Regulating (for the Benefit of) Future Persons: 
A Different Perspective on the FDA's Jurisdiction to Regulate 
Human Reproductive Cloning 

By 

Gail H. Javitt, Esquire 
Kathy Hudson, Ph.D. 
Genetics and Public Policy Center 
Washington, D.C.

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Regulating (for the Benefit of) Future Persons: A Different Perspective on the FDA’s Jurisdiction to Regulate Human Reproductive Cloning

Gail H. Javitt* and Kathy Hudson**

The Food and Drug Administration (FDA) has taken the position that human reproductive cloning falls within its regulatory jurisdiction. This position has been subject to criticism on both procedural and substantive grounds. Some have contended that the FDA has failed to follow administrative law principles in asserting its jurisdiction, while others claim the FDA is ill suited to the task of addressing the ethical and social implications of human cloning.

This Article argues that, notwithstanding these criticisms, the FDA could plausibly assert jurisdiction over human cloning as a form of human gene therapy, an area in which the FDA is already regarded as having primary regulatory authority. Such an assertion would require that the FDA’s jurisdiction extend to products affecting future persons, i.e., those not yet born. This Article demonstrates, for the first time, that such jurisdiction was implicit in the enactment of the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act and that the FDA has historically relied on such authority in promulgating regulations for drugs and devices.

*Policy Analyst, Genetics and Public Policy Center; Adjunct Professor, University of Maryland Law School; J.D., Harvard Law School; M.P.H., Johns Hopkins School of Hygiene and Public Health; Former Greenwall Fellow in Bioethics and Health Policy, Johns Hopkins and Georgetown Universities.

**Director, Genetics and Public Policy Center; Associate Professor, Department of Pediatrics, Johns Hopkins School of Medicine; Ph.D., Molecular Biology, University of California at Berkeley; M.S. in Microbiology, University of Chicago.

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I. INTRODUCTION

Since 1998, the FDA has taken the position that human reproductive cloning using somatic cell nuclear transfer ("SCNT") is within the scope of the agency’s statutory authority.1 Consistent with this stance, the agency has made public its view that any researcher seeking to conduct clinical investigations to clone a human being will first be required to submit an investigational new drug application (IND) to the agency.2 Further, since the FDA believes human reproductive cloning raises safety concerns that remain unresolved, the agency has stated that it will not approve such an application, “until those [concerns] are appropriately addressed in the IND.”3 In short, the FDA has invoked its statutory and regulatory powers in an attempt to administratively prohibit human reproductive cloning in the United States.4

Previous commentators have addressed both the manner and substance of the FDA’s approach to human reproductive cloning, and have also questioned the agency’s institutional capacity to undertake this endeavor. Professor Richard Merrill, noted legal scholar and former FDA chief counsel, has criticized the agency’s failure to follow procedural requirements in asserting jurisdiction, and has questioned whether the FDA’s institutional structure and traditional oversight functions are adequately suited to mediating the societal conversation concerning the ethics of reproductive cloning.5 Merrill has also noted the absence of a clearly articulated legal basis for the FDA’s jurisdiction,6 and has concluded, most recently in testimony before the President’s Council on Bioethics,7 that the FDA “has not yet put forward its best case” for its legal authority to regulate cloning.8

The purpose of this Article is to continue the rich dialogue concerning the appropriate oversight of human reproductive cloning, and to explore at greater length the most plausible basis—i.e., the “best case”—for the FDA’s assertion

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3Id.
6See Merrill, supra note 4, at 105–06, 147.
7The Council was established by President Bush on November 28, 2001 by Executive Order No. 13, 237, 3 C.F.R. 821 (2002).
of jurisdiction over human reproductive cloning. This Article will argue that the FDA could plausibly choose to regulate SCNT as a form of gene therapy. Regulating SCNT in this manner would be consistent with the FDA’s existing definitions for gene therapy. However, whereas current gene therapy protocols seek to deliver genetic material to an existing human being for that person’s benefit, the target of SCNT is an enucleated egg (i.e., an egg from which the original nucleus has been removed) that is intended to develop into a born human being following gestation. The FDA’s regulation of reproductive cloning as a form of gene therapy would therefore need to presume that the agency’s regulatory jurisdiction extends to evaluating the safety and effectiveness of products administered prior to birth, and indeed, prior to gestation.

This Article argues that, although the FDA’s regulations for gene therapy have thus far been focused predominantly on the protection of currently living persons, the FDA’s assertion of jurisdiction over SCNT for the benefit of a future person would nevertheless be consistent with the agency’s historical oversight of products that have the potential to affect future persons. Additionally, it would comport with the legislative history and purpose of the Federal Food, Drug, and Cosmetics (“FD&C”) Act.\(^9\)

II. BACKGROUND

A. What Is Cloning?

The scientific methods that are used in mammalian SCNT cloning have been exhaustively documented.\(^10\) In brief, SCNT entails removing the original nucleus from an egg cell and replacing that nucleus with one from a somatic cell, such as a skin cell. The egg cell, now containing a new (for the egg cell) nucleus, is then induced to divide under laboratory conditions to form an embryo.

What happens next determines whether the process will be termed research cloning or reproductive cloning. The embryo may be used to derive stem cells, which are progenitor cells with the capacity to generate a wide

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