

Legal Barriers to Human Cloning May Not Hold Up

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The letter from the Food and Drug Administration got right to the point.

"You are receiving this letter because in media reports and on your website you have expressed an intention to pursue the creation of a human being using cloning technology," it said.

Human cloning is "subject to FDA regulation," the letter warned. "You should be aware that failure to comply with FDA regulatory requirements may lead to enforcement action."

The March 23 letter went to Brigitte Boisselier, scientific director of an obscure religious group that has said it will clone a dead child, and to Kentucky scientist Panos Zavos, who recently said that he, too, intends to clone someone.

But Boisselier and Zavos say the FDA is bluffing, and they're not alone. Many legal scholars say they find little evidence to support the FDA's assertion of authority over cloning. They say food and drug laws provide no legal basis for stopping doctors from trying to clone a person, and if the FDA tried to do so it would lose in court.

Moreover, the prime alternative to FDA regulation -- a congressional ban on human cloning -- may be just as untenable. The six anti-cloning bills pending before Congress are entangled in the politics of abortion. Some legal scholars suspect that even if a ban were to pass on the Hill, it might be struck down as unconstitutional because it would abridge the fundamental right to procreate.

That could mean there is little to stop anyone in this country from pursuing human cloning. It also suggests that the prospect of human cloning -- until recently just a topic for science fiction thrillers -- could push the Supreme Court to tackle one of the toughest reproductive rights issues since *Roe v. Wade* legalized abortion on demand in 1973: whether there are limits to the number of ways a person can legally reproduce.

"Can the government really stop me from cloning myself?" asked Alta Charo, a University of Wisconsin law professor. Right now, she said, the law is "clear as mud."

The FDA has asserted otherwise since 1998, saying that although it has no authority over how doctors practice medicine, it does have authority over human cloning.

"Based on our legal analysis, we feel very confident that our jurisdiction is appropriate," said Kathryn Zoon, director of FDA's Center for Biologics Evaluation and Research, who signed the recent letters to Boisselier and Zavos.

Zoon says that authority comes in part from the Public Health Service Act, which gives FDA the power to regulate "biological products" that are used to treat medical conditions.

"Biological product" is defined as "any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component . . . or analogous product."

A cloned human embryo (which, to steer clear of ethical land mines, the FDA calls a "somatic cell clone" rather than an embryo) is a "biological product" intended to treat a condition, Zoon says -- most notably infertility.

Lars Noah, a University of Florida law professor who specializes in food and drug law, calls that "a remarkable claim" that goes well beyond any reasonable interpretation of the law.

Besides, he and others asked, does that mean the FDA would not have authority over people who clone themselves for other reasons, such as sheer narcissism?

"It's an undefendable position," said Elizabeth Foley, a law professor at Michigan State University's Detroit College of Law, who has written scholarly articles on human cloning and the law. "It shows that their assertion of jurisdiction is really a stretch."

The FDA also says it can regulate human cloning under the Food, Drug and Cosmetic Act, because, it says, cloned human embryos are "drugs." That act defines drugs as "articles (other than food) intended to affect the structure or any function of the body." According to the FDA, a cloned human embryo is an "article" that affects the structure and function of a woman's body by making her pregnant.

Several experts dismissed that interpretation.

"Congress is not going to buy that an embryo is an article or a drug," said George Annas, a Boston University law professor, noting that many in Congress believe embryos are fully entitled human beings. "Does the FDA have jurisdiction?" Annas asked. "The answer is, 'No.'"

Curiously, the only vocal support for the FDA's claim to authority over cloning has come from those who stand to be regulated by the agency as they work with cloned cells and human embryos.

"We looked into this very seriously and have determined that the FDA does have clear and far-reaching authority to regulate efforts to clone human beings," said Carl Feldbaum, president of the Biotechnology Industry Organization, which represents nearly 1,000 biotech companies.

Michael Soules, president of the American Society for Reproductive Medicine, concurred when he testified before Congress in March. "Therefore," Soules said, "we do not think there is a need for new legislation . . . on this matter."

But Soules's candid opposition to anti-cloning legislation is telling, others said: When it comes to oversight by the FDA or Congress, the FDA is seen as the lesser of two evils.

"Researchers feel that FDA will be more reasonable about this than Congress is going to be," Noah said.

Lawmakers do sometimes blunder on science issues. A loosely worded 1997 California ban on human cloning has inadvertently made it a crime for doctors to use a fertility treatment that does not involve cloning.

But FDA regulation won't satisfy some opponents of human cloning. For one thing, the FDA is legally bound to consider only objective concerns such as safety and efficacy, not moral issues. That means that if human cloning were shown to be safe and effective, the agency would be obliged to allow the research.

Moreover -- and here is where the abortion debate comes in -- the FDA is obliged to protect the consumer of cloned embryos, not the embryos themselves, which it sees as mere drugs. It has no regulatory qualms about scientists creating and destroying cloned human embryos to obtain embryonic stem cells, for example, which have the potential to cure many diseases. But for people who believe that life begins at conception, that research is tantamount to murder.

Hence this year's pressure for Congress to pass a law that would fully block the creation of cloned human embryos or babies -- and the emerging debate among legal scholars as to whether a human cloning ban would pass muster with the Constitution.

The strongest constitutional argument against a ban on human cloning comes from Supreme Court references to human reproduction as a "fundamental right" so "deeply rooted" that the government cannot abridge it unless it can show a truly compelling interest. Even then, the court has said, restrictions on fundamental rights must be tailored as narrowly as possible to address specific and objective concerns.

A 1923 Supreme Court decision, for example, held that the 14th Amendment's guarantee of "liberty" includes the right "to marry, establish a home and bring up children. . . ." The court has also said that "procreation" and the right "to have offspring" are fundamental rights. And in 1971 it said: "If the right to privacy means anything, it is the right of the individual . . . to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."

If the Supreme Court were to hear a challenge to a human cloning ban, it would have to decide whether those statements apply to this new kind of reproduction.

"If they were interested in protecting a broad notion of genetic connection to the next generation," then cloning might be included as a fundamental right, said Charo, of the University of Wisconsin.

On the other hand, the court could interpret procreation more narrowly.

"There is nothing in Supreme Court case law to suggest that noncoital, asexual reproduction is a fundamental right," said Clarke Forsythe, an attorney and president of Americans United for Life, a self-described "pro-life" public interest group.

Which way would the court go? Its statements about *in vitro* fertilization (IVF) might give a clue, since IVF is an intermediate variant of reproduction: it's noncoital, like cloning, but still sexual since it requires two parents. But while the justices have hinted that reproduction by IVF is a fundamental right, the issue remains unsettled. Also, some people say cloning isn't even reproduction but merely "replication."

Even if there were a fundamental right to procreate by cloning, the government could limit the practice if it showed a compelling interest, such as that cloning poses physical or emotional risks to the clones. Nonetheless, a ban ought to be struck down as too broad, said Foley of Michigan, since such restrictions must be narrowly tailored.

"If the government's true interest is health and safety, then there should be a law spelling out minimal safety standards, personnel training standards and so on," Foley said.

There is another constitutional issue that a ban on human cloning raises, experts said: scientists' First Amendment right to pursue their intellectual interests.

"Our society is a marketplace of ideas, so you have to have the means to generate and test those ideas," said Lori Andrews, a professor at the Chicago-Kent College of Law.

Scientists cannot do everything they please, of course. But there is a strong, if still evolving, body of legal opinion that says there is a First Amendment right to follow one's muse and gain personal knowledge, Andrews said. Any limits the government might place on scientific inquiry would have to be narrowly tailored.

"A total cloning ban says, 'Thou shalt not research,' instead of, 'Thou shalt research within certain parameters,'" Foley said. "I don't know of any case, other than its power to limit spending, where Congress has been able to say, 'You just can't do this, period.' "

Whether any of these issues will get to court remains to be seen. Boisselier recently said she is tempted to challenge the FDA's authority. Mark Eibert, a Half Moon Bay, Calif., attorney who wants access to cloning because he and his wife are infertile, is considering mounting a constitutional challenge to California's statewide ban.

But court cases take time, and animal cloning techniques are advancing quickly. By the time the legal issues are settled in this country, several experts said, some human clones may already be swaddled and nursing -- making waves just as Louise Brown, the first IVF baby, did in 1978, and ushering in, for better or worse, a new era of human reproduction.

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