Pseudomedicine and the Marketing of Unproven and Unapproved Stem Cell Interventions for Dementia

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Pseudomedicine: Marketing Unproven & Unapproved Interventions as Treatments

VIEWPOINT

The Rise of Pseudomedicine for Dementia and Brain Health

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The US population is aging, and with it is an increasing prevalence of Alzheimer disease, which lacks effective approaches for prevention or a cure.[1] Many individuals are concerned about developing cognitive changes and dementia. With increasing amounts of readily accessible information, people independently seek and find material about brain health interventions, although not all sources contain quality medical information.

This landscape of limited treatments for dementia, concern about Alzheimer disease, and wide access to information have brought a troubling increase in "pseudomedicine." Pseudomedicine refers to supplements and medical interventions that exist within the law and are often promoted as scientifically supported treatments, but lack credible efficacy data. Practitioners of pseudomedicine often appeal to health concerns, promote individual testimony as established fact, advocate for unproven therapies, and achieve financial gains.

With neurodegenerative disease, the most common example of pseudomedicine is the promotion of dietary supplements to improve cognition and brain health. This $3.2-billion industry promoting brain health benefits from high-penetration consumer advertising through print media, radio, television, and the internet.[2] No known dietary supplement prevents cognitive decline or dementia, yet supplements advertised as such are widely available and appear to gain legitimacy when sold by major US retailers. Consumers are often unaware that dietary supplements do not undergo US Food and Drug Administration (FDA) testing for safety or review for efficacy. Indeed, supplements may cause harm, as has been shown with vitamin E, which may increase risk of hemorrhagic stroke, and, in high doses, increase risk of death.[3,4] The Alzheimer's Association highlights these concerns, noting that many of these supplements are promoted by testimony rather than science.[5] These brain health supplements can also be costly, and discussion of them in clinical settings can subvert valuable time needed for clinicians and patients to review other interventions.

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Patients and caregivers encounter sophisticated techniques that supply false "scientific" backing for brain health interventions. For example, referring to scientific integrity, Feynman coined the term "cargo cult science" to describe endeavors that follow "...the apparent precepts and forms of scientific investigation, but they're missing something essential...."[6] Cargo cult science is apparent in material promoting some brain health supplements; "evidence" is presented in a scientific-appearing format that lacks actual substance and rigor. Feynman suggested 1 feature of scientific integrity is "bending over backwards to show how [the study] may be wrong...," which is a feature that is often lacking when interventions are promoted for financial gain.[6]

A similarly concerning category of pseudomedicine involves interventions promoted by licensed medical professionals that target unsubstantiated etiologies of neurodegenerative disease (eg, metal toxicity; mold exposure; infectious causes, such as Lyme disease). Some of these practitioners may stand to gain financially by promoting interventions that are not covered by insurance, such as intravenous nutrition, personalized detoxification, chelation therapy, antibiotics, or stem cell therapy. These interventions lack a known mechanism for treating dementia and are costly, unregulated, and potentially harmful.

Recently, detailed protocols to reverse cognitive changes have been promoted, but these protocols merely repackage known dementia interventions (eg, cognitive training, exercise, a heart-healthy diet) and add supplements and other lifestyle changes. Such protocols are promoted by medical professionals with legitimate credentials, offer a unique holistic and personal approach, and are said to be based on rigorous data published in reputable journals. However, when examining the primary data, the troubling and familiar patterns of testimony and cargo cult science emerge. The primary scientific articles superficially appear valid, yet lack essential features, such as sufficient participant characterization, uniform interventions, or treatment randomization with control or placebo groups, and may fail to include sufficient study limitations. Some of these poor-quality studies may be published in predatory open access journals.[7]

An argument can be made that even though pseudomedicine may be ethically questionable, these interventions are relatively benign and offer hope for patients facing an incurable disease. However, these interventions are not ethically, medically, or financially benign for patients or their families. While appealing to a sense of hope can be a motivating factor for clinical trials or complementary or alternative practices, the difference is in how these circumstances are framed. Complementary or alternative practices are often adjunct treatments and might not result in direct

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Use of Unproven Therapies by People with Alzheimer's Disease

Laurel M. Coleman, MD, Lauren L. Fowler, BA, and Mark E. Williams, MD

OBJECTIVE: To describe the use of unproven therapies for Alzheimer's disease.

DESIGN: Descriptive survey using a written questionnaire.

PARTICIPANTS: 101 primary caregivers of people with Alzheimer's disease who attended Alzheimer's disease support group meetings.

RESULTS: Fifty-five percent of caregivers reported that they had tried at least one alternative therapy to improve the patient's memory. Twenty percent of caregivers tried three or more unproven therapies. Vitamins were used most frequently (84%), and health foods (27%), herbal medicines (11%), "smart pills" (9%), and home remedies (7%) were also tried. Most caregivers reported trying the therapies in the early stage of the illness and did not notice significant improvement in the patient's memory. Twenty-five percent of caregivers had tried unproven therapies for behavior problems. There was no correlation between the use of alternative therapies and the sex of the caregiver, age of the caregiver, level of caregiver frustration, presence of problem behaviors, or perceived level of physician support.

CONCLUSIONS: The use of unproven therapies by people with early Alzheimer's disease is common and cannot be predicted by characteristics of the primary caregiver. Although this use may be understandable, it exposes vulnerable people to possible side effects, increased costs, and possible exploitation. Health care workers should actively inquire about the use of alternative therapies, and explore the reasons behind their use, so that they can better understand and meet the needs of their patients and their caregivers. **J Am Geriatr Soc 43:747–750, 1995.**

People frequently use unproven or unconventional therapies for their medical problems.[1–6] Proposed reasons for this use of unproven therapies include preference for "natural," "organic," or "holistic" remedies. Others turn to these therapies because no satisfactory conventional approach is available. Several studies document the use of alternative therapies in people with cancer and HIV infection. Cassileth reported that 54% of cancer patients had tried unconventional therapies, predominantly in the early stages of the disease.[2] However, Lerner observed that only 9% of the cancer patients in his sample used unproven therapies, and usage was associated with a prolonged illness.[3] Greenblatt found that 29% of HIV patients used unorthodox therapies, and they also tended to wait until a more advanced stage of illness before beginning herbal therapies, megavitamins, or other remedies.[4]

The situation of patients with Alzheimer's disease resembles that of patients with cancer or HIV. Despite intensive effort, no therapy has been found to significantly retard the progression of this degenerative dementia. Wilson observes, "Persons with Alzheimer's disease are caught between a hopeless prognosis, rising public anxiety about the illness, along with publicity about the new theoretical advances that may have limited clinical applications and the moral and ethical confusion swirling around treatments that are palliative rather than curative. The current situation of Alzheimer's disease, therefore, appears ripe for unproven, imaginative treatments."[7] Health care workers caring for patients with dementia should be especially aware of alternative therapy use because of concerns about side effects, drug interactions, and cost. Persons with Alzheimer's disease, or their families as surrogate decision makers, may be using unconventional therapies, but the extent of this use is not known.

The objective of this study was to describe the use of alternative therapies for Alzheimer's disease. We examined the types of remedies being tried as well as characteristics of the patients and caregivers choosing these therapies. In addition, we were interested whether therapies were tried in order to improve memory or to ameliorate problem behaviors.

METHODS

Sample

Participants in this study were 101 primary caregivers of patients with dementia. They were recruited through support group meetings of the four North Carolina Chapters of the Alzheimer's Association. In November 1993, a letter describing the study was sent directly to the 113 Alzheimer's Support Group leaders in North Carolina. The leaders were asked to

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JAGS 43:747–750, 1995

0002-8614/95/$3.50

Therapeutic Fads and Quack Care

Stanley van den Noort, MD

Proposed treatments for multiple sclerosis (MS) that reach public attention come from several sources. In a few cases, the treatment is based on widely accepted scientific data derived from studies in animals and humans and is designed specifically to attack the presumed pathogenesis of the disease. Examples include the attempts to "desensitize" or effect "tolerance" to basic protein.

In most instances, however, a treatment has been established as useful for some other disease and is being tried in MS for some logical or paralogical reason. Early examples in this category include each vitamin with a corresponding deficit in nerve function, as it became affordable (eg, niacin, thiamine, and cobalamin), and, more recently, all varieties of immunosuppressive therapy that have proved useful in diseases of presumably related pathogenesis (eg, corticotropin, prednisone, azathioprine, cyclophosphamide, and plasmapheresis). Other examples include nutrients of disputed value and presumably ineffective immune-system factors, such as injected proteins or ingested hyperimmune colostrum.

Some proposed treatments are based on chance observation or logic tangential to or deviant from conventional scientific thought, such as polyunsaturated fatty acids and snake venom. Before looking askance at those treatments, one must recall that steroid treatment of myasthenia gravis was in the same category for many years and that the use of levodopa in Parkinson's disease grew from thinking that was certainly tangential to most research of the time.

A fourth category represents agents whose nonspecific effects in chronic illness promote a sense of improvement—or even actual improvement, if "health promoting behaviors" or improved "coping" mechanisms can in fact modify the extent and progress of chronic illness. Examples include unglamorous counseling and candid rapport between physician and patient, as well as acupuncture, meditation, yoga, hypnosis, relaxation techniques, exercise therapy, faith healing, and disease "visualization." Placebos that are happily linked in time to spontaneous improvement and believed in by the patient may belong in this category. Charismatic healers using anything from zucchini to apples may have similar nonspecific but real effects on coping behavior.

A final and rather different category, which includes some of the treatments already mentioned, is made up of agents that may have slight or substantial benefit but affect a small subpopulation of those with the disease, are effective only at critical times, are helpful at one dosage and injurious at another, have serious short- or long-term attendant risks, generate costs out of proportion to the presumed benefit, require so much of the patient's time and effort that they diminish rather than enhance the quality of life, or require a confluence of complex and poorly understood variables that preclude useful study and replication. Hyperbaric oxygen may belong in this category.

FIVE-POINT STRATEGY

Added to all the other problems are the universal joint conspiracies of patients and physicians. Patients want to believe that treatment will help and that their physicians can provide it. Physicians also want to believe that their treatments help—perhaps even a little more when used "their way." The American motto of "at least try something" is superimposed on a medical system rich in things to try at little direct cost to the patient and at no cost (often with actual profit) to the physician. Multiple sclerosis is a disease in which there is passionate hope; it is little wonder that any treatment of MS will cause subjective improvement for a considerable time in most patients. Stating the problems is far easier than defining strategies for their solution, and both are easier than the hard work of effectively implementing change or control on a wide scale in a free and heterogeneous society. We are obligated, however, to try to solve the problems related to MS therapy. I urge consideration of a five-point strategy.

First, we need to educate patients and physicians that the unchanneled pursuit of therapeutic fads has high human and dollar costs. It consumes the time, energy, and resources of patients and physicians in an exercise that will eventually be recognized as wasted human effort better spent in developing patients' abilities rather than in fruitless efforts to remove their disabilities. Physicians need to learn that "busy work," placebos, and therapeutic fads have no place in the management of long-term illness and will eventually hurt their reputations among peers and patients.

The dollar cost must also be considered. If 250,000 Americans with MS were to undergo monthly plasmapheresis at $400 a visit, the national annual cost could be $1.2 billion. Nearly 1% of the national cost of health care would be consumed by less than 0.001% of the population, adding at least $14 to the average insurance premium. It is fiscally and medically irresponsible to permit widespread and indiscriminate plasmapheresis without carefully controlled studies demonstrating both its value and its lack of potential harm (eg, infection or malignancy). The physician is apt to retreat to the limited use of plasmapheresis for patients whose conditions are deteriorating and who can meet the cost. This tendency has caused many problems in nephrology and cardiovascular surgery. The only way to prevent this hazardous compromise is to employ ubiquitous multicentered trials coordinated by some agency, as in cancer treatment.

A second issue is the need to educate physicians, new and old, on the skills required for management of long-term illness. Physicians have been largely trained for acute episodic care. They often wish to relegate long-term care to physiatrists, or, with aged patients, to geriatricians. It is doubtful that this approach best serves the patient, who requires long-term management of the specific or major illness either by an appropriate subspecialist who can also provide general care or by a subspecialist-generalist team, with the subspecialist's role transcending episodic consultation. The conflict between neurology, physiatry, and medicine for hegemony in these areas has important and probably counterproductive consequences. Organized medicine and the National Institute of Medicine would do well to analyze the issues involved. Continuing Medical Education programs specially designed to help physicians gain skills in the man-

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Two Decades of the Stem Cell Sell

Buzz About Stem Cells Spurs Desperately Ill To Seek Help Overseas

By Antonio RegaladoStaff Reporter of The Wall Street Journal
Aug. 27, 2004 at 12:01 am ET

Share Resize

Call David Ames a stem-cell expatriate. The successful young lawyer learned in 2003 that a bothersome weakness in his hands and arms was an early symptom of Lou Gehrig's disease. He would be fortunate to live a few years, doctors said, and nothing could save him.

So Mr. Ames sold his home and his cars and moved to Argentina. There, for more than $100,000, a doctor is giving him a yearlong experimental course of treatment using his own stem cells.

Mr. Ames is one of an expanding corps of Americans afflicted by devastating diseases whose hopes have been raised by talk of stem-cell advances. Now, a growing number of them are traveling to places such as Mexico, Portugal, China and the Caribbean in search of cures.

2008 Study

Cell Stem Cell
Correspondence

Stem Cell Clinics Online: The Direct-to-Consumer Portrayal of Stem Cell Medicine

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Despite the immature state of stem cell medicine, patients are seeking and accessing putative stem cell therapies in an "early market" in which direct-to-consumer advertising via the internet likely plays an important role. We analyzed stem cell clinic websites and appraised the relevant published clinical evidence of stem cell therapies to address three questions about the direct-to-consumer portrayal of stem cell medicine in this early market: What sorts of therapies are being offered? How are they portrayed? Is there clinical evidence to support the use of these therapies? We found that the portrayal of stem cell medicine on provider websites is optimistic and unsubstantiated by peer-reviewed literature.

Few areas of science have generated as much public interest as stem cell research. Advances in stem cell medicine promise novel, cell-based therapies for many diseases in which conventional medicine is ineffective (Bongso and Richards, 2004; Mimeault et al., 2007). But numerous scientific questions remain unanswered, and scientists generally do not recommend these therapies for general access (Braude et al., 2005; Coutts and Keirstead, 2008; Daley et al., 2003; Lassmann, 2005). Nonetheless, patients are accessing putative therapies from privately operated clinics across the world (Lang, 2007; Bodeen, 2008; Baker, 2005; Enserink, 2006). Beike Biotech, a Chinese clinic specializing in neurologic disorders, claims to have treated over 3000 patients at its 24 hospital clinics in China (McCullough, 2008). ACT, from Turks and Caicos, and Emcell, from Ukraine, claim to have treated over 700 and over 2000 patients, respectively (see Table S1 available online). Many of these clinics advertise directly to patients via the internet. This mode of communication is an important means of reaching patients, with 8 million Americans searching for health information on the internet on any given day (Fox, 2006). Indeed, given the uncertain regulatory status of stem cell therapies, the internet may be the *only* means by which these clinics are able to reach patients in North America.

To characterize the direct-to-consumer portrayal of stem cell medicine, we performed a content analysis of websites obtained by a Google (www.google.com) search for "stem cell therapy" or "treatment" in August, 2007 (Weare and Lin, 2000; Zhang, 2005). This "snapshot" of online stem cell clinics returned 19 websites claiming the use of stem cells for the treatment of disease (detailed search and analysis procedures are provided in the Supplemental Data; included websites are listed in Table S1). In addition to treating disease, eight (42%) of these sites treated otherwise healthy patients for cosmesis (three sites, 16%) or health enhancement (eight sites, 42%). Importantly, these clinics self-reported the administration of stem cells. Clinics' uses of the "stem cell" label were taken at face value. Despite adopting this label in the following analysis, we have no knowledge of the true "stemness" of clinics' interventions. Indeed, given the heterogeneity of cell populations and scientists' limited abilities to sort them, it is likely that "stem cell therapies" contain numerous other cells in addition to stem cells, to the extent that they contain stem cells at all. This caveat applies equally to therapies promoted to consumers by stem cell clinics, and to therapies now under investigation in clinical trials.

What therapies are being offered? Adult autologous stem cells were most commonly provided (9 sites, 47%), followed by fetal stem cells, cord blood stem cells, and embryonic stem cells (see Table 1). Stem cells were most often obtained from the patient's bone marrow (7 sites, 37%) and/or peripheral blood (5 sites, 26%), although some sites obtained stem cells from patient fat, blood or marrow donors, aborted fetuses, patient's skin, animal tissues, and human placental tissue. Treatments were most commonly administered by infusion into cerebrospinal fluid (6 sites, 32%). Peripheral intravenous administration was common as well (6 sites, 32%). Four sites (21%) obtained access to deep body cavities. For example, www.nrrfr.com and www.puhuachina.com both advertised stem cells transplanted by injection deep into the brain via craniotomy or by injection into the spinal cord parenchyma via laminectomy. Although a wide range of treatments are represented, the most frequently provided treatment was autologous stem cells obtained from bone marrow or peripheral blood reintroduced into the body by lumbar puncture or IV infusion.

Numerous indications for treatment were observed, representing diverse categories ranging from neurologic disease to allergies (indications are listed in Table S2). The most commonly mentioned categories were neurologic and cardiovascular disease, mentioned by 16 (84%), and 12 (63%) sites, respectively. Among the neurologic diseases, multiple sclerosis (MS), stroke, Parkinson's disease, spinal cord injury (SCI), and Alzheimer's disease were most common. Cardiovascular indications were typically ischemic heart disease related. Seven sites (37%) treated congenital diseases, mainly cerebral palsy, autism, and Duchenne muscular dystrophy. Regarding risks and benefits, all websites (19, 100%) advertised improvement in disease state as a benefit of therapy. In contrast, most (14, 74%) sites did not mention particular risks. A few sites mentioned procedural risks or other risks, such as nonspecific fever or tingling.

How are stem cell therapies portrayed? This question called for the

- Mexico: 4
- China: 3
- India: 2
- Philippines: 2
- Russia: 2
- Thailand: 2
- Barbados: 1
- Costa Rica: 1
- Dominican Republic: 1
- Germany: 1
- Netherlands: 1
- Puerto Rico: 1
- Turkey: 1
- Ukraine: 1

U.S.-based ”Stem Cell” Fraud

New Jersey Doctor convicted of ALS patient fraud

A New Jersey doctor convicted of taking thousands of dollars from patients by falsely promising to cure them of Lou Gehrig's disease has been sentenced to 57 months in federal prison.

At sentencing Wednesday, Charlene C. DeMarco, 55, of Egg Harbor City, was also ordered to pay more than $32,000 in restitution to victims of the fraud and fined $7,500.

U.S. District Judge Joseph H. Rodriguez ordered DeMarco to surrender to the federal Bureau of Prisons by Oct. 19 to begin serving her sentence.

DeMarco and an assistant, Elizabeth Lerner, 38, of Egg Harbor City, were convicted in December on fraud and money laundering charges. Sentencing for Lerner was postponed because she recently retained a new lawyer.

Federal prosecutors said DeMarco, a doctor of osteopathy who specialized in treatment of Lyme disease, falsely claimed that she could treat patients with amyotrophic lateral sclerosis, commonly referred to as "Lou Gehrig's disease," using stem cell therapy.

Associated Press, New York Daily News, September 5, 2007; U.S. Department of Justice, September 5, 2007, Egg Harbor City Doctor Sentenced to 57 Months for Scheme to Defraud ALS Patients

A Second Early U.S.-based Stem Cell Scam

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA	:	CRIMINAL INDICTMENT
v.	:	No. 1: 06CR1534
LAURA BROWN, and STEPHEN MARK VAN ROOYEN aka MARK DEHAVILLAN	:	
Defendants	:	

THE GRAND JURY CHARGES THAT:

COUNTS ONE THROUGH TWENTY-FIVE

THE SCHEME

1. From in or about Spring 2002 and continuing through in or about the date of this Indictment, in the Northern District of Georgia and elsewhere, the defendants, LAURA BROWN and STEPHEN VAN ROOYEN, did knowingly and willfully devise and intend to devise a scheme and artifice to defraud individuals suffering from ALS, multiple sclerosis, and other incurable diseases, and to obtain money from said individuals by means of materially false and fraudulent pretenses and representations.

2. The scheme was carried out by the defendants, LAURA BROWN and STEPHEN VAN ROOYEN, providing false and misleading information to individuals suffering from incurable diseases regarding the current state of the science of stem cell treatment.

2016: 351 U.S. Businesses Operating 570 Clinics & Marketing Purported Stem Cell Treatments

Cell Stem Cell
Forum

Selling Stem Cells in the USA: Assessing the Direct-to-Consumer Industry

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Direct-to-consumer marketing of unapproved stem cell interventions is a well-known phenomenon in countries with lax medical regulations. However, an examination of Internet-based marketing claims revealed widespread promotion of such interventions by businesses based in the United States. Such commercial activity suggests that regulatory agencies must better oversee this marketplace.

Businesses marketing putative stem cell interventions have proliferated across the U.S. This commercial activity generates a host of serious ethical, scientific, legal, regulatory, and policy concerns. Perhaps the most obvious regulatory question is whether businesses advertising nonhomologous autologous, allogeneic, "induced pluripotent," or xenogeneic "stem cell therapies" are exposing their clients to noncompliant cell-based interventions. Such practices also prompt ethical concerns about the safety and efficacy of marketed interventions, accuracy in advertising, the quality of informed consent, and the exposure of vulnerable individuals to unjustifiable risks.

destinations as China, India, Mexico, and the Caribbean if they wish to access businesses promoting stem cell procedures for a wide range of clinical indications. While travel from the U.S. to international "stem cell clinics" continues, the rhetoric of "stem cell tourism" often fails to acknowledge the hundreds of U.S. businesses engaged in direct-to-consumer advertising of stem cell interventions.

To address the urgent need for better information concerning the U.S. marketplace for such businesses, we used Internet key word searches, text mining, and content analysis of company websites to investigate and analyze this arena.

location(s), website address, advertised stem cell types, and diseases, injuries, and other conditions that clinics claim to treat with stem cell interventions. (Table S1 lists and describes all of the businesses we identified).

Figure 1 shows the geographic distribution of such businesses across the U.S. Many stem cell companies employ multiple physicians and advertise interventions available at numerous clinics. Although such businesses are widely distributed all over the county, we found that clinics tend to cluster in particular states. For example, we found 113 clinics in California, 104 in Florida, 71 in Texas, 37 in Colorado, 36 in Arizona, and 21 in

L. Turner & P. Knoepfler. Selling Stem Cells in the USA: Assessing the Direct-to-Consumer Industry. *Cell Stem Cell* 2016; 19 (2): 154-7.

2021: DTC Marketing of Purported Stem Cell & Exosome Products by 1480 U.S. Businesses Operating 2754 Clinics

Cell Stem Cell

CellPress

Forum

The American stem cell sell in 2021: U.S. businesses selling unlicensed and unproven stem cell interventions

Leigh Turner[1,*]

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In March 2021, 1,480 U.S. businesses operating 2,754 clinics were found selling purported stem cell treatments for various indications. More than four times as many businesses than were identified 5 years ago are selling stem cell products that are not FDA-approved and lack convincing evidence of safety and efficacy.

U.S. & International Businesses Selling Purported Stem Cell Treatments for Alzheimer's Disease & Other Dementias

- 2024 research project has found 122 businesses engaged in online marketing of purported stem cell treatments for Alzheimer's disease, other dementias, & memory loss

- 30 businesses are U.S.-based & 92 are international businesses

- U.S., Mexico, & India are 3 "hotspots" for such businesses and clinics

“A Miraculous Therapy”

- "Intrathecal injection of mesenchymal stem cells (MSCs) has emerged as a miraculous therapy for early onset dementia recovery…The results from the the Early Onset Dementia stem cell treatment can last for years or even indefinitely. This is because the stem cells are creating real neurogenesis which means new neurons.”

Cures

- “ALZHEIMER Is Very Effectively Curable With the help of Stem Cell Therapy treatment for Alzheimer's disease in India….Can stem cells cure alzheimer's disease? Absolutely yes... the patient will lead a normal life again."

“Hitting the Reset Button for Your Body”

- “Stem cells can regenerate new nerves, brain cells, and in some cases, reverse 100% the effects of Fibromyalgia, Alzheimer’s, and Parkinson’s (to mention just a few)…Think of stem cells as hitting the reset button for your body, allowing your healthy cells to be loaded back into the system and flushing out the errors.”

Stem Cell Rescue & Repair Crew

- "These cells are akin to having a personalized fire, rescue and repair crew that naturally resides in your body. They wait quietly for a sign of trouble—inflammation—and then home to that signal to do their jobs….By harnessing the power of your own biology, [REDACTED] represents a minimally invasive option for patients with neurodegenerative conditions such as Parkinson's, dementia and Alzheimer's Disease, or after a stroke or traumatic brain injury."

Stem Cells as Superior to Existing Medications for Alzheimer's Disease

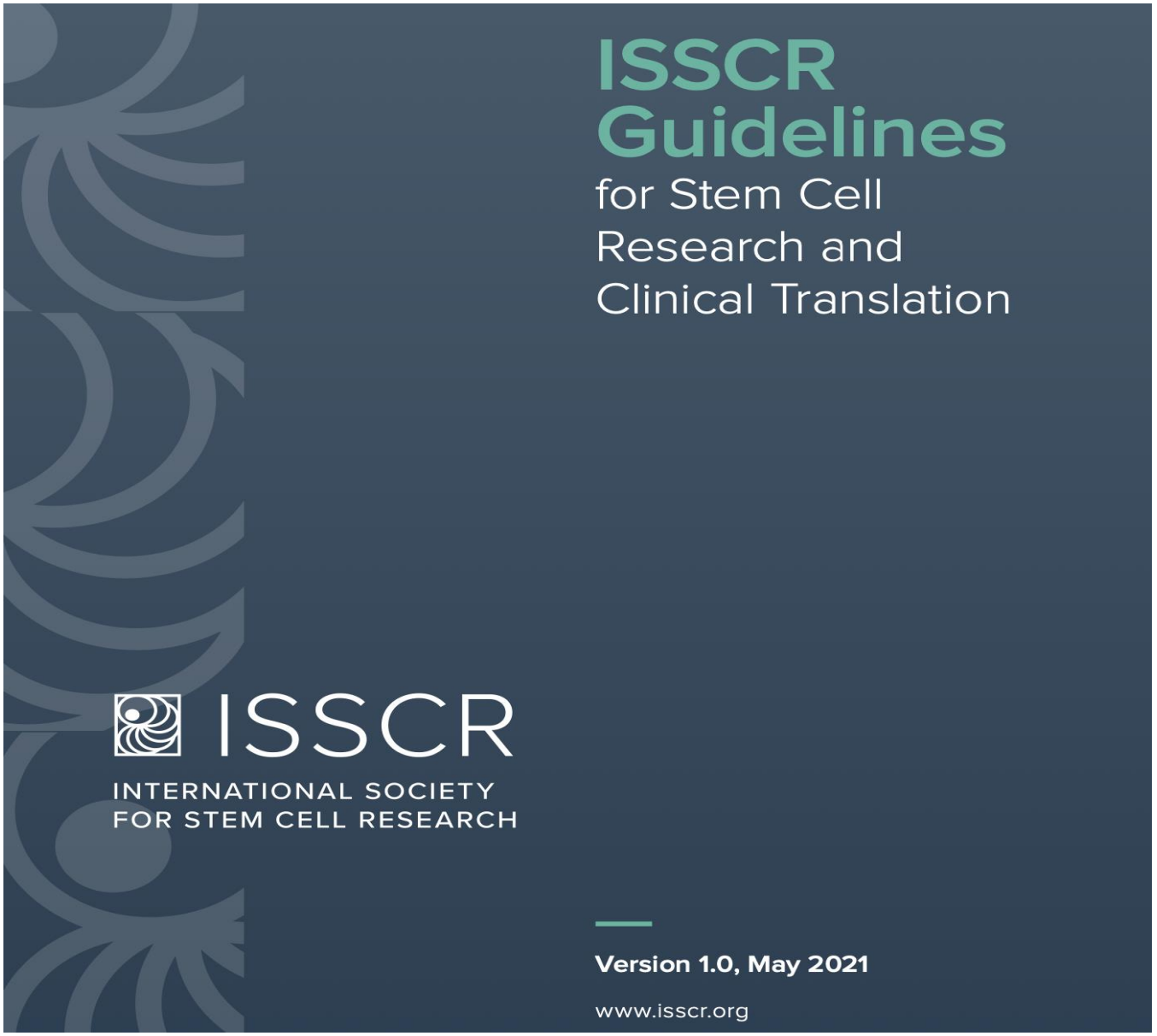
- "Stem cell therapy helps to improve the symptoms of Alzheimer's disease. Through this treatment, the patient's memory function gets improved, neurons in the brain get regenerated, overall functional recovery gets improved, and the damaged cells get replaced with healthy cells….[REDACTED] provides stem cell treatment that has no side effects and is a better method of treatment than the use of drugs."

Halt or Reverse Neurological Diseases With Personalized Treatment Plans

- "…our Neurological Disorders treatment program encompasses cutting-edge adult stem cell therapies designed to address a spectrum of neurological conditions, including Autism, ALS (Amyotrophic Lateral Sclerosis), Alzheimer's Disease, Multiple Sclerosis, Parkinson's Disease, and Traumatic Brain Injury….We aim to halt or reverse the progression of these disorders. Each patient receives a personalized treatment plan tailored to their specific condition…"

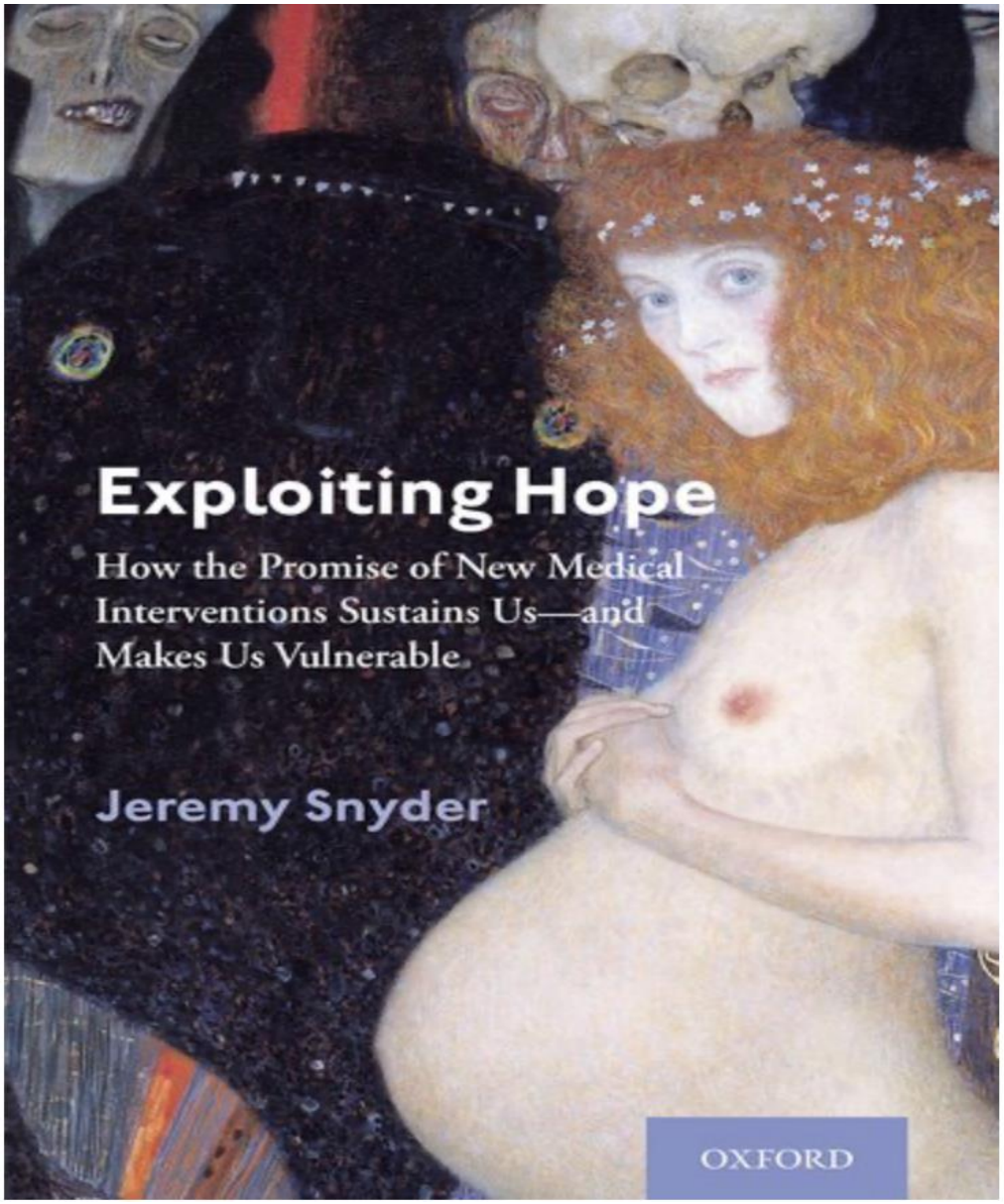
Challenges of Clinical Translation

- .



Misrepresentations Compromise Informed Decision-making

Hope, Desperation, & Exploitation



Crowdfunding & the Amplification of Marketing Pitches

Crowdfunding for stem cell-based interventions to treat neurologic diseases and injuries

Jeremy Snyder, PhD, and Leigh Turner, PhD

Neurology® 2019;93:252-258. doi:10.1212/WNL.0000000000007838

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Abstract

Objective

To characterize the marketplace for direct-to-consumer (DTC) unproven stem cell-based interventions (SCBI) for neurologic diseases and injuries using crowdfunding data.

Methods

Search terms were developed from previous empirical studies of DTC businesses and the International Classification of Diseases–11 for neurologic diseases and used to query GoFundMe's internal search engine. Campaigns initiated November 2017–2018 and seeking SCBI for neurologic diseases and injuries (n = 1,030) were reviewed to identify the number of donors, number of Facebook shares, recipient location, funding pledged, funding requested, underlying neurologic condition, treatment location, and treatment facility name.

Results

A total of 1,030 crowdfunding campaigns for SCBI for neurologic diseases and injuries requested $33,449,979 and received $5,057,069 from 38,713 donors. The most common neurologic condition identified was multiple sclerosis (MS) (n = 404, 35.5%). Of campaigns naming specific destination facilities (n = 392), the most common clinical settings identified were the Stem Cell Institute in Panama City, Panama (n = 91, 23.2%), StemGenex in San Diego, California (n = 44, 11.2%), and Clinica Ruiz in Puebla, Mexico (n = 36, 9.2%).

Conclusions

MS dominated the total number of crowdfunding campaigns. Most campaigns were linked to individuals from regions geographically proximal to destination facilities advertising SCBI for particular neurologic diseases. Most of the clinical destinations were located in comparatively high-income countries such as the United States, Mexico, and Panama. These findings provide considerable insight into the DTC marketplace for SCBI. Analysis of crowdfunding campaigns can be used to develop more targeted patient education initiatives and health policies related to domestic and international travel for unproven SCBI.

Deceptive Advertising & Financial Harm

Los Angeles Times

Column: A stem cell clinic and its doctor will pay a $3.65-million settlement to 1,100 ex-patients

The FDA has been trying to crack down on clinics hawking unproven and ineffective stem cell treatments such as the one that yielded a $3.65-million legal settlement. (Jason Armond/Los Angeles Times)

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FOR SUBSCRIBERS
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BY MICHAEL HILTZIK | BUSINESS COLUMNIST
MARCH 10, 2022 6 AM PT

The story of StemGenex, a onetime stem cell clinic operating out of glossy quarters in La Jolla, appears finally to have reached its well-deserved end.

A $3.65-million settlement with 1,063 former clients reached by the clinic and its former chief medical officer has just won final approval from federal Judge Anthony Battaglia in San Diego.

The clients were plaintiffs in a class-action lawsuit originally filed in 2016, alleging that they were misled by StemGenex advertising and promotional material.

Physical Harms

The deadly business of an unregulated global stem cell industry

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ABSTRACT
In 2016, the Office of the State Coroner of New South Wales released its report into the death of an Australian woman, Sheila Drysdale, who had died from complications of an autologous stem cell procedure at a Sydney clinic. In this report, we argue that Mrs Drysdale's death was avoidable, and it was the result of a pernicious global problem of an industry exploiting regulatory systems to sell unproven and unjustified interventions with stem cells.

THE DEATH OF SHEILA DRYSDALE

In December 2013, the private Sydney clinic of cosmetic surgeon, Dr Ralph Bright, admitted 75-year-old Sheila Drysdale for a liposuction procedure. Dr Bright did not perform this procedure for cosmetic reasons, but rather to 'treat' her advanced dementia with adipose-derived stem cells. Tragically, Mrs Drysdale died within 10 hours of the procedure.

According to the NSW Deputy Coroners' Report,[1] Dr Bright had removed approximately 500 mL of fat from Mrs Drysdale's flanks and buttocks on the day of the intervention. This tissue was then 'processed' in the clinic's laboratory to derive '1.5 billion stem cells' for subsequent intravenous administration later that day. In the immediate postoperative period, Mrs Drysdale was noted to be drowsy and hypotensive. Even though Mrs Drysdale was being monitored and administered medications to assist in her recovery, she continued to deteriorate and died at her nursing home less than 3 hours after being discharged.

The deputy coroner found that the cause of Mrs Drysdale's death was hypovolemic shock due to uncontrolled blood loss following the liposuction procedure. He attributed the blood loss to Dr Bright's failure to ensure that the patient had ceased her antiplatelet medication prior to the surgery. The deputy coroner was also critical of Dr Bright for failing to recognise or appropriately respond to clinical signs indicating postoperative blood loss; discharging Mrs Drysdale prematurely and, when it became clear that her condition had deteriorated, failing to recommend that she be taken to hospital for immediate treatment.

Mrs Drysdale's death, while unfortunate, resulted from a well-recognised complication of liposuction: the likelihood of death following liposuction is estimated to be between 3 and 100 per 100 000 procedures.[2] What makes her death so profoundly tragic, however, is that it occurred as a complication of an intervention for which there is no scientific support. While there are some preclinical data and (weak) evidence from clinical trials to suggest that autologous adipose-derived mesenchymal stem cells may have some benefit for the treatment of arthritis and other joint or muscular injuries,[3] there is *no* published scientific research that indicates *any* benefit for patients with dementia.[4 5]

This fact was not lost on the deputy coroner, who stated that the use of stem cells for dementia was 'highly questionable' and that it displayed 'some of the hallmarks of "quack" medicine: desperate patients, pseudo-science and large amounts of money being charged for unproven therapies'.[1] Consequently, the coroner recommended an investigation into Dr Bright's conduct and called for the relevant agencies to develop guidelines to regulate more rigorously 'experimental' or 'innovative' medical or surgical procedures in Australia.

QUESTIONABLE ETHICS AND REGULATORY FAILURES

This case raises serious ethical and legal issues concerning the professional conduct of medical practitioners and their duty of care towards patients, the regulation of innovative therapies and the global emergence of businesses marketing stem cells directly to consumers. Practitioners have ethical, professional and legal duties to act in their patient's best interests and in ways that provide benefit (beneficence). These obligations can conflict with the commercial imperatives and financial interests of private clinics and businesses that market stem cells.

Importantly, this duty of care is in no way diminished by the provision of information to patients, or demands from consumers for the freedom to access innovative therapies, even if they are risky and are unlikely to be beneficial.[6] This means that novel medical interventions administered outside the context of clinical trials should have, at least, some likelihood of benefit to justify the potential risks of harm. From a legal perspective, one can only consent to a serious bodily medical intervention when that intervention is clinically justified by, for example, a tangible therapeutic benefit. The implication is that if a medical intervention has no therapeutic benefit, it cannot be consented to, and any 'informed consent' will be vitiated. Such 'treatments' are regarded in the common law as assault and/or batteries.[7]

This issue of informed consent was raised in the Drysdale case, with the deputy coroner contending that Dr Bright might not have fully informed Mrs Drysdale's husband (who was her surrogate decision-maker and who had himself been 'treated'

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Unreported Complications

Complications from "Stem Cell Tourism" in Neurology

Katherine Julian, BS,[1,2] Nicholas Yuhasz, BS,[1] Widjan Rai, MD,[1] Jose A. Salerno, BS,[1,3] and Jaime Imitola, MD[1,2,4]

"Stem cell tourism," the practice of offering unproven cellular preparations to patients as approved therapy, is rising in neurology. Currently, the experiences of patients and reported complications from these procedures are unknown in the United States. We evaluate academic neurologists' experiences with stem cell tourism and assess perceived competency on discussing this topic with patients. We found a lack of neurologist preparedness to discuss stem cell therapies with patients and an alarming list of unreported complications from these unregulated procedures. We also identified an urgent need for neurologist education and the creation of a national registry for reporting patient complications resulting from experimental stem cell interventions.

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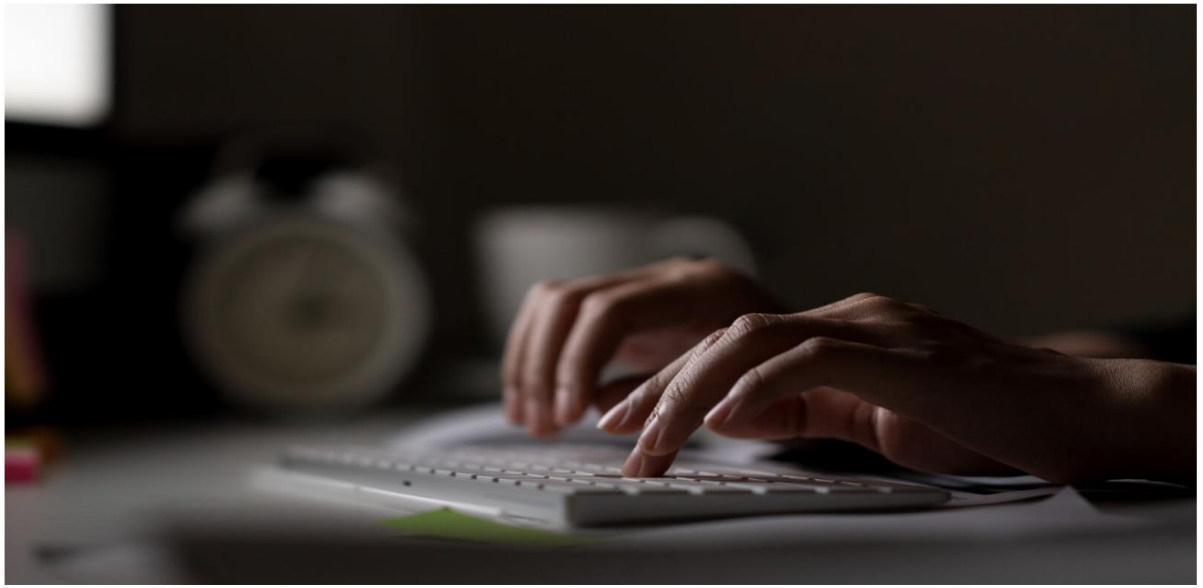
Direct-to-Consumer Marketplace Could Divert Individuals from Participating in Credible Clinical Trials

Marketing Misinformation and Public Understanding

How do you separate scientifically sound stem cell therapies from scams?

By Natalya Ortolano Aug. 18, 2020 Reprints



ADOBE

For patients who've run out of other options, experimental, unproven therapies like stem cell treatments offer new hope. But how do you sort the scientifically legitimate from the dangerous?

Regenerative medicine is a controversial field, still in its infancy. There are academic researchers and major biotech companies testing key treatments in high-profile, vetted clinical trials — but there are also fringe clinics promising stem cell injections that can cure everything from Alzheimer's disease to cerebral palsy, though they have no evidence to back up those claims.

Conclusion

Founder and Chief Executive Officer of Injectable Stem Cell Product Manufacturer Pleads Guilty to Felony Distribution of Unapproved Drug

Tuesday, August 27, 2024

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For Immediate Release

Office of Public Affairs

The founder and chief executive officer of a California-based company that marketed stem cell-based products linked to multiple hospitalizations pleaded guilty yesterday to a felony violation of the Federal Food, Drug and Cosmetic Act.

John W. Kosolcharoen, 53, most recently of Orange County, California, pleaded guilty to introducing an unapproved new drug into interstate commerce with the intent to defraud and mislead. Kosolcharoen is currently in custody serving a sentence for a separate, unconnected conviction. U.S. District Judge Otis D. Wright II for the Central District of California presided over the hearing pursuant to a plea agreement with the government. The court set Kosolcharoen's sentencing for Sept. 23.

According to court documents, beginning in 2016, Kosolcharoen created two companies, Liveyon LLC and Genetech Inc., to manufacture and distribute injectable stem cell products made from human umbilical cord blood. Liveyon marketed the products under different brand names, including "ReGen." In pleading guilty, Kosolcharoen admitted that he and others misrepresented ReGen as suitable for the treatment of a variety of conditions, such as lung and heart diseases, autoimmune disorders, Alzheimer's disease, Parkinson's disease and others. Liveyon marketed the products throughout the United States until about April 2019 using advertising materials that contained multiple false and misleading statements about their purported safety and effectiveness.