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Unproven stem-cell therapy ban

The Bulgarian deputy minister for health has resigned over the country's decision to ban the use of a controversial stem-cell therapy to treat neurological disorders.

The therapy, which since 2005 has been carried out on around 250 patients at St Ivan Rilski Hospital in Sofia, contravenes European Union regulations and is of unproven value, the Bulgarian health ministry ruled on 8 August. Three days later the deputy minister, Matey Mateev, resigned in protest.

The therapy involves harvesting stem cells from a patient's bone marrow, concentrating and purifying them, then injecting them into the same patient's brain or spinal cord. It aims to regenerate nerves and stimulate metabolism after spinal-cord trauma, stroke or neurodegenerative disease, says Venceslav Bussarsky, who heads the hospital's neurosurgery department, and is also president of the Bulgarian Society of Neurosurgery. Each treatment costs €1,000–2,000 (US\$1,500–3,000).

Bussarsky, who claims that companies or individuals with competing financial interests are behind the actions of the health ministry, says that the treatment was successful in nearly half of the patients.

But such stem-cell transplantation is highly controversial. "No scientific evidence has been shown from clinical trials that this treatment would have any positive effect in humans," says Paolo Bianco, a stem-cell researcher at the Sapienza University of Rome.

When Bulgaria joined the European Union in 2007, the country had to comply with the existing European directives on the transplantation of human tissues and cells. The St Ivan therapies contravene these directives, says the health ministry, which is also concerned about the lack of proof that the therapy is effective.

The ministry says that close relatives of Mateev own the two private companies that took part in the St Ivan transplantations — in violation of government ethics codes concerning conflicts of interest for leading officials. Mateev's "retirement" is connected to this violation, according to the ministry.

Mateev insists that the directives have been incorrectly translated into the Bulgarian language. "Also the committee did not talk to any of the medical people involved, they only inspected papers," he says. Mateev, a physician, was director at St Ivan from 2002 until 2006. Maria Rossbauer

his signature of agreement, Bartsch insists he did not request authorship but that Strasser included him "in honour of my seniority". On 31 July Bartsch asked *The Lancet* to withdraw his name, as "Strasser had not retracted the article as I had suggested". Bartsch adds that the agency's report "is not a legal document in any case".

Bartsch says that 'honorary authorship' is given on occasion within his department. He was a member of the university ethics committee until 1997 and, in 2001, he headed an ad hoc committee that oversaw the introduction of 'good scientific practice' in the faculty of medicine. Three years later the university's senate approved a ten-point protocol along these lines, including an explicit rejection of honorary authorship.

The loss-of-confidence motion against Sorg, an immunologist, was brought by the all-powerful university council on 7 July, shortly after the preliminary report was circulated to those involved. The council comprises seven 'high-standing representatives' of Austrian society and has the power to dismiss the rector. The council accuses Sorg of a 'serious breach of duty', in particular by exposing the university to 'the danger of serious economic damage'.

But on 28 July, the university senate voted unanimously that the specific concerns put forward by the council were too trivial to warrant dismissal. Sorg has also received a letter of support from top university officials expressing concern about the council's actions. The council will vote on Sorg's dismissal at a

special meeting on 21 August.

Meanwhile, Austria's science academy has put its investigation into whether the urologists had followed good scientific practice on hold. "We had the impression that the request came from Sorg as a person, not a university representative," says Peter Schuster, the academy's president. "When the problem of Sorg's possible impeachment came up, we put the case temporarily on ice."

Sorg, who says that his request was made in an official capacity as a representative of the university, is now under pressure to decide quickly on consequences for Strasser and Bartsch, given that the council may vote to dismiss him within days. As a first step, he asked Strasser to confirm by 18 August that he retracted all relevant papers. Further disciplinary actions are being considered by Sorg and the head of the university's hospital. Sorg has also asked the council to send its report to the public prosecutor.

In the meantime, several of the hundreds of patients who have undergone the procedure by Strasser's team — within and outside of the trial — claim that they have had serious side effects. Injuries such as sealing of the urinary sphincter and rupture of the bladder have been registered with authorities. Thomas Juen, the Innsbruck lawyer who is representing the patients, says: "This is a very grave scandal for the university, and the pressure on the public prosecutor to bring criminal charges will be very high." ■

Alison Abbott

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Since opening in 2006, the institute has taken an interdisciplinary approach to imaging and modelling neural circuits. The new UCL institute "sounds like Janelia East", says Karel Svoboda, a neuroscientist at Janelia. "That is not necessarily a bad thing," he adds.

Others are concerned that the London institute should distinguish itself from other interdisciplinary centres that are proliferating in this field. "It will be important for the new institute to choose its subject areas carefully to avoid duplication," says Colin Blakemore, a neurobiologist at the University of Oxford.

Svoboda agrees, but says that its central London location and affiliation with a major research university should give a distinctly different character from Janelia Farm. And a Janelia-style centre does not yet exist in Europe, he says. "If organized in the right way, it could really attract fantastic talent."

The institute could be built by 2011. ■

Geoff Brumfiel



UCL: the nerve centre of neuroscience?

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