drug.

Of note, *nesiritide* had fallout years thereafter, and even though it is still approved, it is only used occasionally, in part due to a lack of any long-term benefits and possible negative side effects on the kidneys and the heart.4

In other words, a drug that has study data, that is sponsored by a drug manufacturing company, and that reduces shortness of breath for a very short observation period was (relatively) quickly approved by the FDA for use in humans and subsequently was widely used by physicians—even though no long-term beneficial data was ever seen. So, why was this drug easily FDA-approved and stem cell therapy still awaits
approval, despite the fact that thousands of patients have received stem cell therapies all over the world?

Well, let’s evaluate the reasons from a scientific and rational point of view. Before doing so, however, please let me assure you that I am not against the FDA or its approval of nesiritide. In fact, like many other cardiologists and heart failure specialists, I have been a big fan and frequent user of this drug over the years. My research group even performed an unsponsored clinical trial using nesiritide on an outpatient base in patients with chronic heart failure. I am using this drug as a single example to explain the process and the facts of what it takes to get a treatment or drug approved by the FDA.

1.3 Costs of Industrial Support
Stem cell therapy has no industrial lobby because it is not a drug that can be sold by a pharmaceutical company. It will never create trillions of dollars for the industry.

As a natural consequence of business and profitability, the pharmaceutical industry as a whole has to spend money in order to make money. It is not unusual for a pharmaceutical firm to spend several million dollars to conduct a clinical trial. According to a publication from September 2018, the average cost of clinical trials that support FDA approval is nineteen million dollars, which represents only a small portion of the total cost required to develop a new drug. With drug development, preclinical data, animal studies and laboratory studies, and safety and tolerability studies, the average cost for a new drug is estimated at two to three billion dollars. A company only spends that amount of money if the long-term gain exceeds the initial development expenses.

At this point, there is no industrial partner that would benefit from the use of the patients’ own stem cells or stem cells derived from donor umbilical cord or placenta tissue. No industry is willing to spend millions or more in clinical studies without the anticipation of financial
gains. Therefore, the majority of ongoing stem cell research projects are financed by private, institutional, or federal research funds (such as NIH grants). To receive those “kosher” research grants (how we refer to them in contrast with grants from the pharmaceutical or medical device industry, i.e., those sponsored by an entity that has financial gain in the outcomes of the trial) is not an easy task and usually requires years of research experience and data presentation. Academic researchers, including myself, know very well how difficult it is to get those “kosher” grants after going through the application processes many times over the years.

Not surprisingly, the vast majority of medical breakthrough therapies in this country—and around the world—that are (FDA) approved and recommended per professional society guidelines are, in fact, derived from industrially sponsored clinical trials rather than those sponsored by federal or NIH grants. For example, most of the medical therapies that are part of the standard treatment regimen for the management of patients with a weak heart (heart failure) and are recommended in the guidelines from the American Heart Association/American College of Cardiology and the European Heart Society were based on large-scale clinical trials sponsored by the manufactures of the drugs used in the trials.

Again, I am in no way against the pharmaceutical or medical device industry. In fact, I have performed and participated in several industry-sponsored trials in the past as a principal investigator (more than fifty of them), and I do appreciate what the pharmaceutical industry brings to the advancement of modern medicine. But since I am coming from both worlds—the academic research world and the patient-oriented clinical practice world—I can understand why the industry is not wholeheartedly participating in stem cell research at this time.

1.4 Stem Cell Therapy is Not FDA-Approved
At this point, stem cell therapy marketed and performed outside the bounds of clinical trials in the US is not FDA-approved. However, we
must distinguish between “stem cell transplantation” and “stem cell therapy.” Stem cell transplantation has been an FDA-approved procedure for many years in the treatment of certain blood cancers. It does require immunosuppressive therapies to avoid rejection of the transplanted cells, but it can be a highly potent treatment option for certain malignancies.

*Stem cell therapy is NOT FDA-approved.*

Stem cell therapies by intravenous (IV) injection or tissue injections are quite different from stem cell transplantation. These are usually done without any immunosuppressive therapy, since they are either done from the patient’s own stem cells or from donors with a low rejection potential. Many orthopedic doctors and plastic surgeons use injections for joint injuries, arthritis, or facial rejuvenation purposes, among other conditions. This form of stem cell therapy is somewhat FDA “regulated,” but it is not FDA-approved.

Again, by no means do I intend to criticize the FDA for not approving uncertain procedures. The FDA is a regulatory agency, and its main task is to protect people from using uncertain and possibly harmful substances or procedures. But we also must keep in mind what determines the approval of a drug or a procedure by the FDA. Leaving out industrial pressure and lobbying, which are hard to prove, it is FDA’s job to oversee new therapeutic modalities. Stem cells are not drugs; therefore, I’m not convinced that the FDA in its current model should even be involved in the regulatory processes for stem cells. Instead, since the field of regenerative therapies moves so fast, we should create an independent oversight committee of physicians, regulators, and patient advocates with appropriate experience in these research arenas to regulate and control the broader use of stem cell therapies. If it were left to the FDA, no therapy would be approved unless there was irrefutable evidence of its efficacy, safety, and tolerability with large-scale, randomized, controlled,
multicenter trials—as it should be. These trials usually have very stringent inclusion and exclusion criteria in order to ensure a relative homogeneous study population. If healthcare providers who are not used to conducting scientific studies are involved, there are more inconsistencies in patient enrollment and deviations from study protocols in order to enroll more patients. This, of course, contradicts any scientific research process and leads to bias and data invalidity. Even independent of those possible variables, looking at the published data I summarize below, there are so many different patient groups with different diseases and different stem cell therapy protocols using different forms of stem cells via different routes of administration that uniform data is impossible. This, in turn, makes it impossible for the FDA to approve one method of treatment for one condition at this time.

1.5 Lack of Understanding, Lack of Communication

One of the big missing pieces in the stem cell world is a lack of communication and lack of understanding between basic researchers and clinical doctors using stem cell therapies on patients. Those who use stem cells often lack the scientific background for safe use and the ability to create or follow scientific protocols. Further, many (fortunately, not all) providers use stem cell therapies only for monetary gain since this has become a major business for some. In such instances, some providers treat everyone with the same type and number of cells independent of preexisting conditions or possible long-term effects, expecting that the cells perform miracles in a “one-size-fits-all” manner—as long as it is paid for.

Our group, on the other hand, does not believe in this “one-size-fits-all” concept. For example, I don’t think a dermatologist should treat a patient with heart failure with stem cell therapy if that dermatologist does not know the basics of heart failure therapy and management. (Unfortunately, I have encountered that exact situation before.)
So, how can a consumer, a prospective patient, or the public in general know where to turn, where to go, and how to get appropriate information about stem cell therapy? I would first say the answer is definitely not from internet search engines or “Dr. Google.” But appropriate information is necessary in order to receive clinically indicated therapy that:

1. does not harm,
2. provides the most possible benefits,
3. is not provided by a rip-off,
4. has some existing scientific data on efficacy, and
5. does not interfere with current medicines and treatments prescribed by earlier doctors.

1.6 Words on Anti-Aging

A controversial issue is the often misleading use of stem cell therapy for “anti-aging” purposes. We first need to ask ourselves if there is such a thing as “anti-aging.” Aging is a natural process that none of us can escape—at least, not yet. In order to overcome some unwanted “side effects” of aging (such as the loss of elasticity of the skin or the hardening of the blood vessels leading to atherosclerosis (calcification)), a basic understanding of the pathophysiology and morphological and anatomical changes that occur in our bodies’ cells during the aging process is essential.

*The main side effect of aging is death.*  
*The main risk factor for death is advanced age.*

Condemning the concept of “anti-aging medicine” overall is as delusional as the belief in immortality. We do practice concepts of anti-aging, which can lead to a delay of cellular and tissue degeneration rather than an inhibition of aging. But this delay can result in improved quality of
life, improve functionality of different organ systems and the organism as a whole, and cause people to look younger and feel better at high numerical ages. The use of stem cell products in the cosmetic industry in creams and gels for skin cell regeneration, for example, lacks scientific proof, and the often-used label “clinically tested” or “clinically proven” has hardly any meaning for a serious researcher unless controlled and reliable study data has been published. But our experience using stem cell therapy for skin rejuvenation over the last twenty years also has shown astonishing results and is currently highly sought by many individuals seeking to look younger and healthier.

Stem cell therapy has been recognized for decades among academicians and has been used for certain blood cancer treatments for approximately thirty years. The concept, however, became more popular in the year 2000 when the so-called clinical landmark studies were published. These studies showed promising repair of damaged organs through regeneration induced by cells that have the ability to develop into special tissues. These cells are the driving factors of human development; thus, they are abundant in embryonic tissue and umbilical cord blood. But some organs in our human body do have the same regenerative powers and can repair damage at least in part, such as the skin and the liver. So, our bodies do contain stem cells for regenerative purposes. We age in part because we lose those regenerative powers, which leads to a loss of the elasticity of our blood vessels, which then results in lack of oxygen, subsequently leading to cellular death—the complete reversal of our organ development in utero and after birth.

So, if the skin and the liver have the ability to regenerate dead tissue, why do other organs in our body not have the same ability? And shouldn’t we try to induce such repair mechanisms? That is one of the goals of modern stem cell therapy. It aims to repair damaged tissue by introducing multipotent cells into host organs and having those cells not only survive but actually develop into functional host tissue.
Of note, every single study using stem cells published so far in the scientific literature has shown the benefits of stem cell therapy, but stem cell therapy is still not in widespread use to treat patients. The pharmaceutical industry has no interest in supporting stem cell research; therefore, large-scale studies are lacking. Even many of the academic basic researchers have secondary interests since some own stem cell companies and are interested in their own financial gains. The academic institutions depend on larger translational studies and the disconnect between clinical doctors and laboratory scientists often prevents bench-to-bedside trials from being sufficiently conducted.

The FDA is helpless when it comes to approving therapies without the intellectual property registration processes and regulation procedures typically used by drug companies for new therapies. Many nonacademic or pseudoacademic physicians and their business partners offer unapproved but somewhat regulated stem cell therapies both outside and within the US for cash prizes that cost patients several thousands of dollars. Some of them do not have any research background or pathophysiologic knowledge of cellular processes and lack a clinical reputation amongst their peers for obvious reasons, but they are frequented by celebrities and multimillionaires who believe they can pay enough to live longer. These physicians give the validity of stem cell therapy a bad reputation since they often claim success rates without the experience or capacity to publish their data in a scientific and reproducible manner.

There are others, however, who do have the appropriate scientific background, the clinical expertise and knowledge, and the drive to use available research data for the benefit of their patients with “off-label” therapies. My group sees ourselves among those physicians, and our patients are the ones who usually do not fit into the randomized clinical trials at the academic centers because they are too old and too sick and would skew any trial results. For patients, it is basically impossible to know the difference, since no quality measures or controls exist and,
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*How could anyone know the difference?*  
*As a simple reminder, among other distinguishing features, the good ones usually do not advertise their services on billboards or in magazines.*