CellR4 2013; 1(2): E401

ARE EXCESSIVE REGULATIONS PROHIBITING DOCTORS FROM TRYING TO CURE PATIENTS?

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Keywords: Stem cells, Regulatory, Cell therapy, Ethics, Safety, FDA.

Imagine you are one of the millions of patients suffering from illness or injury who has lost the ability to lead a "normal" life. New discoveries reveal the tools to save lives in the patients' own bodies, but the FDA forbids doctors to use these tools.

I was injured in a car accident more than two decades ago. As my back and knees rapidly deteriorated, I began researching alternative ways of treating them. I rejected traditional surgical options for my conditions because they are invasive and risky, and frequently lead to further surgeries and drug dependencies. Aware of the potential of stem cell therapies to revolutionize the practice of medicine, I was optimistic that my own stem cells could heal me. As soon as my hopes rose, they were dashed: I discovered the FDA, in an unprecedented case of bureaucratic overreach into the practice of medicine, had defined a person's own stem cells as "biological drugs." This designation makes the use of one's own stem cells subject to FDA regulation, as opposed to being classified as "medical procedures" regulated by state medical boards[1].

Surgeons transplant hearts and other body parts on a routine basis; these are classified as "medical procedures" and not subject to FDA approval. There are many stem cells in a transplanted heart, for example, yet heart transplants are classified as "medical procedures." In Vitro Fertilization (IVF) is considered a "medical procedure." IVF involves using sperm cells from one person, egg cells from another person and manipulating them in a lab to create a third person. In the case of surrogacy, this highly manipulated material is implanted into a fourth person. The entire process is defined as a "medical procedure," therefore IVF is not subject to FDA regulation. However, taking one's own cells, manipulating them and injecting them back into one's own body now causes those cells to be classified as drugs.

"[Dr. N.] Riordan believes the FDA's regulation of stem cells is misguided. Speaking at a conference last July in Arizona, he said the FDA needs to view stem cells as what they are – human tissue – not a drug. He pointed out that hearts, lungs, kidneys, corneas, skin and other organs are transplanted in the U.S. every day, all without FDA approval. 'The drugs that suppress your immune system so you can receive that heart and survive – those are FDA approved, but the transplant isn't. It's a procedure. It's exempt. I think ultimately these (stem cells) should be exempt as well, and should fall under the practice of medicine. That's my opinion'"[2].

According to Robin R. Young, medical technology expert, in the New York Stem Cell Summit '12 Adult Stem Cell Fact Sheet, "Harvesting stem cells from adult patients and then re-injecting them into the same patient has been a routine therapy in U.S. medicine for decades. More recently, as stem cell research has developed, the precise method of harvesting, processing and then re-injecting into patients has changed and improved. Roughly one million patients have been treated with their own stem cells since the mid-1980s in the United States. The most common therapeutic use of stem cells by physicians in the United States is to harvest them from one part of the body where they exist in greater amounts and then re-implant them at the site of injury – where they are most needed but are in short supply. For adults with diminishing stores of stem cells, this is an effective way to stimulate healing at sites of injury. Frankly, this process of harvesting cells (be they bone marrow, skin, fat or any other cells) from one part of the body and then re-implanting them in another part has been an important

aspect of medicine for, literally, hundreds if not thousands of years."

Dr. Chris Centeno, who is suing the FDA over this issue, said, "We see this lawsuit as a 21st century civil rights issue that will define what control you have about the use of your own cells and tissue. If a loved one is dying in intensive care and a well done study shows that the patient's own cells can be used to help, does the patient get to decide to use those cells, or is that a decision for the FDA? Will the patient still be alive while we wait on Washington to issue this decision?"[3].

The FDA's action in classifying autologous stem cells as drugs is a prime example of regulatory capture. Regulatory capture occurs when an agency, which ostensibly exists to protect the public interest, becomes beholden to and dominated by the industry it was intended to regulate. The result is the agency, in this case the FDA, inevitably acts in ways that favor the industry it is supposedly regulating; it is analogous to the "revolving door" of politicians and lobbyists. According to Dr. Marcia Angell, former editor of the New England Journal of Medicine and author of *The Truth About the Drug Companies*, "Over the past two decades the pharmaceutical industry has moved very far from its original purpose of discovering and producing useful new drugs. Now, primarily a marketing machine to sell drugs of dubious benefits, this industry uses its wealth and power to co-opt every institution that might stand in its way, including the US Congress, the FDA, academic medical centers and the medical profession itself"[4].

Professor Mary Chirba, Ph.D. in Public Health from Harvard and Professor of Healthcare Law at BC College, disagrees with holding the use of one's own stem cells to the regulatory standards of those regarding the use of allogeneic stem cells because use of one's own stem cells is not a public health threat. "In her submission to the FDA, Professor Chirba critiques changes made to the regulations by the FDA without public comment. In 2006, the FDA replaced the wording regarding the use of tissues 'into another human' with the wording 'into a human.' Although it involved only one tiny word swap, it completely redefined the circumstances which draws the line between practice of medicine, where a physician uses tissues from the patient being treated, and drug therapy, where a physician uses tissues from a separate donor. Dr. Chirba's suggestion to the FDA is to treat autologous stem cell therapies not as it treats drug therapies, but rather to treat them in the same capacity as IVF therapies. This would make regulations less burdensome and allow autologous adult stem cell therapies…to come to market much quicker[5].

"We got off track in America because adult stem cells are confused with embryonic stem cells," according to stem cell patient Michael Phelan. "You have [both] religious and financial interests halting progress in America. [Autologous] adult stem cells can't be patented, limiting the financial incentive. Plus, there are… stem cell 'experts,' whose research is in embryonic stem cells, spreading misinformation about adult stem cells. As a result, the FDA created a new 'minimally manipulated' threshold, which gives them authority over a medical procedure. This is a crime against ill people who can't afford to travel overseas for treatment. America should be fast tracking this treatment, not slowing the adoption process to the crawl involved in drug approval." The FDA requirements, designed for products manufactured and sold on a mass scale, can't be readily satisfied when it comes to treatments that are personalized to individual patients. This is a medical procedure, not a drug. Phelan cites Former FDA Deputy Director Scott Gottlieb's position that urged the FDA to let adult stem cell treatment proceed in the U.S., unencumbered by unnecessarily oppressive regulations[6]. This "minimally manipulated" standard is so poorly written that many doctors and researchers cannot agree upon what "minimally manipulated" means. Doctors were shocked to receive letters from the FDA stating that their work constituted the creation of a "biological drug" under these new, nebulous standards.

Safety and ethics are red herrings in the debate over autologous stem cells. If heart transplants had been held to these new regulatory standards, they would never have become standard practice of medicine. Autologous stem cells, administered properly, have been found safe in numerous studies, despite some media articles that portray autologous stem cells as risky. We, as members of Patients For Stem Cells, appreciate the CellR4 Journal's efforts to promote an accurate depiction of the benefits derived from such therapies while exposing the biases of those who seem to portray all physicians providing these therapies as purveyors of snake oil[7-11].

I have already spent a fortune over the last two decades on FDA approved, standard of care medications and treatments for my back and knees, to no avail. Moreover, many of my medications and approved treatments have dangerous side effects or simply do not work at all. I find those treatments to be unsafe and unethical. I find it unethical that, under the current FDA overreach, I will be forced to travel outside the US for autologous stem cell treatments for my back conditions. I find it unsafe and unethical that the currently approved treatment options for my back and knees are invasive, risky, and typically lead to additional surgeries and life-long drug dependencies. FDA approved drugs have to only be slightly more efficacious than placebos to get approval in many cases. How is that safe or ethical? FDA approved drugs are one of the leading causes of death in this country. How is that safe or ethical?[12-15].

Autologous stem cell treatments are being defined as drugs to protect the pharmaceutical industry's profits, as the FDA admitted in court[16,17]. Regulating one's own stem cells in the same manner as mass-produced pharmaceuticals places undue burdens on physicians and stifles medical innovation[18]. Allowing patients to use autologous stem cells will revolutionize the practice of medicine in this country. Our own cells provide doctors with the potential to cure or ameliorate many chronic diseases, illnesses and injuries in a safer, less invasive and more cost effective manner. The potential overall health care savings are enormous and the societal benefits incalculable. Imagine disabled people returning to the workforce; imagine fatal disorders becoming temporary problems. Imagine debilitating, chronic pain becoming a warning that something needs to be fixed, rather than a life sentence.

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