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## FDA to take key step in stem cell research

*Government advisors meet this week to discuss designs for embryonic stem cell human experiments.*

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NEW YORK (CNNMoney.com) -- The Food and Drug Administration looks like it's bowing to the inevitable this week and drawing the blueprint for the first-ever human experiments with human embryonic stem cells.

FDA advisors meet Thursday and Friday to begin to design how these embryonic stem cell tests will be conducted. It's an important regulatory step that could lead to human testing as early as this year. So far, biotechs have tested their spinal-cord drugs in animals, not people.

"[The FDA meeting] is the first step towards clinical trials," said Laurie Zoloth, professor of medical humanities and bioethics at Northwestern University. "It's an important moment. And it's only the very beginning."

Human embryos are prized by medical researchers because of their fast and malleable regenerative properties. In theory, they could be used to heal severed spines, as well as damaged or diseased brains, hearts and other organs.

But their use is one of the most controversial issues in medical research, a controversy that centers on whether embryonic cell groupings, called blastocysts, are considered human life.

Dave Prentice, senior fellow for life sciences at the Christian organization Family Research Council, opposes the use of human embryos in research. "You shouldn't be destroying human embryos at the earlier stage of human life to harvest cells," said Prentice, who has a PhD. in biochemistry from the University of Kansas.

Other stem cell options are available, he said, such as harvesting them from umbilical cord blood or adult tissue, or ["reprogramming" adult](#) cells to behave like stem cells, as demonstrated in recently-released but early-stage studies.

Zoloth said she supports stem cell research because "the human embryo does not have the moral status of a dying child." Like other supporters, she pointed to the vast potential - though still unproven - of this science in healing traumatic injuries and degenerative diseases.

"I strongly support learning as much as we possibly can about human embryonic stem cells, as well as learning about other types of regenerative medicines," she said. "The fact that science could develop ways of healing very tragic human fates is an extraordinary capacity that we have been given by God. For people who aren't religious, you might say that we stand in a remarkable moment in human history."

## Safety over ethics for the FDA

The FDA seems to be more concerned with the stem cells' possible side effect of producing tumors. Because of the "potential risks" of human embryonic stem cell products, data showing a drug's effectiveness "may need to be particularly strong," the document said.

An administration spokesman would not comment further than the released document.

"The FDA needs to feel comfortable that the cells we use for our cell products will not cause teratomas," said Alan Lewis, chief executive of privately-held biotech Novocell, which hopes to begin human stem cell testing within three years for a possible diabetes treatment.

Lewis described the teratomas as non-malignant but unwanted pieces of muscle, hair or other matter that form as an offshoot of embryonic stem cells, which replicate quickly and can morph into different types of tissues, such as the liver or pancreas.

## The biotechs line up

Geron ([GERN](#)) could be the first company to conduct [experiments in humans](#) with drugs made from human embryonic stem cells. The biotech is developing a treatment to repair spinal cord injuries. Geron has already filed an application to the FDA to begin human testing, according to analysts. But the biotech refused to confirm this and would not discuss the upcoming meeting.

So far, Geron's animal experiments have been tumor-free, said UBS analyst Graig Suvannavejh, who doesn't expect the company to run into problems with the FDA.

"For Geron, the best possible outcome overall is for [the] FDA to be peachy with everything they've done so far," said Suvannavejh in an email to CNNMoney.com. He believes Geron could begin human testing by mid-2008.

Steve Brozak, analyst for WBB Securities, emphasized that tumor-safety is imperative, and there is little room for failure in the current environment.

"It is one of the things that can be a problem if the science is not understood completely," he said. Geron needs "to make sure that the critics of the field don't have room to assail them with."

Advanced Cell Technology is using embryonic stem cells to develop a treatment for vision loss. Chief scientific officer Robert Lanza said his company plans to file an application for human testing to the FDA within months. He said the company has found a way to "differentiate" stem cells to reduce the possibility of tumor formation.

Neuralstem ([CUR](#)) works with stem cells derived from a donated human fetus, rather than embryonic stem cells. CEO Richard Garr said his company is developing a treatment for Lou Gehrig's disease, which degrades spinal cord nerve cells. He intends to file an application for human testing to the FDA in September or October.

Garr said that his company's pig tests have been tumor-free, and he hopes the FDA panelists focus on the science of stem cells, not the controversy, in designing requirements for clinical trials.

"What we hope to come out of this meeting is rationality," said Garr. "[We] hope that this isn't just something that a stem cell-unfriendly administration is trying put in place before they leave." ■