

FDA

Proposed Guidelines for Emergency Research Aim to Quell Confusion

Doing research in the emergency room would be difficult even if the rules were clear, but many clinicians say they aren't. Last week, the U.S. Food and Drug Administration (FDA) suggested revisions to its regulation over an ethically fraught but critical area: studies conducted in emergency situations, when subjects may be unconscious and unable to give consent. The current 10-year-old FDA rule permits emergency research under narrow circumstances—in life-threatening medical conditions in which available treatments are unsatisfactory.

Hoping to clarify the responsibilities of investigators, institutional review boards (IRBs), and others involved in emergency research, FDA has released draft guidelines



Under review. Research in emergency situations, which raises tough ethical questions, is receiving FDA scrutiny.

that spell out each group's responsibilities. The agency is now accepting comments on the document (www.fda.gov/OHRMS/DOCKETS/98fr/06d-0331-gd10001.pdf)

STEM CELL RESEARCH

Scientists Object to Massachusetts Rules

Massachusetts stem cell researchers thought they were home free last year when the state legislature, overriding a veto by Republican Governor Mitt Romney, sanctioned research using human embryonic stem (hES) cells. But newly adopted final regulations to implement that legislation would cut off what some argue is an important potential avenue of stem cell research.

In May 2005, state lawmakers passed a measure that explicitly permits scientists to do things that federally funded researchers cannot—derive new lines of hES cells, including disease-specific lines produced using somatic cell nuclear transfer (SCNT), otherwise known as research cloning. The law allows ES cell lines to be produced from spare embryos left over after in vitro fertilization but prohibits the “donation” of embryos created just for research via IVF. Violating that provision, added to satisfy those who worry about “embryo farms,” is punishable by up to 5 years in jail and a \$100,000 fine. But the wording does not forbid scientists from working with such embryos if they weren't made in Massachusetts.

Romney tried unsuccessfully to amend the bill so that “use” of any such embryos in research would also be illegal. After the

Democrat-controlled legislature overrode his veto, the state Department of Public Health trumped the lawmakers by inserting the wording Romney wanted into the regulations. “The prohibition on the creation of embryos [by fertilization] solely for use in research is implicit in the language” of the law, contends the Public Health Council, the nine-member body that makes the regulations. “[W]here the primary purpose is research, only the asexual creation of an embryo is permitted.”

When the proposed regulation was pre-



More options. Harvard's Kevin Eggan says purpose-bred embryos may be needed if nuclear transfer doesn't work for creating disease-specific cell lines.

and will hold an 11 October public meeting on the subject. One concern for FDA is that some terms that guide emergency research, such as “life-threatening,” may be defined differently by different people. In its proposal, the agency explains that “life-threatening” includes nonfatal risks, noting that emergency research on, say, victims of stroke or head injury could explore a treatment's ability to prevent disability as well as death.

Emergency research came under scrutiny earlier this year after *The Wall Street Journal* described a blood-substitute trial in trauma patients unable to consent, in which some suffered heart attacks. FDA officials said in a conference call last week that its review had already been under way and was unrelated to the blood-substitute flap. “It's taken time for us to develop and gather a sizable body of data on how this regulation has actually worked,” said Sara Goldkind, an FDA bioethicist. The agency, she notes, has received roughly 60 applications for emergency research that allows for exceptions to informed consent and so far has approved about 20.

Physicians who perform such trials ▶

sented in May, eight Boston medical institutions argued that it would “give the force of law to a provision the legislature specifically rejected.” Scientists from those institutions reiterated their concerns last week when the final rules appeared. Harvard stem cell researcher Kevin Eggan says the regulation would prevent Massachusetts scientists from using cell lines derived in other states if they came from embryos created for research purposes. He stresses that it's important to preserve this option as an alternative to SCNT—which has not yet been proven—for creating disease-specific cell lines.

But some scientists question the rule's impact on research. “I don't see it as a problem,” says stem cell researcher Evan Snyder of the Burnham Institute in San Diego, California. “Most scientists agree that you don't want to make embryos specifically for research,” he says, because it appears to be “ethically dicey.”

The lawmakers are prepared to reassert their authority, starting with a hearing later this month. The leading gubernatorial candidates in the fall election (Romney is not running for reelection) support stem cell research, suggesting that the political winds are also favorable for a revision. **—CONSTANCE HOLDEN**

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