

DRAFT OUTLINE
REGULATION OF CLONING
Presentation by R.A. Charo
7 August 2001
N.A.S., Washington D.C.

1. Introduction:

The regulation of cloning and stem cell research is best understood in relation to the regulation of ARTs
ARTs include artificial insemination and IVF

2. History of ART and embryo research regulation.

1970s -- research on fetuses raises eyebrows; leads some states to enact statutes prohibiting or limiting fetal research; definitional sections of some statutes make them appear to cover research on extrauterine embryos as well

1970s -- new federal regulations on human subjects research; growth of IRBs; OPRR and FDA triggers; note distinction from practice of medicine

late 1970s -- proposed regulations on research on embryos, aimed at IVF; creation of EAB

early 1980s -- moratorium on federal funding for embryo research by allowing EAB to collapse; also moratorium on fetal tissue research funding

1980s -- IVF develops without federal funding; generally done without IRB oversight either because it is considered merely innovative practice of medicine or because there is no OPRR/FDA trigger. Fetal tissue research develops without federal funding despite recommendations of HFTTP

1980s through 1990s -- medical malpractice litigation related to human reproduction draws attention to question of liability for bad birth outcomes due to failures in use of genetic testing; although early cases suggest some liability to child, later cases consolidate toward position that there can be liability to parents (wrongful birth) but not to child (wrongful life). IVF cases are not featured; IVF cases are few, and tend to concern dispositional authority over extrauterine embryo, which slowly comes to be determined first in favor of progenitors, and where progenitors disagree, then either by prior agreement or by sweat equity arguments.

Late 1980s -- OTA et al draw attention to ARTs, especially IVF, and Ron Wyden (then Rep, now Sen.) leads move toward consumer protection in this area

Early 1990s -- Clinton administration lifts moratoria on federal funding; small level of federal funding for fetal tissue research begins; NIH foregoes embryo research funding pending further study

1993-94 -- NIH HERP recommends federal funding on embryo research, including limited funding for research that involves making embryos solely for research purposes. NIH ACD accepts all recommendations but Clinton rejects latter recommendation and remaining recommendations go without implementation due to congressional action to prohibit all federal funding for "non-therapeutic" embryo research

3. Cloning

1997 -- Dolly is born. NBAC (created 1996) concludes that regulation of reproductive cloning would be extremely difficult because:

(a) in some cases, it will be presented as "practice of innovative medicine" rather than research, and thus beyond the scope of research regulations;

(b) even if done as research, there would be no FDA or OPRR triggers if done in private facility with private money in the absence of an MPA

(c) although not written up in NBAC report, FDA jurisdiction appears to be lacking.

Therefore, NBAC concludes, reproductive cloning should be subject to temporary legislative moratorium 1998-2000 -- various states enact anti-cloning statutes.

1997-98 -- FDA claims jurisdiction over reproductive cloning, and embed claim in overall move toward more extensive regulation of genetic testing, cell based therapies and tissue transplantation (eg bone and skin). Scholars express skepticism over basis of FDA authority, noting embryo is not an "article" subject to regulation, and even if it is an article, it is not being used to treat a disease or condition; FDA reiterates authority until present day. FDA continues in efforts to regulate tissue transplantation, and issues rules governing control of infectious disease from sperm transfers (AID and IVF) and other tissue transfers.

1998 -- announcements from UW and JHU on stem cell retrievals from embryonic and fetal tissue sources

1999-2000 -- NBAC, AAAS and NIH all call for federal funding of research on stem cells derived from surplus embryos; NBAC also calls for federal funding of stem cell derivation but says no funding needed at this time for making research embryos either through IVF or cloning although such need might be demonstrated in the future. All authorities converge on rules governing funded research, including strict attention to informed consent from progenitors who donate the embryos and research funding limited to areas in which work cannot proceed adequately with non-human models. NIH issues funding guidelines and begins accepting grant proposals. Fetal tissue related work remains eligible for funding as well.

2001 -- Bush administration puts a hold on stem cell research funding; House passes HR 2505 which criminalizes both reproductive and research cloning

4. Avenues of regulation for cloning

(A) Criminalization: several states have already criminalized reproductive cloning; the trick here is to have adequate definitional sections (eg, to avoid criminalizing so-called cytoplasmic rejuvenation) and to survive constitutional challenge based on right to procreate (see presentation by John Robertson). Criminalization of research cloning (HR 2505) also would need to survive constitutional challenges based on lack of federal jurisdiction under the commerce clause and based on a right to do research (see presentation by John Robertson).

(B) Regulation: FDA could regulate if authority is upheld or, in the alternative, clarified and extended by federal legislation. FDA authority generally limited to issues of safety and so is not easily responsive to other social concerns. Authority is somewhat clearer with regard to research cloning (where embryo and derived cells are used for therapeutic purposes) than with regard to reproductive cloning.

(C) Tort Reform: States could adopt tort liability rules rendering professionals strictly liable for any bad birth outcome related to conception by cloning; would require that they eschew negligence standard (as this compares professional behavior to standard practice, an unworkable approach in an evolving field without a standard practice). Would also need to clarify issue of proximate cause (ie remove "parental" consent as a relevant intervening factor), statute of limitations (in order to ensure that defects discovered long after birth are still compensable), and cause-in-fact (ie set presumption that bad outcomes are due to cloning conception rather than other causes). Prospect of liability should significantly deter most professionals, as few insurers would be willing to offer coverage under these circumstances.