Stem Cell Research in Limbo After Ruling

BY MARY ELLEN SCHNEIDER

Some researchers studying human embryonic stem cells are surprised, disappointed, and even angry over the legal back-and-forth over the federal government policy on funding research using the cells.

On Aug. 23, a federal judge issued a ruling that barred the use of federal funds for any research involving human embryonic stem cells. As a result of the temporary injunction, the National Institutes of Health stopped accepting submissions of information on human embryonic stem cell lines for NIH review and suspended all review of embryonic stem cell lines. On Aug. 31, the Justice Department asked for a stay of the lower court's injunction, which was granted on a very short basis on Sept. 9. The Sept. 9 temporary administrative stay granted by the U.S. Court of Appeals for the District of Columbia Circuit called on both parties to the suit to present information to the court by Sept. 20.

Last year, President Obama greatly expanded opportunities for embryonic stem cell research when he issued an executive order that eliminated many of the restrictions placed on funding during the George W. Bush administration. The NIH followed with guidelines that allowed research to be conducted on embryonic stem cells derived from embryos created through in vitro fertilization and donated for research.

With the judicial ping-ponging, some researchers worry that the development of therapies that use embryonic stem cells will be set back and that the loss of federal funding will have a chilling effect on newly minted researchers who are considering whether to enter the field.

The Coalition for the Advancement of Medical Research, which advocates for stem cell funding, called the original injunction a "blow to the hopes of millions of patients and their families suffering from fatal and chronic diseases and disorders."

The halt on funding for embryonic stem cell research has implications for all types of stem cell research, said Alan Trounson, Ph.D., president of the California Institute for Regenerative Medicine, which issues grants to researchers in California who use state funds.

"The decision is a deplorable brake on all stem cell research," he said in a statement. "Many discoveries with other cell types, notably the so-called reprogrammed [induced pluripotent stem] cells, would not happen without ongoing research in human embryonic stem cells."

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Dr. Trounson said the California institute's funding plans would not be affected by the federal court decision. Institutions that have obtained private funding for their stem cell work will also be able to continue their work. However, even those with deep pockets are concerned that private funding alone is not enough.

"It's a blow to us," said B.D. Colen, a spokesman for the Harvard Stem Cell Institute. "It's a blow to the field." The institute, a collaborative of stem cell researchers from around Massachusetts, has raised $120 million in private funds since its founding 2004, but those sources are not unlimited, Mr. Colen said. The loss of federal funding that was expected to go to the institute's researchers will be disruptive, he said, and the impact will be worse for those researchers who do not have private funding sources to fall back on.

Another concern involves legal issues. An earlier lawsuit challenging the Obama stem cell guidelines had been dismissed after the court ruled that the plaintiffs had no standing to challenge it. However, the recent injunction came about after the court decided that two researchers who work with adult stem cells could challenge the guidelines because funding of embryonic stem cell research was harming their chances for receiving federal funds for adult stem cells.

"This judge opens the door for every scientist who ever has a grant request rejected on the merits to sue the federal government," the American Society for Reproductive Medicine said in a statement condemning the court decision.

In granting the temporary injunction, Judge Royce C. Lamberth, chief judge in the U.S. District Court for the District of Columbia, said the NIH guidelines violated the intent of Congress to bar the use of federal funds for research in which human embryos are destroyed. He said the rules violated the Dickey-Wicker amendment, a rider generally attached to health spending bills each year. It prohibits the use of federal funds for the creation of a human embryo or embryos for research purposes or research in which a human embryo or embryos are destroyed or discarded. The Obama administration has argued that the amendment doesn't apply because federal funds are used for research on the embryonic stem cell lines, not in the destruction of the embryos.

Judge Lamberth did not find the argument persuasive. "[Embryonic stem cell] research is clearly research in which an embryo is destroyed," he wrote in the order. "Despite defendants' attempt to separate the derivation of [embryonic stem cells] from research on the [embryonic stem cells], the two cannot be separated." ■

N.Y. Palliative Care Law Not Likely to Change Practice

BY ALICIA AULT

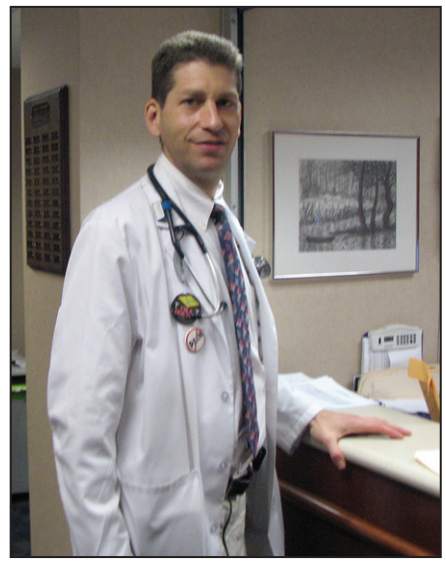
A new law requiring New York physicians to discuss palliative care and end-of-life options with terminally ill patients is well intentioned, but may not do much to change clinical practice or institutional culture, according to some observers in the state.

The New York Palliative Care Information Act was signed into law by Gov. David Paterson (D) in August. Perhaps as a sign that palliative care is being embraced more readily and becoming better understood, it took just 14 months from the bill's introduction in the state Senate (S. 4498 and A. 7617) to its signing.

Even so, "whether or not it will change behavior is a bit of a black box," said Dr. Bradley Flansbaum, director of hospitalist services at Lenox Hill Hospital in New York. "It's a nice thought, but I don't know how they're going to put it into effect."

Under the law , physicians and nurse practitioners are required to provide a patient who has less than 6 months to live with information and counseling on palliative care and end-of-life options, including "the range of options appropriate to the patient, the prognosis, risks and benefits of the various options, and the patient's legal rights to comprehensive pain and symptom management at the end of life."

The physician or NP can refer the patient to another provider who is willing to meet the legal statute or who is "professionally qualified" to offer the services. There is no reimbursement offered for the required services.



COURTESY LENOX HILL HOSPITAL

Offer the care sooner, and to more patients, says Dr. Bradley Flansbaum.

Because it is an amendment to the state's public health law, violations of the new law could result in penalties or fines. It's not clear how it will be enforced or what might trigger the penalties; the health department has until the law's effective date (February 2011) to devise regulations, said David Leven, executive director of Compassion and Choices of New York.

That advocacy group helped devise the proposal and then shepherded it though the legislature, said Mr. Leven. California has a similar statute, but is not as strong because it does not put the onus on physicians, he said.

The organization sought the legislation because even with increased training on end-of-life issues, too few physicians are having conversations with their dying patients, Mr. Leven said. That means patients' wishes are not being respected, to the detriment of both patients and the practice of medicine.

The organization also hoped that the law would be a catalyst to improving end-of-life education in medical school and at the professional level, he said.

Dr. Wendy Edwards, director of the palliative medicine program at Lenox Hill, said that education would be a key component, but there appeared to be no such formal requirements in the law. She said she wasn't sure that the new law was the way to increase attention to palliative care, but that it had likely come about as a result of frustration and impatience on the part of palliative specialists.

The law will be positive, however, she said. Palliative care won't just be the standard of care, but will be the law, which gives some backing to hospitals that seek to implement and strengthen their quality of care, and end-of-life care in particular.

Although the Hospice and Palliative Care Association of New York State supported the law, the Medical Society of the State of New York did not. The medical society, which represents 25,000 physicians, opposed the law because of concerns that it would interfere with the way each and every doctor navigates through end-of-life situations with each individual patient, said Elizabeth C. Dears, the society's senior vice president for legislative and regulatory affairs.

The medical society also said that physicians are not licensed to provide legal advice in areas such as pain or symptom management, and that they may not know what they are supposed to be communicating to patients under certain provisions, while still being subject to penalties.

Although the medical society might object to requiring any such talk, both Dr. Flansbaum and Dr. Edwards said that, realistically, the law should be requiring palliative care to be offered sooner in the disease process and to a broader group of patients, such as those who have chronic life-limiting conditions such as heart failure.

"By the time you're invoking palliative care in terminal patients, you're behind the curve," said Dr. Flansbaum. ■