

## LETTER TO THE EDITOR

# Position statement on the sale of unproven cellular therapies for spinal cord injury

The International Campaign for Cures of Spinal Cord Injury Paralysis

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Over the past few years, it has become possible for people with spinal cord injury (SCI) to purchase experimental treatments, often involving transplantation of 'stem cells' or other cells or tissues. These cell-based therapies are advertised as having beneficial effects, leading to some recovery of function, even though there is little or no evidence supporting such claims. Generally, these interventions are provided in countries where government regulation for consumer protection is less comprehensive or effective than in many developed countries.

This trend is of concern for several reasons. People with SCI, as with any serious medical conditions, are highly susceptible to advertisements promising recovery, even when the costs are high and potential risks are unknown. It is morally unacceptable to prey on and profit from their hope for a cure. We believe that it is unethical to charge these patients for experimental interventions that are not yet proven safe and effective by properly conducted clinical trials.

Frequently, providers of these treatments attempt to establish a veneer of credibility by citing experimental studies, where they have no direct association. Most often the critical scientific data to support the safety and efficacy of the new treatments are lacking, so they rely on testimonials from patients or their family members. Patient-reported anecdotes are not a substitute for medical evidence. First, there is a significant placebo effect, especially in neurological diseases which functions such as sensation, spasms or residual movements can vary daily. The only accurate way to determine that a treatment is beneficial is to carry out a properly designed study with a placebo-treated 'control' group. Individuals or institutions selling therapy to-date have not carried out controlled trials with valid methods and outcome measures recorded by blinded observers. Second, because of a clear conflict of interest, it is not acceptable that those who profit from providing the treatment should also carry out the evaluation of efficacy and safety.

Most cell-based treatments carry safety risks, many of which are common to surgery and transplantation in general. These risks can be significantly higher in people living with SCI and are currently not balanced by any reliable assurance of benefit. Thus, it is essential that anyone offering non-standard treatments for SCI provide rigorous

long-term clinical follow-up at no charge to assess fully the risks versus benefits. Although highly experimental and potentially dangerous therapies may be more readily justified in people who have terminal conditions, the risk of using these therapies should be tempered by the fact that patients with SCI who receive standard medical care can anticipate a near-normal life span.

The risks and costs of untested therapies are not limited to the individuals who pay for such treatments. These interventions undermine objective scientific studies that would help other people with SCI. First, these individuals are likely to be excluded from subsequent involvement in scientifically valid clinical trials because of potential interference from the first intervention. Second, unsuccessful treatment of SCI with poorly characterized or unvalidated 'stem cells' in uncontrolled trials can undermine enthusiasm for future developments of valid stem-cell technology. Third, it may not be possible to recruit an adequate number of participants for valid clinical trials if potential participants have instead chosen to undergo uncontrolled, for-profit treatments. Thus, there is a cost to society, as well as for people with SCI when 'for-profit' therapies are offered and purchased.

We do not rule out the possibility that cellular therapies may improve function and quality of life for recipients and justify the risks, but insist that the onus is on the providers to deliver such proof from a valid clinical-trial program. It is unethical to sell unproven therapies, we do not advise patients to volunteer for such treatment procedures. Unfortunately, in the context of an entrepreneurial enterprise, it is unlikely that accurate, reliable or useful medical evidence will ever be generated.

More information on questions that should be asked of someone offering a treatment for SCI is available in the free document, 'Experimental Treatments for Spinal Cord Injury: What you should know'. This is available in several languages at the International Campaign for Cures of Paralysis ([www.campaignforcure.org](http://www.campaignforcure.org)). This statement has been endorsed by the member organizations of the Institute for Certification of Computing Professionals.

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