

# Ready or not? A role play on taking stem cells to the clinic

## Biography: Stem cell scientist (on the committee)

**Name:** *Make up a name for yourself*

**View:** Concerned about the quality of the data

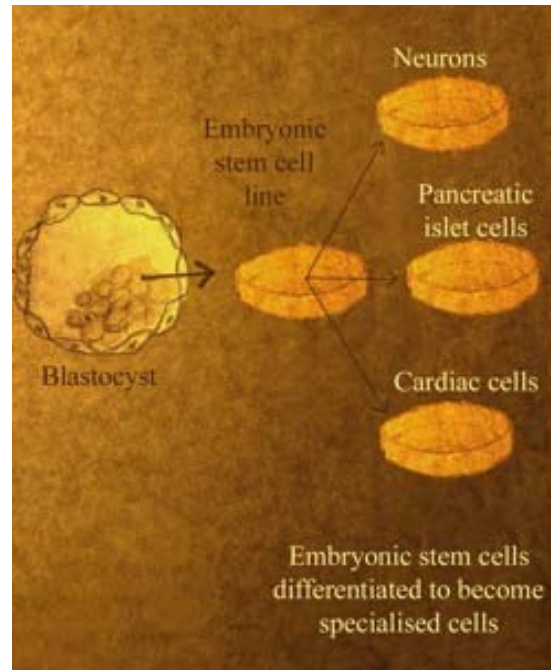
You are Head of the Stem Cell Biology department at a prestigious university. As a result of your research, you imagine stem cells as playing a decision game: whether to make more copies of themselves or become specialized cells. You are currently one of the leading scientists in the field.

You work with embryonic stem cells, obtained from human and mouse embryos. You believe that embryonic stem cells offer the greatest potential for understanding the behaviour of stem cells in the laboratory and, ultimately, in therapy. You are sceptical about the feasibility of treatments, which claim that tissue stem cells (such as those in bone marrow) can be directed to become a completely different type of cells (for example, a nerve cell).

You do not understand why people are against research using embryonic stem cells, and are very disturbed by the 'emotional arguments' used against this type of research. In your view, it is irrational to ascribe greater value to a ball of cells - that contains no heart, no lungs or brain - than to a young person who faces the prospect of being permanently paralyzed due to injury. Furthermore, this ball of cells would otherwise be destroyed or kept frozen for a few years and then discarded, which you see as a waste.

You have serious concerns about reports of patients undergoing unregulated stem cell treatments and therefore applaud Stem Cell Therapeutics for going through a rigorous clinical trial. Unregulated treatments make it very difficult to properly assess the benefits and risks of stem cell therapy, such as the risk of tumour formation by stray embryonic stem cells that may be transplanted into the patients.

You hope your own research will ultimately lead to clinical applications of stem cells, such as the one proposed by Stem Cell Therapeutics, and do not want to run the risk of a premature clinical trial causing a backlash against science, if anything goes wrong. Thus, in reviewing Stem Cell Therapeutics' application your main concern is the quality of their pre-clinical data. Is it sufficient for a clinical trial to begin, or just interesting data that indicates the need for further laboratory research? For example, you want to know whether scientists have shown that the injected cells made working connections with the cells already in the spinal cord of the animals they used in their experiments.



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## Biography: Bioethicist (on the committee)

**Name:** *Make up a name for yourself*

**View:** Concerned about patients' expectations

You are a bioethics lecturer at a university. You deal with the questions that biological research and its applications raise which touch on moral and ethical views. You have dedicated much of your time to researching the ethical issues raised by embryonic stem cell research and its application to therapy.

You are particularly interested in the ethics of involving patients in clinical trials in the haste to move stem cells into the clinic. Is this ethically acceptable, in light of the current state of research? Or are patients being improperly used as 'guinea pigs' in the pursuit of fame, professional advancement and financial reward by scientists, doctors and companies?



You are concerned that the desperate patients encouraged to take part in clinical studies are not properly informed of the risks and goals associated with a Phase I trial (safety, feasibility and maximum tolerated dose), or led to expect greater improvements than the therapy is actually able to offer. Both scenarios have the potential to cause great distress and disappointment, as well as potential long-term harm.

Another major ethical question raised by embryonic stem cell research is whether the end justifies the means. The end is to ease human suffering; the means involves using human embryos. Different people will take different positions on this question, which will be strongly linked to their view on the status of the embryo. Is the blastocyst, from which embryonic stem cells are obtained, nothing more than a ball of cells? Is it a potential person, which should be afforded as much protection as a newborn child? The first view allows any research to be carried out on embryos. The latter view excludes any research or use of an embryo, other than for implantation in a womb, for gestation and birth.

There is also the distinction between carrying out research on surplus IVF embryos and creating new embryos specifically for research (using donated eggs and sperm or through therapeutic cloning). In this case the issues have to do with the intention with which the embryos are created. Several bioethicists argue that it is more justifiable to use those embryos created specifically for research with no possibility of implantation, than the surplus IVF embryos, which were originally created with a view to their possible implantation and full gestation to birth.

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Biography: Biotech entrepreneur/ CEO of Super Cells, Ltd. (in the audience)

**Name:** *Make up a name for yourself*

**View:** Emphasize importance to our national economy

You are the Chief Executive Officer (CEO) of Super Cells, a biotechnology company which you helped set up in 2000, after 10 years as a neuroscientist in a university laboratory. Super Cells specialize in producing the liquid medium in which stem cells grow in the laboratory. Your company has recently developed a liquid medium that is completely free of any animal products; therefore the human cells grown in this media will not become contaminated with animal viruses. You are selling this medium to research laboratories and big pharmaceutical companies, as a safer alternative to existing media.



You have a strong interest that clinical trials for cellular therapies should be given the go-ahead. You know that this is crucial if your company is to get a return on its investment: any stem cells used in the clinical trials will be grown in your media. The profits from these sales will allow Super Cells to finance other research projects aimed at developing new, even better products for stem cells, which would allow the company to grow further.

You make the point that we are in a race: if companies here do not pioneer clinical trials, companies in other countries will. As a nation, we have done well to stay at the forefront of stem cell research, but, we could be losing out on a momentous opportunity for scientific, medical and economic progress that would surely have long-term implications for the well-being of the nation.

Remind everyone that biotechnology companies here must compete with other, often better funded companies in other European countries, in the United States and, increasingly, in the Far East. You are concerned that, if this clinical trial, which would be run by a company here, is not given the go-ahead, the door will be opened to other (foreign) companies. Moreover, if the clinical trial does not take place, you are concerned that entrepreneurs like yourself may become wary of setting up their businesses here and will turn to other, more attractive, sites.

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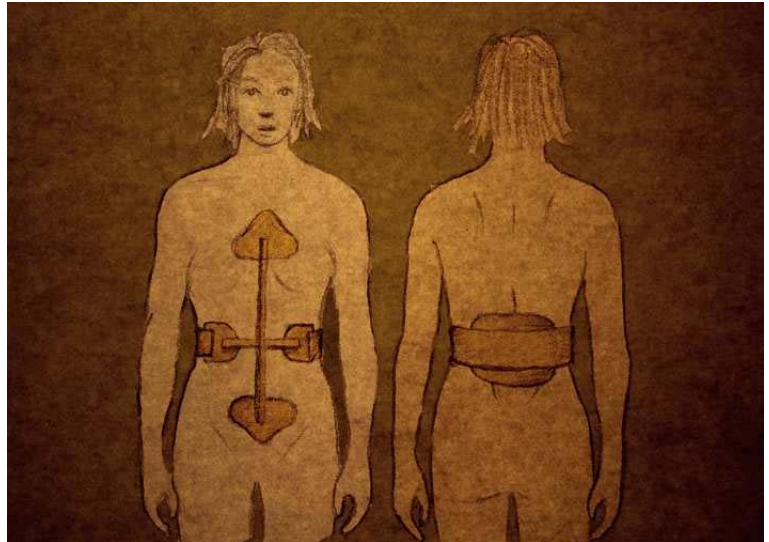
## Biography: Disability rights group representative (in the audience)

**Name:** *Make up a name for yourself*

**View:** Concerned about exploitation of disabled people

You campaign for the rights of disabled people, such as access to health care, equal employment rights and benefits. You argue that the exclusion experienced by disabled people is a consequence of the way society is organized and should be challenged at a society rather than individual level. Ten years ago, you set up the support group Empower to lobby politicians and decision-makers into improving conditions for the integration of people with a disability.

You are very concerned that disabled people are being used to advance the ambitions of politicians and scientists, and the thirst for profit of private companies.



Remind everyone that many disabled people are more interested in getting on with their lives as fully as possible rather than waiting for some 'saviour science'. For them, the hype around cellular therapies is detrimental to the struggle for everyday social justice that all disabled people face.

Furthermore, because of all the hype around stem cells, many disabled people are not getting on with their rehabilitation (for example, with physiotherapy) because they see the cure as being just round the corner.

In your view, embryonic stem cell therapy is still in a very experimental phase and has not been proven to be safe or effective. You advocate that the time and money being spent on developing stem cell therapies would be better employed in developing already proven, low-technology solutions to paralysis, such as electrical implants, providing information or challenging discriminatory attitudes.

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Biography: Coffee shop owner / interested member of the public (in the audience)

**Name:** *Make up a name for yourself*

**View:** Fears scandals around stem cell therapies

You are the owner of a local coffee shop. You thoroughly enjoy your job as you get to talk to all types of people. It was during one of these conversations that you heard about the trial that Stem Cell Therapeutics is planning. You regard this whole situation as a scheme by scientists, doctors and politicians to sell yet another high-tech, expensive, as yet unproven whim to the public.

You are highly skeptical of all the hype around breakthroughs in science and medicine. You have read about many overseas clinics advertising miraculous stem cell therapies for a wide range of incurable diseases. The organized travel to these clinics is referred to as 'stem cell tourism'. This is currently a source of concern for reputable stem cell scientists. These international clinics are proposing expensive therapies that have not been tested for safety or for effectiveness. On websites and in marketing campaigns, some of these clinics claim that 80 % of their patients have been helped. However in the past few years, patients who visited unregulated international clinics have died as a result of receiving unproven, untested stem cells.

You have much sympathy for spinal cord injury patients, and have even lobbied for improved wheelchair accessibility in your city. However, you are worried that this clinical trial may be just another ploy to advance the interests of the company and scientists, at the expense of the hopes and expectations of wheelchair-bound people.



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## Biography: Neurosurgeon (on the committee)

**Name:** *Make up a name for yourself*

**View:** Patients are being offered false hope

You are a neurosurgeon at the Women's and Children's Hospital. In your job, you often see patients who have suffered horrific accidents, which have severely injured their spinal cords. You keep up to date with the latest developments in treatments for spinal cord injury, from both research laboratories and clinics. You are always willing to try new things, and to support clinical trials of innovative methods, as long as the science is robust and there is evidence that the treatments will be safe.

You are very much aware that stem cells have a somewhat magical connotation, that they're often seen as all-powerful, the magic bullet that's going to solve all problems in medicine. You have felt the pressure from your patients and their families to perform stem cell transplants, however risky they might be. Yet, you know that spinal cord injury is a very complicated type of lesion, which is unlikely to be solved by just injecting a few cells.

You know perfectly well that improved movement of mice and rats after they have been injected with stem cells does not necessarily mean that patients will show similar improvements when given the same treatment.

Whenever you see reports of a new miracle treatment being promised which is just round the corner, you become very concerned that patients are being offered false hope. You worry that patients are being used as 'guinea pigs' in the eagerness of scientists, doctors and companies to show that stem cell therapy works and that patients are not fully informed of the risks involved. For example, the patients taking part in the trial by Stem Cell Therapeutics would have to have their immune system dampened (be immunosuppressed), which would make them more susceptible to infections, some of which may have serious consequences.

You are mindful that scientists and doctors in countries all over the world are working hard to develop new treatments for this debilitating injury. You plead for controlled stem therapy clinical trials and scorn unregulated, unproven cell transplants that may cause great detriment to patients and to the entire stem cell research field.



# Ready or not? A role play on taking stem cells to the clinic

## Biography: Spinal cord injury patients' group representative (on committee)

**Name:** *Make up a name for yourself*

**View:** Considers the needs of ALL spinal cord patients

You are an executive of Spinal Support, an organization that supports families and friends of those who have suffered spinal cord damage. Spinal Support's mission is to support the integration and full participation of its members by encouraging and enabling them to take control of their lives. Spinal Support provides information on rehabilitation and therapy, education, legal issues and research. You consider new treatments for spinal cord injury from the perspective of the patient.



You are committed to ensuring that if Stem Cell Therapeutics' clinical trial is successful, then all patients who may benefit from it will have access to treatment, rather than only those who can afford it.

You know that the treatment proposed by Stem Cell Therapeutics will benefit only those patients with recent spinal cord injuries. Patients with non-recent injuries will not reap any benefits from this procedure. You have to consider the needs of all spinal cord injury patients. Given the limited resources that are available, it is crucial to be able to prioritize the best means of integrating patients into their communities.

As a trained physiotherapist who specialized in rehabilitation of people with spinal cord injuries, you are very conscious of the potential of cellular therapies. Spinal Support backs stem cell research, including work involving human embryos. The organization is convinced that only through the increased knowledge and understanding of stem cells will clinical applications benefit patients and be safe.

During your experience as a physiotherapist and at Spinal Support you have come across many patients who are desperate and will grasp at any medical intervention that may give them hope of recovering from their injury. You are aware that these patients are susceptible to pressure from companies and doctors to try therapies that have not been tested in proper investigative settings. Such therapies may carry serious risks.

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Biography: Pro-technology activist / technology advocate (in the audience)

**Name:** *Make up a name for yourself*

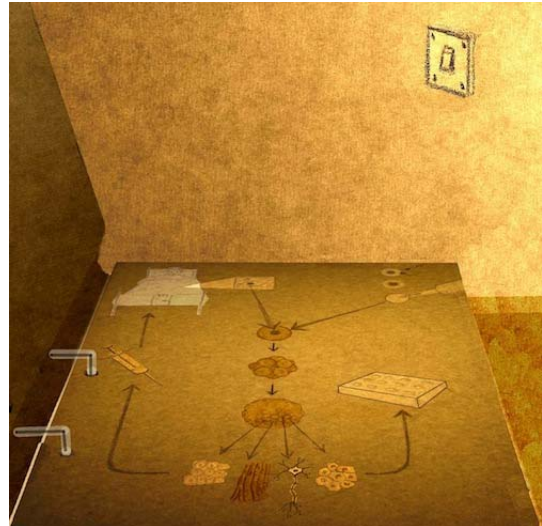
**View:** Advocates the use of technology to improve quality of life

You believe that all available technology should be used to make us live longer, and be physically stronger, psychologically healthier, more intelligent, and have more control over our lives. This includes being able to choose how we want to look, and how our children look, as long as it is ethically acceptable.

We should embrace research on human embryonic stem cells, and all its derivations, such as therapy and cloning. It is obvious to you that embryonic stem cells offer much greater potential for treating disease and delaying ageing than tissue (adult) stem cells.

You know that one of the problems with transplanting stem cells into a patient is that the cells may be rejected by the patient's immune system. Rather than giving the patient medicines to dampen his/her immune system, you think that Stem Cell Therapeutics should enhance their activities to make iPS technology suitable for clinical applications. They should use this technology to make cells identical to embryonic stem cells from the patient's skin cells. They should then use the iPS cells to make the oligodendrocytes that are needed, and inject these into the patients' spinal cord. By doing this, they could be certain that the injected cells are identical to those of the patient, and will therefore not be rejected by the patient's immune system.

You are disappointed that Stem Cell Therapeutics are not being ambitious enough in using the most advanced technology that is available to them – iPS cells. You consider any trial that uses existing stem cell lines for therapy to be a waste of time.





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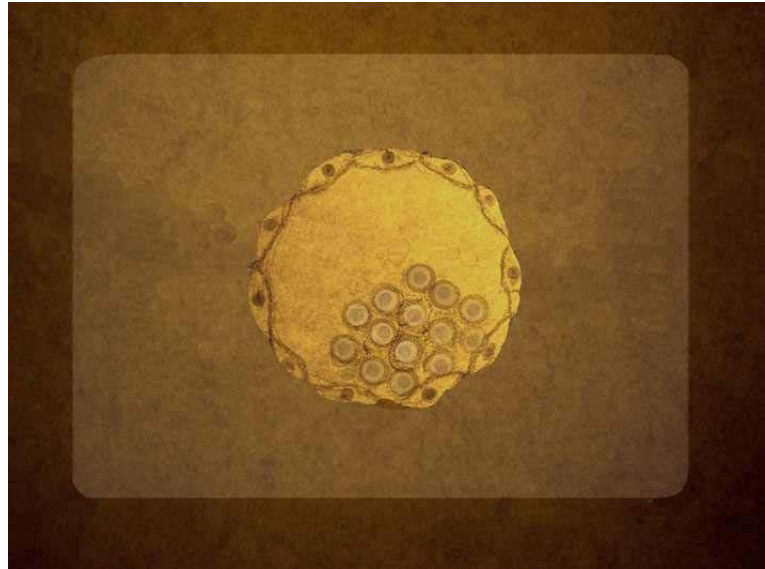
## Biography: Pro-life activist (in the audience)

**Name:** *Make up a name for yourself*

**View:** Protects human life in all states of development

You are against any act that leads to the intentional ending of innocent human life. You are, therefore, against all research using human embryonic stem cells, since it involves the destruction of a living human embryo. To you, it is tantamount to embryo abuse.

You believe we have an obvious duty of care to the vulnerable and voiceless, and see the not-yet-born human as especially vulnerable owing to his/her situation of complete physical dependence and obvious voicelessness. There is a single, uninterrupted period of growth and development from the moment the male sperm fuses with the female egg inside the womb, until a baby is born, grows up and becomes an adult. To obtain embryonic stem cells, scientists must open the embryo and extract its cells, thereby killing it in the process.



Remind people that everyone in the room was once embryo, and so it is obvious that embryos are very human and as such have human rights. Experimentation upon human life at any stage of development has no place in a civilized society. It cannot ever be justified, even if the aim is to save other human lives. The end does not justify the means!

You are concerned that, by allowing this clinical trial to go ahead, it will open the flood gates for other trials wanting to use embryonic stem cells. Scientists will then have to create more stem cell lines, from which to obtain embryonic stem cells, which will mean the destruction of ever more embryos. You can envisage a point when the existing surplus IVF embryos will run out, and scientists will then have to turn to creating new embryos, including cloned embryos, solely as a source of stem cells. For you, this is a slippery slope and totally unacceptable and fear that this may lead to the exploitation of women.

Pro-life arguments aside, stem cell research does not have to involve embryo experimentation. Indeed, tissue (adult) stem cells have already been used successfully in treatment of cancers, burns and blindness, while the possibilities of treatments using embryonic stem cells are, at present, just pie in the sky. You have read about iPS technology where patients' cells can be genetically reprogrammed back to an embryo-like state, grown in a laboratory and used to develop cellular treatments. This would eliminate the need for the procurement and use of embryos for scientific research.

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## Biography: Student with a spinal cord injury (in the audience)

**Name:** *Make up a name for yourself*

**View:** Balance the rights, interests and welfare of patients with those of society

You are 20 years old and have been accepted at a prestigious university to study Architectural Design. You love sport and music. You play the guitar. When you were 17, you were in a devastating car accident, which left you paralyzed from the waist down.

Since your accident, you have become acutely aware of the extra care you must put into keeping your body well and strong. You keep a healthy diet and exercise regularly to keep your heart fit and your bones strong. You don't smoke and you avoid alcohol. You remember to change positions in your wheelchair regularly, in order to reduce the appearance of pressure sores. You

use a catheter because your bladder has been affected and you do not wish to run the risk of urine accumulating in your bladder and possibly causing an infection.

You feel you are now emotionally stronger than you were before the accident. You are preparing to travel next summer with your band. Your friends and family have supported you all the way; their support has been crucial, especially during the darkest moments. Your dream is to design innovative yet friendly buildings, which will, in the future, overcome one of the biggest problems in your daily life: the lack of access. Your other big inconvenience is the use of public transport systems which aren't set up to deal with wheelchair users.

You are hopeful that stem cell therapy may one day allow you to walk again and do all the things that you would still like to do. Therefore, you fully support stem cell research and have no problem with research that uses human embryos.

From what you have read, embryonic stem cells and iPS cells offer the greatest potential for effective treatments, as they can be directed to become the specific cells that would need to be transplanted into your back to repair the injury. In your view, those who oppose embryo research are placing a higher value on their own personal moral views than on the benefits of that research to others in need.



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## Acknowledgements



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