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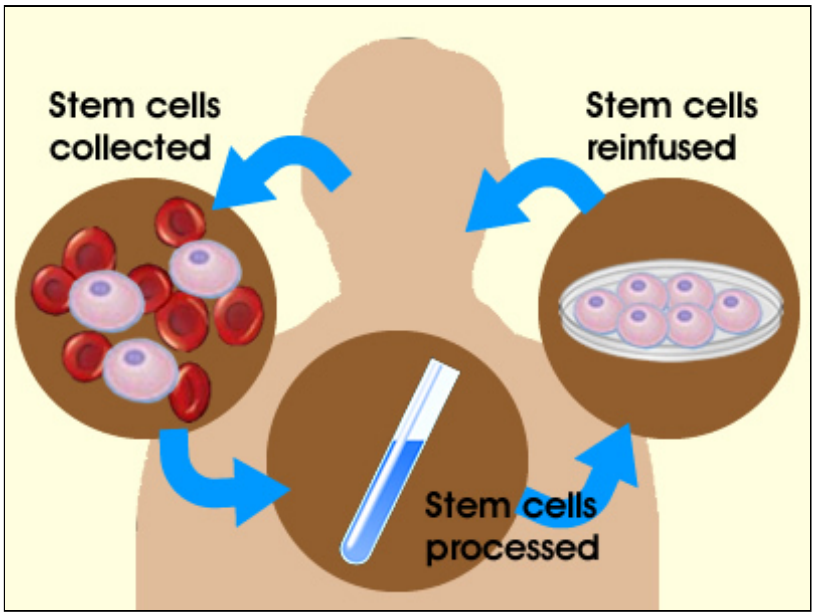



In autologous adult stem cell therapy, the patient uses their own stem cells for healing.

# Why Can't We Use Our Own Stem Cells to Heal Our Bodies?

by Berkley Bedell, former Congressman

About every one hundred years there is a new medical paradigm shift in medical care. Two hundred years ago Edward Jenner had a flash of insight that milkmaids seemed to be immune from smallpox. He realized they had all had cowpox and deduced that the immunity carried over to smallpox. It was the beginning of the theory of vaccines. One hundred years ago Dr. Flemming discovered penicillin which has also created a huge shift in medicine. Today the discovery of the body's own repair and regeneration system – autologous adult stem cells – represents an equally incredible discovery.

Berkley Bedell

This relatively new discovery of a healing system within the body opens up a whole new vision for treating disease. We all have a banking facility for autologous (the patient's own) stem cells within our bodies in our bone marrow, fat, and other areas. As needed, these cells are called upon to heal injuries or insults within. As we age the reserves of stem cells within our bone marrow and fat begin to diminish. When we do not

have enough stem cells to address illness or injury, symptoms occur, and we no longer effectively heal with chronic illness being the result. The process of extracting stem cells from the bone marrow or fat and reintroducing them in adequate numbers into the body allows the body to heal as it is meant to naturally. It represents a new avenue to avoid chronic illness and the high cost in dollars and in pain and suffering for the patient and their family which chronic illness carries.

President Obama issued Executive Order 13563: A Retrospective Review "Look Back" at existing regulations. It is our belief the FDA regulation found at 21 C.F.R 1271.3 (d) is a candidate for this review. Under the Bush Administration on April 1, 2006, the FDA changed the definition of human cellular and tissue-based products from "any human tissue derived from a human body and intended for transplantation **into another human**...." to "(d) Human cells, tissue, or cellular or tissue-based products (HCT/Ps) means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer **into a human recipient**...."

This change was made without compliance to the Administrative Procedures Act requiring an "extensive public comment period." The change effectively moves therapies and procedures involving autologous adult stem cells into the jurisdiction of the FDA. There are a number of reasons this is a bad regulation including the following:

1. All three branches of government uphold the principle that the FDA cannot oversee the practice of medicine. This definition change brings autologous adult stem cell (AASC) therapies, which are the practice of medicine, under FDA oversight. This is the first time in history the FDA has encroached into practice of medicine oversight. In addition, now that the FDA has crossed the line they recently have gone even further and have taken control of tissue practices that have successfully been used for years in the practice of medicine.
2. Proper jurisdiction is the issue at hand. Embryonic and allogeneic stem cells belong under the jurisdiction of the FDA as they involve transferring tissue from one individual to another. AASC jurisdiction should be with the state medical boards because it is a treatment between only the doctor and patient; does not involve interstate distribution; or threaten the general public.
3. The FDA has banned the use of many aspects of AASC therapy, except same day therapies, rendering advancement of the technology literally impossible. Since body parts and tissues cannot be patented (including AASCs) no one will spend the money necessary to do the lengthy and expensive clinical trials required by the FDA under current regulations.
4. AASC therapies quite likely represent a new paradigm shift in medicine which happens about every 100 years. Other countries around the globe are developing AASC technology and administering treatment with the United States remaining in the dark ages.
5. Currently, with AASC therapy available in other parts of the world, United States citizens are required to travel to get treatment. Medical Tourism abroad creates safety issues for our citizens and represents a drain on funds that could be spent at home.

Changing this regulation offers a number of tremendous opportunities for the United States:

1. Cost savings to the healthcare system through the advancement of AASC therapy is remarkable. Even in the short run, AASC therapies offer a less expensive, comparatively safe, and more effective

outcome for many diseases than treatments conventional medicine can offer especially considering the high risk of invasive surgeries. AASC therapies are reparative in nature returning the patient to health rather than palliative care.

2. AASC therapies not only address remarkable savings regarding the procedure, but offer people an opportunity to "get their lives back" eliminating the drain on society and public resources created by the chronically ill.
3. AASC therapies involve only the use of an individual's own body parts and represent no ethical or genetic contamination issues present when discussing allogeneic and embryonic stem cells.
4. The human element of offering a therapy that heals, relieves pain and suffering not only is a gift to the patient, but to the family as well. AASC therapy has a high efficacy rate.
5. Being the practice of medicine, AASC therapies allow the physician the right to advance the therapy through the age old practice of physician innovation which has advanced many other life saving therapies such as heart bypass surgery and other therapies regulated by state medical boards.
6. Clinical and Laboratory Guidelines have already been created to give guidance to physicians and state medical boards to insure safety and reliability. A Patient Registry is in place and accessible for physicians to escalate the advancement of this therapy.

We would like to take each of these points and explain them in more detail.

## Jurisdiction

FDA's Center for Biologics Evaluation and Research (CBER) merged two previously distinct categories of products, embryonic/allogeneic stem cells and AASC's into one category. This placed AASC's, which represent "minimal, if any risk" in the same category with all other stem cells which represent higher risk and made AASCs subject to the same regulatory oversight as mass-produced pharmaceutical agents. This successfully accomplished efforts to keep AASC stem cell therapy from advancing technologically and away from the patient. There are no ethical issues or concern of genetic contamination when the patient uses their own stem cells to heal. The use of one's own body parts to heal is done every day in hospitals and clinics in the United States with skin grafts, bone grafts, bone marrow injections, heart bypass, vascular grafts, and invitro fertilization, to mention a few, as the practice of medicine regulated by state medical boards.

**AASC therapies involve only the patient and the doctor**. The Practice of Medicine as defined from the House of Delegates of the Federation of State Medical Boards of the United States includes: " (1) Offering or undertaking to prescribe, order, give or administer any drug or medicine for the use of any other person. (2) Offering or undertaking to prevent or to diagnose, correct and/or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition of any person, including the management of pregnancy and parturition. (3) Offering or undertaking to perform any surgical operation upon any person. (4) Rendering a determination of medical necessity or a decision affecting the diagnosis and/or treatment of a patient." [1 [#sdfootnote1sym]](#) **The action of a physician using a patient's own stem cells to treat the same patient within their own professional practice constitutes the practice of medicine**. With over one million physicians in practice, their oversight and all aspects of this therapy can only be effectively accomplished by the individual state medical boards. Enforcement mechanisms

for physician oversight at the state level include state medical board sanctions, professional organization sanctions and malpractice liability.

It has always been the intent of all three branches of government to protect the right of the doctor to practice medicine. For this reason, throughout history, it has been clarified that the FDA cannot oversee the practice of medicine.[2 [#sdfootnote2sym],3 [#sdfootnote3sym],4 [#sdfootnote4sym],5 [#sdfootnote5sym],6 [#sdfootnote6sym],7 [#sdfootnote7sym],8 [#sdfootnote8sym],9 [#sdfootnote9sym],10 [#sdfootnote10sym],11 [#sdfootnote11sym]]Various court cases have upheld the distinct line drawn by Congress between the FDA and the practice of medicine stating "Congress did not intend the Food and Drug Administration to interfere with medical practice as between the physician and the patient." [12 [#sdfootnote12sym]]By changing the definition of tissue use from "into another human" to "into a human recipient" the FDA has, for the first time in history, encroached on this long held truth and stepped into the realm of oversight of the practice of medicine by not allowing the practitioner to perform AASC therapy as they see fit. To date, the FDA has banned the use of AASC for various processes and procedures. The FDA has become aggressive towards doctors who use AASC therapy and has brought suit against a doctor who was using AASCs in his practice. The case is still pending.

The big concern is that the FDA has not stopped there. Once they crossed over by calling autologous stem cells "drugs" they have recently expanded their encroachment into therapies that have been successfully used in the practice of medicine for years. The FDA has been sending practitioners, labs and device manufacturers Untitled Letters indicating FDA's new authority over their practices. Take adipose cells (fat) as an example. For decades physicians have been using these cells in the practice of medicine. These cells are processed at the bedside during fat transfer surgeries where a surgeon moves fat from one part of the body and places it in another. However, the FDA recently asserted that if the structure of the fat is broken down, as is common in a new same-day stem cell procedure, then this creates a drug of the patients own cells [http://www.box.com/s/v8du7czi944s3xlblr5g] . The FDA's Tissue Reference Group (TRG) has in fact sent letters to physicians performing adipose cell transfers, stating that even if they process these cells during the same surgical procedure in their offices with no culture involved, the practice is still creating a new drug. The FDA also recently sent a Warning Letter to one company who was processing fat on behalf of physicians [http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm297245.htm] . The letter claims that the simple breakdown of the structural component of fat is more than minimal manipulation. Cytori Therapeutics [http://en.wikipedia.org/wiki/Cytori_Therapeutics] is a company that created a new device to process fat to isolate stem cells resident in the tissue. It's a simple process and in Europe the machine was quickly granted approval. In the U.S. however, the department within the FDA that regulates stem cells has made it a nightmare to get the machine approved. In essence, while the FDA admitted the machine does what it says it should do and produces a mix of cells free from contamination (all that's required to get it approved), it claimed that since the product of the machine was the patient's own stem cell mix, that it would consider the machine the same as a new drug. The big concern raised by the FDA was that the machine's stem cell mix could be used off-label by a doctor (the machine's approval was to treat a rare disease). Off-label use by doctors has been considered sacred, important by the courts, and a distinct benefit to society. Many devices are used off-label to help patients. In addition, the action of the FDA violates the judge's order in U.S. v. Evers and ignores his conclusion that off-label use by doctors is important to society. These new regulatory actions by the

FDA are a disaster to patients, as each cell type turned from body part to drug costs the nation tremendously in increased costs and delayed access to these therapies.

The historical barrier between the FDA and the practice of medicine is vital. As can be seen with the example above, once the line has been crossed there could be no end to the encroachment. The importance of ending the efforts of the FDA to oversee the practice of medicine and return the FDA focus to issues it has jurisdiction over cannot be overstated.

The bottom line question regarding this regulation always gets back to "jurisdiction." Any therapy which is between the doctor and the patient, creates no threat to the public at large, and does not involve distribution or interaction over state lines is outside the jurisdiction of the FDA and within the jurisdiction of the state medical boards. Historically, the FDA has carefully balanced its regulatory actions to minimize public health risks and allow adequate access to beneficial new therapies through the practice of medicine. As an example, invitro fertilization and compounding pharmacies both represent areas outside the authority of the FDA, both clarified as such by a Compliance Policy Guide issued by the FDA. Since these therapies represent one on one (between the patient and the doctor) medical risk, no different than any other medical procedure, the FDA places these in the arena of the practice of medicine and both are regulated by the state medical and pharmacy boards. AASC therapies represent one on one medical risk and do not involve interstate commerce and belong under the jurisdiction of the states.

Because AASC therapy is outside the jurisdiction of the FDA, any arguments the FDA present (such as non-homologous use, more than minimal manipulation, or physician oversight) to try to maintain control of the therapy are irrelevant. These issues are to be dealt with within the proper jurisdiction of the state medical board. The additional argument from the FDA that AASCs that are multiplied may cause cancer has been refuted by research. The largest complications database published to date demonstrates that there is no evidence that culture, expanded autologous mesenchymal stem cells cause cancer at re-implanted sites.[13 [#sdfootnote13sym]] The complete absence of re-implant site tumor formation among 223 patients is consistent with the findings of authors who have reported a lack of neoplasia in mesenchymal stem cells cultured for short periods.[14 [#sdfootnote14sym]] In addition, karyotyping can be used as a risk mitigation tool assuring that all cells for re-implantation are normal.[15 [#sdfootnote15sym]]

Whether the FDA is holding tight to AASC control because it is doesn't have the infrastructure to deal with cellular medicine or whether there are other motives, the result of pulling AASC therapy into their domain has been to protect special interest groups such as the pharmaceutical industry who may see a healing therapy as a threat to future drug sales. It has also successfully stifled opportunity to advance the science. Some research is being done using AASC, but most researchers are diligently studying applications for embryonic and allogeneic stem cell therapies which they can patent and realize great returns in the future. An emphasis on embryonic or allogeneic therapy will inevitably drive up the cost of future treatments using stem cells, as has been witnessed by other patented applications for medical care. Very little money is justified for the rigorous clinical requirements of the FDA for AASC therapy because body parts (AASCs) cannot be patented. Several special interest organizations which are busy procuring patents, including the California Institute for Regenerative Medicine (CIRM) and the International Society for Stem Cell Research (ISSCR) have disseminated misleading information

regarding the use of AASC and safety concerns in an attempt to protect patents, keep research money flowing in their direction, and keep AASC therapy from advancing within the practice of medicine. Past and current presidents of ISSCR hold a number of very valuable patents making it obvious why they wish to keep AASC out of the mainstream practice of medicine.

### Financial conflicts as told through the patents held by past, present, and future ISSCR presidents

#### 2008 President: George Daley, Children's Hospital

- Creating Embryonic Stem Cells for Mass production – PCT/US2007/019935
- Method for Enhancing Proliferation of Stem Cells – PCT/US03/29185
- Proprietary Kit to see if an iPS Cell is Correctly Manufactured – PCT/US09/57849
- Method to Create iPSC's (artificial stem cells) – PCT/US08/12532

#### 2010 President: Irving L. Weissman, Stanford University

- Method for Isolating a Stem cell Type – Issued Patent US7592174 [http://www.google.com/patents/US7592174?dq=Irving+L.+Weissman+stem+cells&ei=J2OLT6zgEuKpiALmwtC_Cw]
- Regenerating a Liver with a certain Stem Cell Type – US 2001/0049139 A1
- Method for Culturing Embryonic Stem Cells – US 2006/0172414 A1
- A Method for Concentrating Stem Cells of the same Type – Patent Number US 5087570
- A Device for Isolating Stem Cells – US 2004/0038316 A1
- Methods to Isolate and Culture Certain Blood Stem Cells – US 2009/0191164 A1

#### 2011 President: Elaine Fuchs, Rockefeller University

- A Method for Changing Skin Stem Cells – US 2012/0034616 A1
- A Method for Isolating a new Stem Cell Type – US Patent 7829336
- A Method for Modulating Hair Growth – US 2009/0203574 A1
- A Method for Isolating Hair Stem Cells – US 2008/0213882 A1

#### 2012 President: Fred Gage, Salk Institute for Biological Studies

- A Method and Device for Extracting Stem Cells – US 2007/0190649 A1
- A Method to turn Stem Cells into Nerves – US 2010/0166710 A1
- A Stem Cell Therapy to treat Brain Diseases – US Patent number: 6451306
- A Method for Culturing Stem Cells from Deceased Patients – US 2002/0098584 A1
- A Method to use a Centrifuge to Isolate Nerve Stem Cells – US Patent number: 6767738
- A Method to use IGF-1 to turns Stem cells into Certain Nerve Cells – US 2005/0148069 A1
- A Patent on using a Molecular Switch to turn Stem Cells to Nerve Cells – US 2006/0234378 A1

#### 2013 President: Shinya Yamanaka, Center for IPS Cell Research & Application

- A Method for Producing Induced Pluripotent Stem Cells – US 2011/0250692 A1

- Another Method for Producing Induced Pluripotent Stem Cells – US 2009/0227032 A1
- A Method for Improving the Efficiency of Induced Pluripotent Stem Cells – US 2011/0039338 A1
- Reprogramming Factors to create iPS Cells – US Patent number: 8058065
- Yet Another Method for Producing Induced Pluripotent Stem Cells – US 2011/0003365 A1
- A Method to create Nerve Cells from Stem Cells – US 2011/0183350 A1
- A Method of treating Nerve Problems with Stem Cells – US 2009/0208465 A1
- Another Method for reprogramming Cells to Stem cells – US 2010/0279404 A1
- A Method to create Platelets from iPS Cells – US 2011/0053267 A1
- A Method to find Substances that will Reprogram Cells to iPS Cells – US 2008/0274914 A1
- A Gene only expressed in Embryonic Stem Cells – US 2008/0299548 A1

## Global Clinics and Medical Tourism

Many countries including France, Ecuador, Argentina, Spain, Israel, Korea, China, Mexico, Cayman Islands, Bahamas, Brazil, Peru, and Panama have aggressive programs offering treatment and advancing the technology of AASC therapies. This kind of diligence has ranked many of these countries higher than the United States on the WHO Health Performance ranking. While other countries are offering their citizens cutting edge therapies using AASC therapy that brings health care into the 21st century, the United States is doing relatively nothing due to the restricting regulations created by the FDA. As a result, United States citizens are forced to travel abroad to receive AASC life saving treatment. This creates issues on several fronts. There is no guarantee of the quality of care, compared to required standards in the United States. Travel abroad and payment for treatments is funding other countries' economies and health care systems. Follow up care can be complicated for these patients. Only those citizens with adequate funds are capable of accessing AASC treatments. When AASC therapies are allowed in the United States the availability of this treatment will continue to make the therapy more affordable.

On the positive side, there are many reasons for returning AASC therapy to the jurisdiction of the state medical boards where it belongs.

## Efficacy

Learning how to support and integrate AASC therapies into clinical practice is changing the way the world treats heart disease, MS, orthopedic issues, diabetes, Parkinson's disease, cerebral palsy, autism, macular degeneration, organ failure, ALS, COPD, Alzheimer's disease, paralysis, traumatic brain injuries, lung disease, bacterial infections, and arthritis, as examples. AASC therapy is the use of the body's own repair system. Conventional medicine does not have effective curative treatment for many of the above diseases, but can only offer ways to alleviate symptoms. AASC therapy offers the body an avenue for healing, regeneration, inflammation inhibition, immune modulation and reversal of disease. Clinics abroad report that two-thirds of their patients experience improved lives with all types of AASC treatment, even with the therapy being relatively new. In cases of many diseases, efficacy of AASC therapies has exceeded conventional approaches due to the healing nature of the therapy. The ultimate result is reduction in chronically ill people.

In many cases the cost of AASC therapies is substantially less than current conventional methods to treat the same illness. As an example let's look at an orthopedic application, knee replacement. By 2030 there will be 3.5 million procedures annually covered by Medicare alone.[16 [#sdfootnote16sym]] Knee replacement comprises the 4th largest single expenditure for hospitalization and the cost for an average knee replacement using conventional medicine is approximately $40,000. The approximate cost for AASC therapy to bring about repair and regeneration of the knee is $10,000. With AASC used for 25% of these cases between 2012-2017, 8000 lives will be saved and Medicare will save $10 billion dollars. [17 [#sdfootnote17sym]] AASC therapies offer a safer option for treatment in general. In traditional surgical knee joint replacement for 223 patients, 17-23 patients will suffer serious surgical complications, 1-2 will die as a result of the surgery, 1-2 will experience a pulmonary embolism, 1-2 will suffer a heart attack, and 2-11 patients will require hospital readmission for serious infection requiring IV antibiotic.[18 [#sdfootnote18sym]] Risk of serious infection and death can be as high as 22 people in elderly patients out of the 223. In comparison, in AASC therapies in place of knee replacement for 223 patients the physician had no significant severe level complications in patients followed for 3 months to 3 years. [19 [#sdfootnote19sym]] The cost of addressing complications is significant and represents a substantial savings when avoided. Currently, the use of AASC shows comparable efficacy to available conventional approaches to orthopedic applications. In the knee AASC treatment 89% of the patients experienced greater than 50% improvement and of those 89%, half had greater than 75% relief.[20 [#sdfootnote20sym]]

To quote Andrew Von Eschenbach,

> *"When I was commissioner of the Food and Drug Administration (FDA) from 2005 to 2009, I saw firsthand how regenerative medicine offered a cure for kidney and heart failure and other chronic conditions like diabetes. Researchers used stem cells to grow cells and tissues to replace failing organs, eliminating the need for expensive supportive treatments like dialysis and organ transplants."*[21 [#sdfootnote21sym]]

This animal research confirmed the efficacy that is being seen in clinics around the world in humans.

## Human Factor

Cost savings is a very real piece of this puzzle, but the human factor cannot be overlooked. Consider the patient who is paralyzed and has the opportunity through AASC therapy to walk again; or the patient with heart disease who is told to "get his/her affairs in order" with no more conventional treatment options for his/her failing heart, receiving a second chance; or the COPD patient who has to be on oxygen day and night to prevent suffocating, experiencing new life in their lungs. With AASC therapy these patients can be offered reasonable hope to reverse their life threatening and often painful condition. One patient we met who received AASC therapy abroad had a remarkable story. He was 50 years old and suffered from MS. He endured an average of 20 seizures a day with pain that could not be mitigated. He was preparing to enter a nursing home and was taking $50,000 in medication annually. He received AASC therapy and soon after the seizures stopped and his pain was resolved. We saw him one year after his treatment. He no longer required medications, had returned to work and was enjoying a normal life. It was heartwarming. Patients around the world are experiencing this kind of success. This impact has a huge ripple effect not only for the patient, but for their families and often their

community.

## Physician Innovation

Physician innovation has been protected since the beginning of our democracy in order to assure the advancement of medicine. As mentioned, all three branches of government have confirmed that the FDA cannot oversee the practice of medicine or make requirements when dealing with protocols between the doctor and patient. It is via this vehicle that therapies, heart bypass for example, have advanced. As AASC therapy advances through physician innovation the technology and efficacy will raise exponentially and costs will continue to decline. Organizations such as the International Cellular Medicine Society (ICMS) are working diligently around the world to help advance AASC therapies. ICMS has developed a complete set of Clinical and Laboratory Guidelines for the use of AASC therapies. In addition, ICMS has developed a Patient Registry for physicians to document therapies, successes and failures. This type of registry will serve to advance successes in the technology quickly and effectively. Some individual states have also developed guidelines for their respective state medical boards.

## What Can Be Done

Since the **FDA currently has control over the use of your own body parts**, only **the Administration**, which is supposed to oversee the FDA, **or the Congress** which has legislative power over the FDA **can bring about change**.

As with other issues historically which were controlled by special interests, **it is likely this effort will require a grassroots movement** by those of us who are ill or have family members who are ill and want to receive this life saving treatment. If you have read this and are moved to make a difference, share this article with them. **Talk to your family, friends, and neighbors**. **Talk to your doctor**. **Write letters to the editor** of your newspaper. **Speak to groups** that you belong to and educate them on the issue. Mostly, **contact your Congressman and Senator**. The more people they hear from the more likely we will see change. It will take a ground swell and **if everyone who is sick or has a family member suffering makes an effort, we will see results**.

The reality of using the body's own healing system has arrived. This is witnessed by the presence of clinics in many countries around the world. Imagine what future generations will say if we continue to withhold this lifesaving treatment from the American public. This is a golden opportunity for the Congress to right a wrong, correct a jurisdiction error, lower skyrocketing health care costs, and offer hope to many ill and suffering Americans.

## Cost Savings

If a person experiences resolution to their illness then the savings is considerably higher considering the fact that the person is no longer in the "patient pool" of the chronically ill. If the patient experiences improvement, but requires additional AASC treatments in ensuing years, the cost over the lifetime of the patient is still considerably less than conventional treatment for a chronic illness. Consider the savings for the health care system when a patient with serious chronic illness is actually healed and returns to a productive life in comparison with the patient who constantly attempts to treat symptoms and deal with continuing decline in health. Of course it will take a while for this therapy to become universal to reach maximum opportunity for savings, but already there are several anti-aging organizations who are training physicians in AASC treatments here in the United States so they can

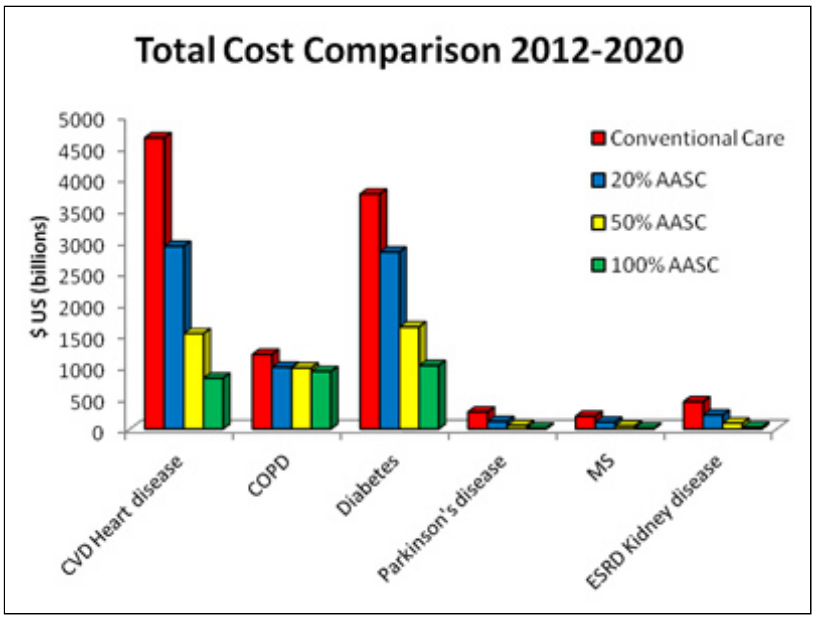
integrate the therapy into their practices shortly after the jurisdiction returns to the state medical boards.

The annual cost of heart disease (2010 estimate from the American Heart Association) was $503.2 billion dollars, lung disease (2007 estimate from the American Lung Association) was $154 billion dollars, and diabetes (2007 estimate from the American Diabetes Association) was $174 billion dollars. The cost of type 2 diabetes management by 2020 is projected to be $500 billion dollars per year. [22 [#sdfootnote22sym]] If the cost of these treatments can be reduced by 50-75% in a substantial number of cases, this represents a huge savings for the health care system. In many cases the cost of the treatment of the illness, resulting care, and drain on society from loss of productivity creates a savings of even more than these percentages. Since this therapy is not considered practice of medicine by the FDA, determining the cost of prospective treatments can only be estimated by using fees charged by clinics offering treatment in other countries. Currently AASC treatment at reputable clinics for various conditions are as follows: heart disease is generally $20,000, MS ranges from $12, 000 to $18,000, Parkinson's disease starts at $6,000 , Alzheimer's disease begins at $15,000, traumatic brain injury runs $15,000, lung diseases range from $15,000 to $22,000, diabetes type I and 2 runs $15,000, kidney failure is $15,000 and spinal cord injury treatments range from $15,000 to $20,000, to mention a few.

Following is more information on just a few of the diseases which can be successfully treated with AASC.

- Chronic Obstructive Pulmonary Disease (COPD) [aasc-heal-ourselves-copd.pdf]
- Diabetes [aasc-heal-ourselves-diabetes.pdf]
- Heart Disease [aasc-heal-ourselves-heart-disease.pdf]
- Kidney Failure [aasc-heal-ourselves-kidney-failure.pdf]
- Multiple Sclerosis [aasc-heal-ourselves-ms.pdf]
- Parkinson's Disease [aasc-heal-ourselves-parkinsons.pdf]
- View all cost comparisions [aasc-heal-ourselves-cost-comparisons.pdf]

Many more, such as cerebral palsy, autism, macular degeneration, organ failure (transplant), ALS, Alzheimer's disease, paralysis, traumatic brain injuries, bacterial infections, arthritis, and all orthopedic treatments, represent additional opportunities to lower the cost of health care. The potential cost savings per year are calculated over the next nine years and then averaged specifically for heart disease, diabetes, Parkinson's disease, kidney failure, lung disease, and MS.




All things considered this represents a dramatic savings over the cost of conventional medicine to treat these diseases. These calculations involve the estimated expense per patient for conventional medicine; cost for AASC therapy; a 70% success rate for AASC; and new diagnoses less death statistics for ensuing years. These calculations may be conservative as current overseas clinics sometimes charge high fees, once this treatment becomes main stream in the United States domestic competition and innovation will lower charges, and finally, conventional care costs were not increased during the 9 year period for these calculations.

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2 [#sdfootnote2anc] Dent v. West Virginia, 129 U.S. 114, 122-124(1889).

3 [#sdfootnote3anc] Watson v. State of Maryland, 218 U.S. 173-178(1910).

4 [#sdfootnote4anc] Gonzales v. Oregon, 546 U. S. 243, 248-249, 269-270 (2006).

5 [#sdfootnote5anc] Barsky v. Board of Regents of the University of the State of New York, 347 U. S. 442, 449, 74 S Ct. 650, 654, 98 L. Ed. 829,838 (1954).

6 [#sdfootnote6anc] Pub. L. No. 102-493, 3(i)(1), 106 Stat. 3146(codified at 263a-2(i)(1)) (2010).

7 [#sdfootnote7anc] Pub. L.No. 105-115, 214,111 Stat. 2296, 2348 (codified at 21 U.S.C. 396) (2010).

8 [#sdfootnote8anc] Pub. L. No. 106-210, 3502, 114 Stat. 1222, 1226 (codified at 21 U.S.C. 823 (g)(2)(H)(i)).

9 [#sdfootnote9anc] Department of Health and Human Services, FDA Drug Bulletin, "Use of Approved Drugs for Unlabeled Indications," Vol. 12, No. 1. (April 1982).

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Foundation for Alternative and Integrative Medicine | PO Box 2860 | Loveland, CO 80539 | Email