STEM CELL RENEGADES OR PIONEERS?

An increasing number of centres offer expensive stem cell treatment. But should they simply be dismissed as "rogue clinics," or can lessons be learnt from their work? **Jonathan Gornall** reports

The "before and after" videos seem to show a series of miraculous transformations. Patients in the terminal phase of amyotrophic lateral sclerosis (ALS)—each one, to varying degrees, quadriplegic, unable to swallow or speak, and reliant on mechanical ventilation—seem to regain the ability to talk, swallow, breathe unaided, move limbs and fingers, and even, with support, to walk.

This is the "show reel" of Dr Haluk Deda, a Turkish neurosurgeon who is setting up shop in Dubai, where he plans to offer autologous stem cell transplants to treat chronic spinal cord injuries and ALS, a condition with no known cure that generally leads to death within three to five years of diagnosis.

A new transplant technique

Dr Deda says he developed the transplant technique in Turkey and has carried out 26 procedures. Bone marrow is extracted from the outer edge of the patient's pelvic girdle and processed in a specialist laboratory to obtain "purified" mononuclear cells. Under general anaesthesia, a laminectomy is performed at the C1-C2 level of the spine to expose the cord, into which the cells are injected at several sites.

The cost of the procedure, $50 000 (£32 500; €36 800), does not include transport, and most patients with ALS travelling from overseas would have the additional cost of hiring an air ambulance.

Dr Deda shows the images to local journalists and prospective patients. He says that many of the partial and, he concedes, temporary recoveries have taken place within only days of treatment.

No advertising needed

He also projects on to the wall of the conference room in his new offices in Dubai Health Care City some of the hundreds of emails he says he has received from patients around the world, including the United Kingdom, the United States, Netherlands, Hong Kong, Mexico, and Brazil. Although he plans to do so, he has yet to advertise his services on a website. It seems unnecessary. With lifespans often measured in only months, desperate patients and their carers looking for hope keep on top of the published literature. What has brought so many to Dr Deda's door are the only two papers he has published on the subject and which, he says, offer proof that his technique is effective and ready for clinical use.[1 2]

Several experts spoken to by the *BMJ*, including Professor Nigel Leigh, director of the motor neurone disease care and research centre at King's College London, disagree. "I have read the [ALS] paper [2]; there is no scientific basis for accepting the outcome as positive," he said. "All the so called positive outcomes are unconvincing for the simple reason that there was no randomisation and no blinding . . . and in addition there is no solid evidence from basic science to suggest that these cells are likely to be effective in ALS."

Not clear how it works

Dr Deda admits it is not clear how his treatment works, but he insists it does bring improvements, at least "for a period." In his research he has concentrated on treating patients in the final stages of the disease and says that in Dubai he will also limit the treatment to patients who have nothing to lose. For him, this means there is no ethical quandary.

"They want to come here because there isn't any chance," he said. "Otherwise, they die. They are dependent on ventilator, no movement in arms and legs, even not being able to speak. Maybe in a few months they will die."

Dr Deda's Halman Neurotherapy Centre is just one of the latest in a burgeoning series of "offshore" clinics that offer expensive stem cell treatments to patients from highly regulated countries where such techniques remain entirely experimental. In fact, the first phase I trial of adult stem cells as a treatment for ALS has only just begun in the US.

For now, there is no cure for ALS, which is thought to affect about 2000 people in England and Wales.[3] The only drug approved for use in the US and the UK is riluzole, which at best offers patients a gain in tracheostomy free survival time of between two and four months. [4]

Warnings of "rogue" clinics

Authorities and organisations in the US and UK have been quick to warn patients not to look for hope in unverified treatments for a range of conditions, including multiple sclerosis, Parkinson's disease, spinal injuries, Alzheimer's disease, and muscular dystrophy. The International Society for Stem Cell Research, an independent non-profit organisation based in the US, which was established "to promote and foster the exchange and dissemination of information and ideas relating to stem cells," has issued a general warning about "rogue clinics around the world [that] exploit patients' hopes by offering unproven stem cell therapies, typically for large sums of money and without credible scientific rationale, over-

The website of Dr Haluk Deda's Halman Neurotherapy Centre in Dubai, where he plans to offer autologous stem cell transplants to treat chronic spinal cord injuries and ALS

Sir Muir Gray, who, as chief knowledge officer of the NHS, said in 2008, "When you are desperate any offer seems attractive, but stem cells and gene tests off the web are a no-no"

Beike Biotech in Hangzou, China, one of a number of clinics that have stirred up controversy in the Western media by advertising its stem cell services on the internet

Dr Gabriel Lasala, president of TCA Cellular Therapy of Louisiana, who believes the West has held back research that could lead to properly authenticated treatments

sight or patient protections."[5] This exhortation is echoed in the UK by the Department of Health,[6] and the General Medical Council recently took action against a Dutch doctor who sent UK patients with multiple sclerosis for stem cell treatment at a clinic in Rotterdam. Robert Trossel, who practised in Wimpole Street, London, was cleared of dishonesty but found guilty of exploiting vulnerable patients. During his hearing, Dr Trossel said he had believed there was "no reason not to give [stem cell therapy] a try."[7]

A position statement on stem cell tourism by the UK National Stem Cell Network, an independent body set up in 2006 to promote and coordinate stem cell research in the UK, urges caution to the "many patients in the UK who currently suffer from incurable and painful degenerative diseases and who are prepared to take uncalculated risks to improve their quality of life, even if only for a short time." It says that many "purported treatments" are available overseas only at great cost: "It is clear that some providers are motivated by finance and may effectively be using patients as human guinea pigs."[8]

Desperate patients, desperate measures

But such warnings carry little weight with patients who cannot wait for lengthy trials to take their course and for whom the alternative is an inevitable degeneration of their faculties or even certain and imminent death. All very well for Sir Muir Gray, then chief knowledge officer of the NHS, to say in December 2008: "When you are desperate any offer seems attractive, but stem cells and gene tests off the web are a no-no."[9] For such patients, blanket condemnations fail to take account of the individual suffering that has led to the growth of this alternative treatment market, and the portrayal of patients as ill informed gullible victims is wide of the mark.

Take Russ Kleve, a 49 year old senior litigation paralegal from Oregon. In March 2009 he travelled to Hangzhou in China to undergo a stem cell treatment not available in the US. Like his mother, two brothers, and twin sister, he was born with the hereditary disease facioscapulohumeral muscular dystrophy, which causes progressive wasting of muscles. Although the condition is regarded as "relatively benign," 20% of patients become wheelchair bound.[10]

Mr Kleve's condition first affected him in his late 20s, and by the time he travelled to China last year, he was struggling with many daily activities, including walking and rising from a seated position, and he had reached the point where he was prepared to spend $50 000 to travel overseas for an unproven treatment, in which umbilical stem cells were given intravenously or by injection into his muscles.

As objectively as he could, Mr Kleve documented every step of his treatment on a blog. "It has been just over eight months since I returned from Hangzhou," he wrote on January 12. "While my initial results were great, it seems they have levelled off and I am now losing ground . . . It appears my treatment only went so far for so long."

Despite his disappointment, however, Mr Kleve told the *BMJ* he would return to China for more treatment if he could afford it. "I'd do it again because I felt I did get some benefit from it," he said.

Mr Kleve said he had researched advertised treatments on the internet, exchanging information with other patients. Alerted to the potential of embryonic cells to cause tumours, he opted instead for treatment with umbilical cord cells and compiled a list of half a dozen companies around the world that offered this. After comparing costs, transparency, and protocols and speaking to patients who had undergone treatments, he settled on Beike Biotech, a company that has attracted controversy in the West.

"My experience was great," said Mr Kleve. "The Beike staff and doctors were wonderful, the service was completely professional, and I did not pay anything more than what they had told me two months before I arrived . . . I remain supportive of stem cell treatment generally and Beike Biotech specifically. Perhaps some day new techniques will be found to make this treatment work better for MD [muscular dystrophy] patients."

In the Western media, Beike's activities, along with those of many similar clinics offering stem cell treatments and advertising their services on the internet, are characterised as controversial, [11 12] and the companies classed as renegades.[13]

A complex reality

But, says the head of a company pioneering stem cell research in the US, the reality is more complex. "There are some institutions [in relatively unregulated countries] without supporting evidence for their treatments," said Dr Gabriel Lasala, president of TCA Cellular Therapy of Louisiana. "There are however, other institutions that do have supporting evidence

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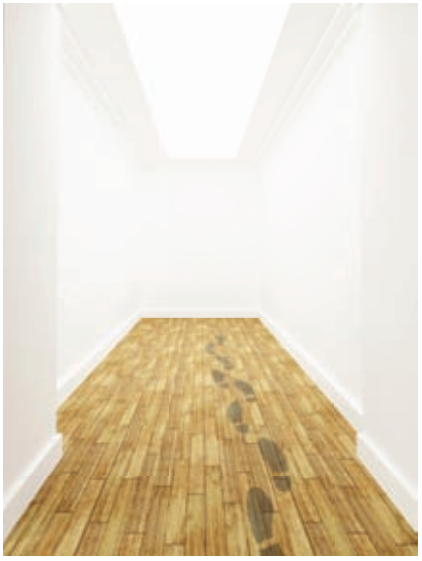
- Doctor is found guilty of exploiting "desperate" MS patients. *BMJ* 2010;340:c2009
- A tale of blind faith. *BMJ* 2008;338:b2069.

and reputable scientists behind them."

Furthermore, he believes, the Western regulatory system has a lot to answer for, holding back the research that could lead to properly authenticated treatments being developed.

"The question is why such institutions are proliferating everywhere and not in the US or UK," said Dr Lasala. "The answer is simple. The difficulty and restrictions imposed by the governmental institutions are of such magnitude, that scientists are discouraged to proceed with potentially promising research or treatments . . . The proliferation of these institutions is the consequence of inefficient first-world countries' governmentally run institutions and the desperation of patients who find no hope in their developed medical systems."



"Now all scientists must pass through the door, otherwise how can we develop the science? This is a treatment necessary for patients all over the world"

Only as recently as January TCA Cellular Therapy was given the go ahead by the Food and Drug Administration to conduct the first ALS stem cell trial in the US using patients' own cells.[14] The phase I trial is only the second investigation of the effect of stem cells on ALS to be approved in the country. In September last year the FDA approved a phase I trial of neural stem cells patented by a company called Neuralstem, to be injected into the patient's spinal cord. Eva Feldman, the professor of neurology at the University of Michigan who is the trial's principal investigator, told a press conference: "This is a major stride forward in what still could be a long road to a new and improved treatment for ALS", although she added: "We don't want to raise expectations unduly."[15]

Expectations have already been raised, however. Like it or not, in the West, stem cell research is a miracle in waiting, whose ability to deliver on the promise has been outstripped by its own PR.

The difficulty in raising research funding was also crucial, said Dr Lasala. Whereas traditionally drug companies subsidised research projects in the hope of developing a marketable drug, "This does not apply to stem cell therapies; the concept of stem cells in a vial is unrealistic. This precludes scalability and therefore makes the product less attractive to pharmaceutical companies seeking a profit."

Worse, the cost of stem cell research is higher than for drug development. A cardiac stem cell protocol in the US would cost an estimated $30 000-$40 000 per patient.

All of this, said Dr Lasala, was why "The issue of charging for stem cell research therapies is far more complex than it appears on the surface." It meant that the prospect of patients paying for research was "a reasonable possibility if the patients are willing to pay for an unproven therapy."

Similar problems exist in the UK. A report published in April last year by the Institute for Science and Society at the University of Nottingham, funded by the Engineering and Physical Sciences Research Council, concluded that although "UK academic regenerative medicine is thriving . . . lack of access to capital, regulatory hurdles [and] a dearth of clinical evidence on (cost) effectiveness is leading to problems . . . compounded by an NHS culture that is considered to be unsupportive in utilising innovative products, and does not provide an attractive environment for the commercialisation of regenerative medicine products. These have all been suggested as having contributed to hindering the progress that the science has made thus far."[16]

For Dr Lasala, the tragedy of the situation is summed up by the story of two dying men who came to his company for help. "More than two years ago, our company sent three letters to the FDA requesting to treat, on a compassionate basis, a 42-year-old gentleman who was dying from ALS," he said. "The proposed treatment was using the patient's own cells with little risk to the patient. Despite the letters and multiple phone calls, we were not allowed to provide the treatment. The patient died eight months later."

Not long after, he says, another man came to his company under similar circumstances, but "did not have enough time to wait for the FDA to approve our protocol." Instead, he went to Monterrey, Mexico, where he sought out a team investigating transplantation of autologous stem cells into the frontal motor cortex. "He paid and received a treatment provided by great scientists who later published their research in a reputable medical journal."

The patient was one of 20 enrolled in a controlled trial at the Hospital San JoséTec de Monterrey, in which five men and five women underwent the treatment. The paper, published in the journal *Cytotherapy*, found that the survival of treated patients was statistically higher and concluded: "Stem-cell transplantation in the motor cortex delays ALS progression and improves quality of life," although further studies "with a greater number of patients are necessary to define the usefulness of stem-cell therapy in patients with confirmed ALS."[17]

Although this patient's ALS did not improve greatly, said Dr Lasala, "The most important issue appears to be the progression of disease. ALS is rapidly progressive. In this particular patient it appears that the progression of disease has halted. It is difficult to draw conclusions from one patient but it is encouraging that the cells have caused no damage and they might have helped him."

Support groups and the internet

Stephen Byer, whose son Ben was diagnosed with ALS in 2002, says Dr Hector Martinez and his colleagues in Monterrey are "the good guys," some of the "fine neuroscientists steadfastly working to find solutions." Stephen and his wife Barbara founded ALS Worldwide, a support and information group for patients and their families, and after their son's death in July 2008, continued the organisation's work, "both despite his death and because of his death."

For families such as theirs, the internet is "both a friend and a demon," he says, offering

"a plethora of relevant, legitimate and valuable information as well as a host of disreputable and illegal offers. ALS patients and their families are most susceptible to being duped because of the desperation that surrounds their lives."

In 2004, Stephen took his son to China for fetal stem cell transplantation. The procedure, he says, "was a mess," with little in the way of quality postoperative care and some patients dying from complications such as infection, heart attacks, and pneumonia. The experience "became the foundation of 'what not to do'."

Mr Byer believes that, "the few good practitioners are probably lumped in with the 'baddies' by the medical establishment," for a variety of reasons. "Ignorance breeds fear and fear breeds hostility. There is also competitiveness [and] anger, in the US, at being under the thumb of the misguided, self-deceiving, pseudo-religious based non-science of the years of the Bush administration [and] envy at the relative freedom of other countries to pursue stem cell therapy."

In his view, "as the US, UK and other countries see what is happening elsewhere, they are starting to lose their animus toward those who are momentarily in the driver's seats and learn from them."

Renegade or pioneer?

Back in Dubai, Dr Deda denies he is exploiting desperate patients. Instead, he sees himself as having "opened a door; now all scientists must pass through the door, otherwise how can we develop the science? This is a treatment necessary for patients all over the world."

The expense of his procedure he attributes to the high cost of having to ship the bone marrow to a specialist laboratory in Jordan to isolate the correct stem cells. He intends to operate on only three or four patients a month and will continue to work as a neurosurgeon in Turkey for two weeks at a time. "I'm not a businessman," he says. "I am a doctor. This is a chance for these patients, otherwise they are dying." He gestures towards the screen and footage of a 41-year-old man—raising one knee and moving his hands and fingers, apparently only one day after the transplant—and spreads his arms expressively: "I show that these stem cells gain some time for our patients. This is useful, isn't it?"

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See EDITORIAL, p 985, HEAD TO HEAD, p 1008

Where's there's smoke, there's fire

doc2doc

Following a post questioning whether tobacco is good or bad for you, smoking is once again under debate on doc2doc, BMJ Group's global online clinical community.

Odysseus: "Smoking is good for you if you are a tobacconist; chest physician or surgeon; lung function technician or salesman of lung function equipment; cardiologist; cardiac surgeon; radiologist; funeral director; maker of sputum mugs and spittoons; manufacturer of oxygen concentrators; or a big tobacco firm. If you are a smoker, well, not so good."

Jon Peterson: "My grandfather in law is 93 and declining relatively rapidly, but none the less he is still independent and lives in the house he built himself. He has yellowing, nicotine stained carpet and ceiling, and next to his pipes is not a tin of his favourite Navy Cut or an old pouch of Cherry Shag but a full colour photograph of a man with throat cancer, and the words: 'Smoking causes a slow and painful death.' Does this make this old man's death any quicker, and any less painful?"

Could tobacco smoking ever be anything but bad for you? Have your say at http://bit.ly/cJtTja

FROM BMJ.COM

Elbows, bellies, and other body parts

Andrew Burd—professor of plastic, reconstructive, and aesthetic surgery at the Chinese University of Hong Kong—outlines the case of a baby who experienced a scald injury while being bathed by a nurse. The investigating disciplinary panel focused on the fact that the nurse did not undertake "the elbow test" to measure the temperature of the bathwater. Professor Burd looks at the background to this test and finds that evidence is lacking. His advice? "Test the temperature of the water with the hand."

Julian Sheather reviews a lecture on ethics, obesity, and public health titled "Whose potbelly is it anyway?" and ponders the question of stigma associated with obesity. "For liberals stigma is a bad thing," he says, adding: "The surest way to remove stigma is to re-evaluate something, to turn it from being bad to being good. But if obesity ceases to be a bad thing, how do you motivate people to avoid it?"

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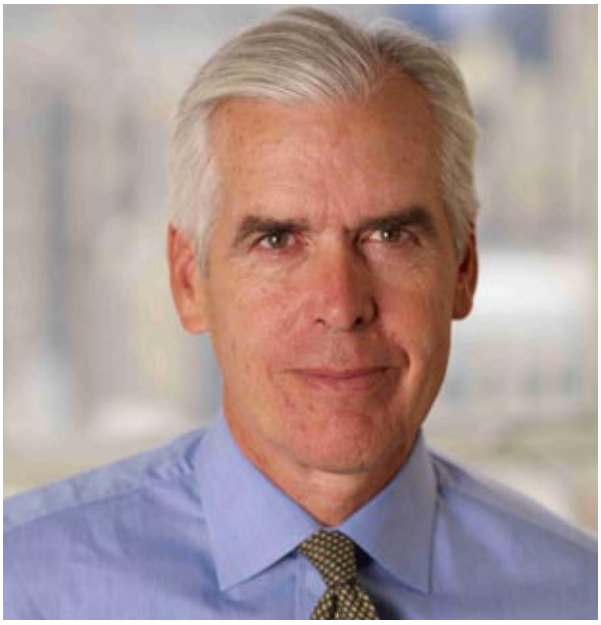
FAREWELL, 12 GOOD MEN AND TRUE

Compensation for medical injury costs the US billions but, as **David Payne** reports, lawyers and doctors could see their earnings curtailed under a new system



Philip K Howard, an "anti lawyer lawyer"

Two months ago Barack Obama earmarked $50m (£33m; €37m) for pilot projects that could sweep away the jury system for dealing with medical injury litigation in parts of the US, replacing them with full time judges dedicated solely to healthcare cases.[1]

In a letter to Congressional leaders after the televised bipartisan summit on healthcare reform on 25 February,[2] President Obama referred to the special health courts—a concept developed by Harvard School of Public Health and the legal reform think tank Common Good (http://commongood.org).

The president's funding pledge would allow individual states to pilot alternatives to resolving medical malpractice disputes, including health courts, which would function as administrative tribunals that use specially trained judges and neutral expert witnesses instead of juries.

For New York lawyer and legal activist Philip K Howard, the president's announcement was a breakthrough. Mr Howard was described recently by CNN correspondents John D Sutter and Richard Galant as an "anti-lawyer lawyer" who crusades "against the excesses of his own profession." In 2002 he founded Common Good, a non-partisan coalition "dedicated to restoring common sense to America."

Mr Howard explores the commonsense theme in his 2009 book *Life without Lawyers*. He did so also in February this year, when he received a standing ovation at the TED (Technology, Entertainment, Design) conference in California after outlining a four point plan to fix his country's legal system.[3] The TED talk was an impassioned plea for the law to be rehumanised and simplified—for to it be judged by its effect on society rather than on individual disputes.

In it, Mr Howard mentioned a paediatrician friend in North Carolina who told him: "I don't deal with patients in the same way anymore. You wouldn't want to say something off the cuff that might be used against you."

AMERICAN MEDICAL ASSOCIATION'S VIEW ON HEALTH COURTS

In June 2007 the AMA adopted a policy that set principles for health courts. They are designed to serve as guidelines for state medical associations, local governments, insurers, and hospitals. The principles cover structure, selection, and training of judges and experts, damages and medical error reporting.

AMA board William A Hazel described the courts as "a promising reform that merits more investigation," an alternative to California's 1975 Medical Injury Compensation Reform Act, which includes a $250 000 cap on non-economic damages.

Compensation culture

The drive to eradicate the "bad values" of the 1960s—racism, sex discrimination, pollution—has delivered a legal quicksand, paralysing a society which for 200 years had relied on a written constitution of just 16 pages, he concluded.

One consequence of this is that medical malpractice litigation is big business in America. Mr Howard estimates it swallows up $28bn a year in direct costs alone and has led to a poisoning of the culture so that all patients are seen as potential plaintiffs and it is no longer fine to be a professional.

Unlike in the UK, there is no schedule that limits the amount of an award for specific damages (£3000 for the loss of a finger, for example). The UK abolished trial by jury for most civil cases in 1927.

Special health courts, Mr Howard argues, would gain the trust of doctors because they would deliver swifter and more consistent judgments and award lower settlements as they do in Sweden and New Zealand. "In New Zealand and Sweden the system assumes that even the best doctors make mistakes and provides compensation," he says.

"It's natural that the medical profession doesn't trust the current system in the US. It's not that juries are generally unwise, but they do tend to err towards compensation in tragic situations, with the assurance that the insurance companies will pick up the tab.

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"Lawyers go to the jury and say: 'What would you take—$20m, $30m?' as if that would bring someone back from the dead. The money that could be used to take care of people goes to make a family rich, because of a tragedy. Our idea is to create a panel of expert witnesses in advance that is respected by its peers."

Mr Howard illustrates his point by citing the legal career of former senator John Edwards. In 1985 Mr Edwards won a $6.5m settlement for a child with cerebral palsy because a doctor did not perform an immediate caesarean delivery when a fetal monitor showed she was in distress.

The presiding judge later upheld the verdict but halved the settlement. It was increased to $4.25m on appeal.

Mr Edwards later became known as North Carolina's most successful plaintiffs' attorney, filing 20 lawsuits and winning settlements totalling more than £60m.

Another option being floated by legal reformers is the idea of a federal "safe harbour." This would retain the current adjudication process but protect doctors from liability if they could prove they had adhered to evidence based practices.[4]

Mr Howard does not think this solution is workable. "It sounds fine in theory but every patient involves a different set of facts. It's hard to find a choice in life that doesn't involve the application of human judgment. All you'd need is a lawyer with an IQ above 80 who can plead."

Pilot prospects

President Obama's letter gives the green light to individual states to pilot alternatives to resolve medical malpractice disputes. What interest have they shown to date in trialling special health courts, and how will they be assessed?

Mr Howard says New York Presbyterian Hospital and Johns Hopkins Hospital in Baltimore have shown interest in a pursuing a pilot project, although no launch date has yet been identified.

The expectation is that a government agency, most likely the state health department, will oversee any pilot.

He adds: "There are two goals. The first is to show whether the system can work as intended. The second is whether you can restore reliability. Special health courts have the goal of reliability. And can you rebuild the culture of healthcare delivery to be less defensive?"

Defensive medicine can be lucrative for doctors. According to Mr Howard, reliable estimates put earnings at between $60bn and $200bn a year, enough to provide health care for all the people in America that don't have access to it. So will doctors participate in a pilot scheme?

Mr Howard expects opposition from both doctors and lawyers, but he argues: "Nobody likes to go through life with a little lawyer on their shoulder. Most doctors want to get rid of the fear and the distrust.

"However, when you start putting real responsibility back on physicians to be prudent in their use of healthcare resources, they will absolutely be resistant. The whole system is designed to be what you can be reimbursed for."

"Reliable estimates put earnings at between $60bn and $200bn a year, enough to provide health care for all the people in America that don't have access to it"

Like millions of Americans, Mr Howard has personal experience of this. "A few months ago I was at work and found my heart was racing. I'm 60. I went to the doctor. He said you have atrial fibrillation and asked what I'd done the night before.

"I told him I'd watched my daughter singing in a nightclub, and I'd had to watch 20 other singers before she came on.

"I was told I had 'holiday heart,' after drinking too much. But to be on the safe side he made me an appointment with a cardiologist using lots of fancy equipment. Then I had a stress test.

"$8000 later, with my heart rate back to normal, I knew what I knew at the beginning. I had drunk too much."

Another question is whether US citizens suing or being sued in the federal courts will willingly waive their constitutional right to a jury trial. Precedents do exist, according to a 2008 article on special health courts for medical injury.[5]

It highlights numerous examples (including workplace injury claims) where areas of law previously heard by juries were replaced by administrative "jury-free" remedies.

SPECIAL HEALTH COURTS AT A GLANCE

- Full time judges dedicated to healthcare cases appointed through a non-partisan screening commission
- Judges to select neutral experts from a panel in each area of medicine, replacing the "hired gun" experts that Common Good says confuse and prolong disputes today
- Patients reimbursed for all medical costs and lost income, and a fixed fee that would be predetermined according to a schedule for specific types of injuries

The article concludes: "If Congress chooses to replace claims in front of juries with an administrative system, it may do so provided that the new system is fair, benefits all categories of interested parties, and involves important public policies."

Desire for change

Mr Howard also points to "overwhelming" public support for change. An August 2009 poll by Clarus Research Group showed 83% of people believed the medical malpractice system should be overhauled in the US, with 67% supporting special health courts without juries.[6]

For Mr Howard, the ultimate goal is to create conditions under which medical professionals can do the best possible job. "That requires a legal structure which they trust.

"Tort reform in the US misses the point. It doesn't make the ultimate result trustworthy. Trust is essential. The system just needs to be fixed."

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