Why Clinics that Use Adult Stem Cells Administered by Physicians Represent a Threat to Industry

[http://www.cellr4.org/wp-content/uploads/2013/06/busta.gif](mailto:Twitter@SCPioneer) Hanson B

It is encouraging that the ongoing debate on current regulations and other obstacles to translation of cellular therapies to the clinic is now offering an opportunity to voice and consider patients and lay organizations’ perspectives [1](http://www.cellr4.org/article/395#link_ajs-fn-id_1-395) , [2](http://www.cellr4.org/article/395#link_ajs-fn-id_2-395). It is important for CellR4 to provide such platform, where patients and scientists could improve communication and reciprocal understanding on why, for example, from a patient perspective evidence-based medicine should not constitute a barrier to try to explore new potential therapeutic strategies and even unproven hypothesis.

My story begins in 2006 when a man posted something about stem cell therapy on an online COPD discussion board. He was immediately branded a quack and a con artist by the moderators and his posts were not allowed. There were a few of us however, who were interested in what he had to say. We tracked him down and learned that he was in his 70’s, had very severe COPD and had flown to Argentina to have autologous stem cell treatment with a doctor there. His improvements were remarkable. He said he had one foot in the grave before getting treated and now he was back to his daily routine and even able to fly internationally to visit his children. I am happy to report that he recently celebrated his 83rd birthday.

To anyone not familiar with COPD, the NIH website states, “COPD is a major cause of disability, and it’s the third leading cause of death in the United States. Currently, millions of people are diagnosed with COPD. Many more people may have the disease and not even know it.

COPD develops slowly. Symptoms often worsen over time and can limit your ability to do routine activities. Severe COPD may prevent you from doing even basic activities like walking, cooking, or taking care of yourself.

COPD, or chronic obstructive pulmonary (PULL-mun-ary) disease, is a progressive disease that makes it hard to breathe. “Progressive” means the disease gets worse over time.”

That description doesn’t begin to cover what someone with severe COPD may be dealing with. Something as simple as taking a shower, laughing or walking more than a few feet can leave one totally out of breath, gasping for air. Panic attacks often accompany those unable to breathe properly. Catching a cold can end up in a hospital stay. Frequent bouts of bronchitis and pneumonia are common. Depression can make a person who suffers from such low quality of life suicidal. Many patients depend on a caregiver to take care of them. The cost to society is enormous, not to mention the cost to individuals and their families.

One of the other ladies who had helped track this man down and I decided we would like to try stem cell therapy too. After discovering the rigors of trying to get to the location of the clinic in Argentina, we faced the reality that it probably was not something either of us were able to physically do since we both were on supplemental oxygen 24/7.

We continued to research and she found a company in California who offered stem cell treatments in Tijuana, Mexico. That location was much more feasible and we made arrangements to get stem cell treatment. Our naivety was only exceeded by our excitement. That was in April, 2007.

We were treated in a small clinic in Tijuana. When we returned to our respective homes, we both became seriously ill. So ill, that she eventually had to be hospitalized. To make matters worse, there was simply no support or information available to patients back then. We both eventually recovered, but realized we were babes in the woods. Desperately ill, we had simply gone off trusting that the clinic we went to was going to produce the same results as the man who had gone to Argentina who was treated by a well known Argentinian cardiologist.

It was at this point that my son suggested we start our own discussion forum. He set it up and the Stem Cell Pioneers [3](http://www.cellr4.org/article/395#link_ajs-fn-id_3-395) site for patient support and stem cell discussion was born. Over the years, it has grown in its scope. While continuing to be completely patient moderated, we do invite a guest host each month from the stem cell community to field questions from members.

One of the hardest parts of being involved in the Stem Cell Pioneers is having members pass away who lived with the hope that stem cell therapy would become an accessible reality for them in their lifetime. This situation, as well as my own success with subsequent stem cell therapy, has caused me to take a hard stance against the overreach of the FDA when it made the decision to regulate our own stem cells as drugs.

It has opened my eyes to the power and profit involved in that decision. I don’t believe such unprecedented regulation is about protecting patients at all, especially not when they’re dying. It’s about protecting those who want to profit from our misfortune of being ill. The amount of money involved is staggering.

Our country is undergoing major political and cultural changes. It seems like everyone is fighting for their civil liberties. Healthy people are able to march on Washington, lobby, hold rallies across the country and gather thousands of signatures almost instantly for one cause or another. Sick people on the other hand are fighting daily just to stay alive. We don’t have the same voice as the healthy. The public has little understanding of our plight, as the media most often seeks its sources from those who have conflicts of interest who tend to make them not support patients being treated with their own stem cells by a physician. Who profits from that? The answer stands out like an elephant in the room. Physicians of course will profit to a small extent, but not like academia and Big Pharma will, as they patent designer type cells and off the shelf stem cell products. Let’s not forget that jobs and research grants also play a huge part. Again, money takes precedence over patients.

The media tends to be so biased and misinformed that a new group was formed by patients to try to force the media to vet its sources and present both sides to the story. I am proudly a member of this group – Patients For Stem Cells [4](http://www.cellr4.org/article/395#link_ajs-fn-id_4-395).

What is particularly degrading is the paternalistic attitude that is given to patients by many in the industry. We hear that we don’t know what’s good for us. We need to be protected. Stem cell treatments are risky. They aren’t ready for the clinic. They can cause tumors and graft vs. host disease. They aren’t proven and therefore we would be fleeced of our hard earned money. We are told that we need to get into FDA approved clinical trials, not seek treatment elsewhere, ad nauseam. When asked to produce published evidence of the risks, most of these “dads” are silent or they bring forth the same worn out stories of some treatment gone wrong that was obviously medical malpractice and unrelated to the stem cells themselves. When confronted with the fact that most patients do not qualify for a clinical trial even if there was one for their disease, they have no answer. When reminded that we are simply asking to be able to access our own stem cells, which would not endanger us getting graft vs. host disease, we still are treated as if we are small children unable to make rational decisions on our own. We are treated as mindless and unable to understand the “science.” It’s degrading and it must stop. Patients should be treated with dignity and respect. That respect includes the right for patients, especially no option patients, to be able to access experimental stem cell treatment by informed consent if they wish.

Academia has brought on a lot of this controversy. If money played no part, there would be few protestations against patients getting treated by their physicians, even if that treatment was experimental. What has been done by researchers is particularly egregious. The holy grail of stem cells has been dangled in front of us for years now by scientists worldwide. Instead of moving forward in the U.S., however, we seem to be slipping back in terms of patient access. We have waited patiently, paid our tax dollars into the coffer to fund research and yet here we are years later mired in a political quagmire and government overreach that has left no option patients now desperately trying to get to offshore clinics to save their lives.

The burden of going offshore is tremendous. Not only the cost in financial terms, but also many sick people have a difficult time traveling to a doctor’s office, let alone to another country. If medical malpractice occurs, patients have no legal options offshore. That is why it is imperative to allow access to patients here in the U.S. to autologous stem cell therapy as the practice of medicine. Protections are already in place as physicians must be licensed in the states in which they practice and carry medical malpractice insurance. A patient registry could be implemented to track patients to help further establish efficacy.

Patients also question why there are no such regulations in place for IVF procedures, blood transfusions or surgeries, so why has the FDA encroached on the practice of medicine when it comes to our own stem cells denying us our civil liberties to use them in clinically relevant treatments? Again, we have to look at power and profits. Even former FDA commissioner Dr. Andrew von Eschenbach, cited current FDA Commissioner Margaret Hamburg’s concession before Congress that, “The FDA is relying on 20th century regulatory science to evaluate 21st century medical products” [5](http://www.cellr4.org/article/395#link_ajs-fn-id_5-395).

He further stated, “Breakthrough technologies deserve a breakthrough in the way the FDA evaluates them. Take regenerative medicine. If a company can grow cells that repair the retina in a lab, patients who’ve been blinded by macular degeneration shouldn’t have to wait years while the FDA asks the company to complete laborious clinical trials proving efficacy. Instead, after proof of concept and safety testing, the product could be approved for marketing with every eligible patient entered into a registry so the company and the FDA can establish efficacy through post market studies” [6](http://www.cellr4.org/article/395#link_ajs-fn-id_6-395).

While I agree with Dr. von Eschenbach when it comes to embryonic stem cells, iPS cells and other designer cells, I don’t think the FDA should be regulating treatments involving our own stem cells at all. There is already a multitude of published data supporting safety. Doctors should not be subject to FDA regulations when performing stem cell transplants utilizing our own stem cells any more than they should when prescribing drugs or doing surgeries. Our own stem cells should never have been lumped in with embryonic stem cells, iPS cells or other designer type stem cells. The FDA either made an enormous mistake by regulating our own cells as drugs, or did so because of power, profits and pressure from those who stand to lose big time if cures or life improvements are dramatic with simple procedures done with a patient’s own stem cells administered by a physician.

The lack of empathy from the public is also troubling to patients. While such an attitude has come to be expected from those with their own conflicts of interest in the industry, it is hard to understand with society in general. I believe the public is simply not aware of the plight of terminally and chronically ill patients because unless you are sick or know someone intimately who is sick, you probably don’t spend much time thinking about it. The media is quite biased as mentioned above, often not vetting sources that may have conflicts of interest or ignoring the opposite viewpoint. They also continue to perpetuate the story that President Bush is responsible for the delay of research and treatments using stem cells. “If it weren’t for Bush we would all be able to access stem cell treatment!” I hear that from otherwise educated people all the time. The media continues to perpetuate this notion because it isn’t interested in doing real investigative reporting. Media continue to recycle the same sources from academia and those with a certain political viewpoint over and over. It’s a tough battle for patients to fight. I also believe that most Americans want to believe that the FDA is protecting us from harm, not doing harm.

My quest to right this wrong continues. I do battle everyday with bloggers, legislators, the media, and the uninformed. I do it because I believe that other patients should be as fortunate as I have been in being able to improve their lives with autologous stem cell treatment. It hasn’t been easy for me either, but at least I know how to fight this fight. Many patients simply don’t.

In February 2012, I received an autologous stem cell treatment that has completely changed my life for the better. Am I cured? No, but the quality of life improvements I have had are remarkable. I wish them for everyone who suffers from any disease. I am now back to doing things that I had given up on. I can plan ahead with no fear that I will have a bad day and have to cancel. I am no longer consumed with thoughts of COPD and all its limitations. I have had no flare ups since the treatment. My spirits are lifted. Life is worth living again because of the healing power of my own stem cells. While I am joyful, many are suffering badly. What an unnecessary travesty.

The moderators on the original COPD blog where I first learned of stem cells are all dead. I don’t know if stem cell treatment could have helped them live longer, but I turn to the example of the man who went to Argentina who is still going strong. I took a trip to visit him. He is a remarkable man who most likely saved my life. Why is it that 7 years later, patients aren’t able to easily access stem cell therapy in clinics all over the U.S.? His voice was stifled years ago because of fear and ignorance. Today our patient voices are still stifled because of fear, but this is a different kind of fear. This is the fear of those who have conflicts of interest losing power and profits if commercial clinics that use adult stem cells administered by physicians are allowed to proliferate.

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# FDA and Pharma: Emails Raise Pay-for-Play Concerns



## by [John Fauber](mailto:JFAUBER@journalsentinel.com) *Reporter, Milwaukee Journal Sentinel/MedPage Today*

For more than a decade representatives of some of the nation's leading pharmaceutical companies paid entry fees running into the tens of thousands of dollars to attend invitation only conferences with FDA and NIH officials, according to a trove of emails provided to theMilwaukee Journal Sentinel/MedPage Today.

The emails, most of which track correspondence among founders of an organization called[IMMPACT](http://www.immpact.org/), academics, NIH researchers, and FDA officials, raise serious questions about the way in which federal regulators interact with the pharmaceutical companies they regulate.

Entry to these meetings was secured by annual fees that ranged as high as $35,000. The drug companies that paid those fees were guaranteed the right to send a representative to the annual meetings of the organization known as IMMPACT, meetings that were also attended by officials from the FDA and other federal agencies..

The IMMPACT web site, states that the organization's goal is to improve the design of clinical trials conducted to develop new pain treatments.

But the emails raise concerns about a possible pay-for-play arrangement in which drug companies were able to buy access to invitation-only meetings where they could meet with FDA officials and possibly influence FDApolicy regarding approval and regulation of analgesics, said [Michael Carome, MD, director of the health research group of the watchdog group, Public Citizen.](http://www.citizen.org/Page.aspx?pid=5140)

"The whole picture is a troubling one and it warrants an independent investigation," said Carome, who has seen the emails.

**Powerful Strategy or Shortcut to Disaster?**

As an example of an initiative that sprung from the IMMPACT meetings, Carome singled out the FDA's new "enriched enrollment" guidance for conducting pivotal trials of drugs. Enriched enrollment allows drug companies to weed out nonresponders or subjects who have adverse reactions to the drug from enrollment in clinical trials.

Experts say that approach makes it much more likely a drug will prove effective and possibly win FDA approval. It's also cheaper for drug companies to conduct such trials.

However, the approach has drawn criticism because it essentially stacks the deck in favor of the drug. More importantly, experts say, drugs tested that way are not likely to reflect what will happen when a drug gets on the market and is prescribed for large numbers of people.

"It's in fact cheating," said Patrick McGrath, PhD, a pediatric pain expert at the Dalhousie University in Halifax, Nova Scotia.

On its web site, the FDA says that enriched enrollment is potentially powerful strategy for the pharmaceutical industry because when used appropriately it can result in smaller studies, shortened drug development time and lower development costs.

"While enrichment won't save a drug that doesn't work, it will help find one that will,"[Bob Temple, MD](http://www.fda.gov/Drugs/NewsEvents/ucm295045.htm), the agency's deputy director for clinical science, wrote in a piece posted on the FDA's web site last December.

**Behind Closed Doors**

The emails represent another example of how drug company money has influenced the practice of American medicine, a concern that has been raised in ongoing investigative reports in the Journal Sentinel/MedPage Today over the last 4 years.

Several of those stories revealed how companies that make opioid analgesics funded various nonprofit organizations that advocated for expanded use of opioids, particularly in treating chronic pain.

That increased use of opioids over more than a decade has been linked to an epidemic of overdose deaths and addiction.

Last year, the [U.S. Senate Committee on Finance, citing reports in the Journal Sentinel/MedPage Today](http://www.medpagetoday.com/PainManagement/PainManagement/32582), opened an investigation into those financial relationships.

The IMMPACT emails, which run for 409 pages, were obtained through a public records request by Craig Mayton, a Columbus, Ohio attorney who has made claims against drug companies in cases where people have died of opioid overdoses. The emails were provided to Mayton by the University of Washington where, Dennis Turk, PhD, one of the founders of the organization, works as a professor of anesthesiology and pain medicine.

Mayton gave the emails to the Journal Sentinel/MedPage Today.

In an email response to questions about the emails, FDA spokesman Steven Immergut, said the agency was aware of concerns raised about the agency's involvement in the IMMPACT organization and "we take these concerns very seriously. We are unaware of any improprieties..."

In an interview, Douglas Throckmorton, MD, the FDA's deputy director for regulatory programs, said FDA officials who attended the organization's meetings were listening to scientists, not setting policy.

"Pay-for-play is just not the way the FDA operates," Throckmorton said. "That's not part of the culture of the FDA."

He said that while enriched enrollment may have been discussed at the organization's meetings, the FDA's decision to endorse of the concept did not come entirely from the meetings.

The emails paint a picture of another way in which drug companies can exert influence on the practice of medicine.

In a 2003 email, Raymond Dionne, an official with the National Institutes of Health, raised a concern about the closed, invitation-only nature of the organization's meetings and suggested open meeting on the NIH campus.

"The major advantage of having the meeting on the NIH campus would be the ability to open the meeting to all interested parties and avoid the stigma that this initiative is a 'pay to play'process," Dionne wrote.

A day later, Dionne wrote in an email that IMMPACT was inviting criticism that is it "paid for by a few large pharmaceutical firms who are assumed to be influencing the outcomes."

**Brown Bagging It**

In another email about 2 weeks later, Dionne tells IMMPACT that he and other federal officials "if they play by the book" should not accept dinners for meetings at the Four Seasons Hotel.

"I may even bring a brown bag," Dionne says.

In response, [Robert Dworkin, PhD](http://www.urmc.rochester.edu/people/23059177-robert-h-dworkin), the other co-founder of IMMPACT, told Dionne that, if he wished, the organization would order "inexpensive sandwiches for lunch for the government folks."

"The rest of us undoubtedly will feel guilty, but we will probably resist the temptation to have tuna fish in respect for your plight," added Dworkin, a professor at the University of Rochester Medical Center.

Renate Myles, a spokeswoman for NIH, said that because of the federal government shut down she could not provide a response for this story.

Many of the academics invited to the organization's meetings were offered payments of about $3,000 to attend. In a 2002 letter from Turk, the University of Washington professor who is a co-founder ofIMMPACT, a $3,000 honorarium was offered to Robert Rappaport, MD, who heads the FDA division that regulates analgesics, to attend an IMMPACT meeting in Annapolis, Md., The FDA said the payment was not accepted.

In an interview Turk, acknowledged that, dating back to 2002, drug companies paid between $20,000 and $35,000 each to be able to send one representative to the 16 meetings held by the group.

Nearly all the meetings were held over 2 days at high-end hotels in the Washington, D.C. area., Turk said.

Between 25 and 50 people, including regulators, academic researchers and drug company representatives attended each event.

"There was no attempt to do anything more than answer some questions," Turk said.

After the meetings, consensus papers that listed drug company officials, federal health officials and academics as the co-authors were published in various medical journals.

Dworkin, said no more than than one person from any one drug company was allowed to attend the meetings and it was encouraged that companies send researchers, not marketing people.

Dworkin acknowledged that the emails might raise ethical concerns.

"Yes, some of the emails that Dennis and I sent back and forth ... looked problematic on the surface, but the fact of the matter is it was a model that worked that no one complained about," said Dworkin, a professor and pain expert at the University of Rochester Medical Center.

The organization's website lists 11 drug company sponsors, including several that make narcotic painkillers.

In an email, James Heins, a spokesman for Purdue Pharma, the company that makes the narcotic painkiller, OxyContin, said the pharmaceutical industry has been an important participant in the organization's program.

"Our experience conducting clinical trials is valuable to academia and the FDA, especially in improving clinical trial design for analgesics," Heins said.

In an email, Greg Panico, a spokesman for the Janssen Research & Development, said it funded the organization to help improve clinical trials involving pain drugs. Janssen's, parent, Johnson & Johnson, is listed as a corporate sponsor on the organization's web site.

"Our company believes in working collaboratively in public-private efforts to pursue scientific innovation," Panico said

## Compare deaths from medicines, vitamins, and all US wars

by Jon Rappoport  
October 7, 2013  
[www.nomorefakenews.com](http://www.nomorefakenews.com/)  
  
People want to believe medical science gives us, at any given moment, the best of all possible worlds.  
  
And of course, the best of all possible worlds must have its enemies: the quacks who sell unproven snake oil.  
  
So let's look at some facts.  
  
As I've been documenting in my last several articles, the medical cartel has been engaged in massive criminal fraud, presenting their drugs as safe and effective across the board---when, in fact, these drugs have been killing and maiming huge numbers of people, like clockwork.  
  
I've cited the review, "Is US Health Really the Best in the World?", by Dr. Barbara Starfied (Journal of the American Medical Association, July 26, 2000), in which Starfield reveals the American medical system kills 225,000 people per year---106,000 as a direct result of pharmaceutical drugs.  
  
I've now found another study, published in the same Journal, two years earlier: April 15, 1998; "Incidence of Adverse Drug Reactions in Hospitalized Patients." It, too, is mind-boggling.  
  
The authors, led by Jason Lazarou, culled 39 previous studies on patients in hospitals. These patients, who received drugs in hospitals, or were admitted to hospitals because they were suffering from the drugs doctors had given them, met the following fate:  
  
Every year, in the US, between 76,000 and 137,000 hospitalized patients die as a direct result of the drugs.  
  
Beyond that, every year 2.2 MILLION hospitalized patients experience serious adverse reactions to the drugs.  
  
The authors write: "...Our study on ADRs [Adverse Drug Reactions], which excludes medication errors, had a different objective: to show that there are a large number of ADRs even when the drugs are properly prescribed and and administered."  
  
**So this study had nothing to do with doctor errors, nurse errors, or improper combining of drugs. And it only counted people killed who were admitted to hospitals. It didn't begin to tally all the people taking pharmaceuticals outside hospitals who died as consequence of the drugs.**  
  
I found the link to this study at the Dr. Rath Health Foundation, in the middle of a very interesting article by Dr. Aleksandra Niedzwiecki: "Commentary on the Safety of Vitamins."  
  
Here are two key quotes from her article:  
  
**"In 2010, not one single person [in the US] died as a result of taking vitamins (Bronstein, et al, (2011) Clinical Toxical, 49 (10), 910-941)."  
  
"In 2004, the deaths of 3 people [in the US] were attributed to the intake of vitamins. Of these, 2 persons were said to have died as a result of megadoses of vitamins D and E, and one person as a result of an overdose of iron and fluoride. Data from: 'Toxic Exposure Surveillance System 2004, Annual Report, Am. Assoc. of Poison Control Centers.'"**  
  
Summing up:  
  
No deaths from vitamins (2011), and three deaths (2004) from vitamins (plus fluoride!).  
  
106,000 deaths every year from pharmaceutical drugs (Starfield).  
  
Between 76,000 and 137,000 deaths from pharmaceutical drugs every year in hospitalized patients (Lazerou).  
  
The FDA and its "quack-buster" allies go after vitamins, demean "unproven remedies," and generally take every possible opportunity to warn people about "alternatives," on the basis that they aren't scientifically supported.  
  
Meanwhile, the very drugs these mobsters are promoting---and in the case of the FDA, CERTIFYING AS SAFE AND EFFECTIVE---are killing and maiming people at a staggering rate.  
  
The masses are treated to non-stop PR on the glories of the US medical system.  
  
In the Wikipedia entry, "US military casualties of war," the grand total of all military deaths in the history of this country, starting with the Revolutionary War, is 1,312,612.  
  
In any given 10 years of modern medical treatment? 2,250,000 deaths.  
  
Consider how much suppression is necessary to keep the latter number under wraps.  
  
Jon Rappoport  
The author of two explosive collections, THE MATRIX REVEALED and EXIT FROM THE MATRIX, Jon was a candidate for a US Congressional seat in the 29th District of California. Nominated for a Pulitzer Prize, he has worked as an investigative reporter for 30 years, writing articles on politics, medicine, and health for CBS Healthwatch, LA Weekly, Spin Magazine, Stern, and other newspapers and magazines in the US and Europe. Jon has delivered lectures and seminars on global politics, health, logic, and creative power to audiences around the world. You can sign up for his free emails at NoMoreFakeNews.com.

First treatment in 2007. Pioneering ever since.  
  
Barbara