The Columbia
SCIENCE AND TECHNOLOGY LAW REVIEW
www.stlr.org

REGULATING REPRODUCTIVE GENETICS: A REVIEW OF AMERICAN BIOETHICS COMMISSIONS AND COMPARISON TO THE BRITISH HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY*

Margaret Foster Riley with Richard A. Merrill**

Many people are now advocating expanded government regulation of research and clinical use of reproductive technologies. Although many of these technologies have been in use or anticipated for more than twenty-five years, and a number of bioethics commissions have considered regulation of them, efforts to develop broad national regulation have largely failed. This article examines the role that government institutions can play and have played in designing regulation of assisted reproduction and reproductive technologies. We review the history of national commissions as proponents and architects of regulation and explore how their structure, mission, and political placement have influenced their success or failure. We then compare the experience of the United States to that of Great Britain which established the Human Fertilization and Embryology Authority (HFEA) in 1990 and consider whether the HFEA might be a model for future regulation in the United States. We conclude that bioethics commissions can play an important role in formulating policy but they cannot create necessary political consensus if that consensus is lacking. Moreover, while the United States can glean important lessons from the British experience, the two countries' political, legal, and medical cultures differ in ways that suggest importation of the British model would be difficult and perhaps unwise.

I. INTRODUCTION

Many lawyers, political scientists, and bioethicists now advocate expanded government regulation of research and clinical use of reproductive technologies. Reproductive technologies employ the techniques used to create, use and manipulate embryos. These methods may be

* This paper was commissioned by the Genetics & Public Policy Center at Johns Hopkins University, which is supported by The Pew Charitable Trusts. The opinions expressed are those of the authors.

** Margaret Foster Riley is a Professor of Law at the University of Virginia School of Law. Richard A. Merrill is the Daniel Caplin Professor of Law at the University of Virginia School of Law.

arrayed on a spectrum from relatively uncontroversial procedures such as artificial insemination[1] to extremely controversial procedures associated with reproductive cloning. Reproductive technology includes techniques like in vitro fertilization (IVF), which is designed to help infertile people achieve pregnancies, and procedures that rely on reproductive genetics[2] to provide prospective parents with information that will enable them to avoid producing a child with a genetic defect. Reproductive technology may also be used for non-reproductive purposes such as creating a source of embryonic stem cells.

Some contend that new legislation is needed to free scientists to fulfill the potential for human treatments that reproductive technology promises.[3] Others see legislation as necessary to curb scientific exploration of areas that are ethically unacceptable.[4] Some, of course, question the need for any government involvement.[5]

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[1] Artificial insemination has not always been uncontroversial. The Warnock Commission, which studied reproductive technologies in Britain in the 1980s, was attacked by some Jewish scholars for its stance on artificial insemination. *See, e.g.*, Mary Warnock, *A Question of Life: The Warnock Report on Human Fertilisation & Embryology*, viii-ix (1985) [hereinafter *Warnock Report*]. See *infra* notes 223-248 and accompanying text for a full discussion of the Warnock Commission.

[2] Reproductive genetics involves the use of genetic technologies to avoid or diagnose genetic disease in an embryo or fetus, overcome infertility, or to provide information to prospective parents to help guide reproductive decision-making. One reproductive genetic technology is preimplantation genetic diagnosis (PGD). PGD, developed in the late 1980s, allows embryos to be screened for genetic disease. The process usually involves ovarian hyperstimulation and IVF; the eggs are harvested and fertilized and the resulting embryos are tested. The most common test involves testing one cell of an eight cell embryo. The DNA of that cell is extracted and analyzed. Ooplasm transfer also can be considered under the rubric of reproductive genetics since it involves transfer of mitochondrial DNA. Ooplasm transfer involves the transfer of ooplasm (the extranuclear material) from a healthy donor egg into the egg of a woman experiencing infertility, which ostensibly increases fertilization of the recipient egg. This technique was halted by the FDA in 2002. An embryo resulting from ooplasm transfer has three "genetic" parents since it contains mitochondrial DNA from the donor egg. Susan Wolf et al., *Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines & Limits*, 31 J.L. Med. & Ethics 327, 328 (2003); J. Barritt et al., *Mitochondria in Human Offspring Derived from Ooplasmic Transplantation*, 16 Human Reprod. 513, 513-16 (2001).

[3] Eric Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations*, 33 Hastings Center Rep., S18-21 (2003).

[4] Francis Fukuyama, an advocate of governmental limits on novel reproductive technologies, is exemplary:

> [T]he time when governments could deal with biotech questions by appointing national commissions that brought scientists together with learned theologians, historians, and bioethicists . . . is rapidly drawing to a close. These commissions played a very useful role in doing the preliminary intellectual spadework of thinking through moral and social implications of biomedical research. But it is time to move from thinking to acting, from recommending to legislating. We need institutions with real enforcement powers.

Francis Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution,* 203-04 (2002); *see also* President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, 220-4 (2004).

[5] *See, e.g.,* Bulletin from American Society for Reproductive Medicine, *ASRM/SART Comment on the Decline in Multiple Gestations from ART*, *available at* http://asrm.org/Washington/Bulletins/vol6no24.html (Apr. 14, 2004) ("We think this points out that careful evidence-based recommendations from the professionals are superior to the bureaucratic one-size fits all approach that some have advocated.")

This article examines the role that government institutions can play, and have played, in designing regulation of assisted reproduction and reproductive technologies. Specifically, we review the history of national commissions as proponents and architects of regulation and explore how their structure, mission, and political placement have influenced their success or failure.

We begin, in Part II, with a description of U.S. regulation of reproductive technologies as a largely unregulated sector. In Parts III and IV we describe several blue-ribbon panels that have been established in the United States to evaluate, guide, and help control frontier medical research and procedures.[6] Most of these bodies dealt with more than reproductive technologies, and none succeeded in creating any formal regulatory structure.

In Part V, therefore, we cross the Atlantic to study the British Warnock Commission, the Human Fertilisation Act of 1990 (HFE Act) - the legislation which the Warnock Commission inspired, and the entity created by the HFE Act, the Human Fertilisation and Embryology Authority (HFEA). The HFEA regulates all clinical and research activity that involves embryos outside the mother's body. In creating the HFEA, the British government answered the call for regulation in a manner that has so far eluded American advocates of heightened oversight of reproductive technologies.

The HFEA has been promoted as a model for the United States[7] and accordingly, in Part VI, we address the question of why the British were able to introduce comprehensive regulation of reproductive technologies and the United States has not done so. We explore the political and cultural differences that influence how the advisory recommendations were treated in the two countries. Finally, we address whether the British experience holds lessons for the United States. On its face, the British model seems appealing because it deals specifically with assisted reproductive technologies and associated research. However, it was designed to function within a very different political and cultural environment. The goal we suggest, therefore, should be to extract from the HFEA experience specific lessons for the design of a system that must function within the American political and cultural framework.

We acknowledge that blue-ribbon commissions can play an important role in formulating bioethics policy. They can sometimes influence political action and can often provide a forum for public education and debate. But they cannot create political consensus if consensus is lacking within the legislature or among the public at large. The British HFE Act owes its success in part to the structure, composition, and role of the commission whose framework the Act

[6] We do not discuss the Advisory Commission on Human Radiation Experiments (1994-1995). That commission was charged with investigating the history of human subjects research involving radiation exposure, much of which took place shortly after World War II but was not known publicly until the 1990s. While that investigation clearly had a prospective impact, and issues of compensation for injured subjects that were addressed there later became a focus for other bioethics panels, the commission played a very different role than most bioethics advisory committees. Also, it had a very focused and narrow subject matter mandate. It was designed to examine the historical record and determine what actually happened so that a future commission could apply that knowledge to current regulation. *See, generally*, Dep't of Energy, Final Report of the Advisory Commission on Human Radiation Experiments, *available at* http://tis.eh.doe.gov/ohre/roadmap/achre (1995).

[7] The suggestion of using HFEA as a model of regulation in the United States has been made by authors representing wide ranges on the political spectrum. *See, e.g.,* Francis Fukuyama, supra note 2, at 204-205; Parens & Knowles, supra note 3, at S18. Its use as a model has not been embraced by all players. The President's Council on Bioethics has voiced qualms about using a foreign entity as a model for United States regulation. President's Council on Bioethics , *supra* note 4, at 12.

embodies. However, the main reason for its success was a political commitment, coupled with legislative control strong enough to overcome opposition. Neither condition prevails in the United States today.

II. AN UNREGULATED SECTOR

In the United States reproductive technologies are not closely regulated at either the state or federal level. The technologies are used primarily in private IVF clinics. Decisions about what technologies are available and how they are used have generally been made by patients and their doctors.[8] Regulation of medical practice is more generally a traditional province of state, not federal, government.[9] However, even where regulation occurs, it usually stops short of interfering with the physician's clinical decision-making.[10]

Research involving reproductive technologies has similarly eluded direct regulation for more than twenty years; however, such research has been limited because of the lack of federal funding.[11] Private funding supports a small but growing amount of such research.[12] Several

[8] The FDA does regulate many products used by physicians in reproductive medicine. For example, ovulation stimulating drugs are regulated and subject to pre-market approval. However, the FDA cannot fully regulate off-label uses of these products. Indeed, some have criticized off-label use of drugs to stimulate ovulation as risky to women. Such hyper-stimulation is known to cause ovarian hyper-stimulation syndrome (OHSS) in some patients. This may manifest as lower abdominal discomfort, bloating and nausea that may progress to vomiting and, in severe cases, ascites, pleural effusion and even thromboembolic disease. The relation of such hyperstimulation to later cancer is much less clear. *See* Chandra Kailasam & Julian Jenkins, *Infertility: Risks and Benefits of Assisted Conception,* Pulse, Feb 2, 2004, at 46.

[9] *See, e.g., Medtronic v. Lohr*, 518 U.S. 470, 485 (1996); *Collins v. Texas*, 223 U.S. 288, 292 (1912); *Mugler v. Kansas*, 123 U.S. 623, 661 (1887); *see also infra* note 355 and accompanying text.

[10] For example, the 1992 Fertility Clinic Success Rate and Certification Act, 42 U.S.C. § 263a-1, requires that certain data be reported to the Centers for Disease Control (CDC), but the Act restricted both the CDC and the states from establishing, as part of the certification program, "any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproduction technology programs." 42 U.S.C. § 263a-1 (2005). An exception to this reluctance to interfere with clinical decision-making occurs with abortion statutes. *See, e.g.,* 18 U.S.C. § 1531 (2004); Va. Code Ann. §18.2-71.1 (2004).

[11] Much of the history of this ban is discussed later in this article. NIH's exact stance on embryo research was unclear in the early 1970s, but no funding was made available. *See* Human Embryo Research Panel (Ad Hoc Group of Consultants to the Advisory Committee to the Director), U.S. Nat'l Insts. of Health (NIH), *Report, Volume II: Papers Commissioned for the Human Embryo Research Panel*, NIH Pub. No. 95-3916 (Sept. 1994). These papers are authored by J. Van Blerkom, B. Steinbock, L.B. Andrews and N. Elster, and L.B. Andrews. *See also* Robin Marantz Henig, *Pandora's Baby* 90 (2004). In 1979, the Ethics Advisory Board recommended federal funding for embryo research but its recommendations were not implemented. *See infra* Section III.B. Through a combination of administrative restrictions and inaction, no efforts were taken to permit such funding until 1994. In 1994, the Human Embryo Research Panel (HERP) recommended federal funding for embryo research but political divisions blocked implementation of that plan. *See infra* Section III.E. In 1996, an amendment to an appropriations bill blocked federal funding for embryo research. *See infra* note 154 and accompanying text. That ban has been extended by every Congress since then. DHHS ruled in 1999 that stem cell research was not subject to the embryo research ban, but in 2001, President Bush, limited federal funding for stem cell research to existing stem cell lines only. *See infra* Section III.G.

advisory panels have recommended that there should be federal funding for some embryonic research while at the same time endorsing restrictions that would limit such research to an early stage of embryo development. Because such funding has never been provided, however, direct regulation has never been implemented.

In vitro fertilization (IVF) centers are loosely regulated at both the federal and state level.[13] Under the Fertility Clinic Success Rate and Certification Act (FCSRA), IVF centers must report success rates. IVF laboratories are not currently subject to Clinical Laboratory Improvement Amendments ("CLIA"), though some have urged that they should be.[14] Most IVF laboratories are private entities and thus not subject to federal regulation of human subjects research.[15] The FDA has claimed jurisdiction over human cloning procedures and ooplasm transfer,[16] and the agency's authority might extend to other reproductive genetics practices as well.[17] However, the legal basis for the FDA's claim remains untested and unresolved.[18]

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[12] The majority of the most important breakthroughs in treatment of human disease in the United States have been at least partly funded by the federal government. *See, e.g.*, the National Institutes of Health's information on research advances funded through its auspices, *at* http://www.nih.gov/about/researchadvances.htm (last visited May 12, 2005). It is difficult to determine how much private funding is involved in embryo research since private firms, normally fairly reticent about funding because such research is considered proprietary, are even more reticent where it involves potentially controversial research. *See, e.g.*, Marie McCullough & Josh Goldstein, *Stem Cell Research Flourishes,* Philadelphia Enquirer, June 13, 2004, at 2C. However, if public institutions can be viewed as something of a barometer, private sources are increasing funding, at least for stem cell research. Harvard has a fund-raising goal of $100 million for stem cell research. Gareth Cook, *U.S. Stem Cell Research Lagging Without Aid, Work Moving Overseas*, Boston Globe, May 23, 2003, at A1. The University of California at San Francisco, undertaking a similar project, recently received $5 million from one donor. *Id.* New Jersey, the first state to directly fund stem cell work, has launched a $50 million Stem Cell Institute. McCullough & Goldstein, *supra*. Private funding for other types of embryo research seems less robust but IVF centers have long been quite active. One of the largest, the Jones Institute for Reproductive Medicine at Eastern Virginia Medical School, was a major player in early IVF research as well as more recently with ICSI and PGD. *See Research at the Jones Institute, at* http://www.jonesinstitute.org/research.html (last visited May 13, 2005). Some researchers actually favor private funding, arguing that private research allows patients to get access to treatment sooner by avoiding NIH "red tape." *See* Stephen Smith, *Limits on Embryo Research Affect Treatments for the Infertile*, Minnesota Public Radio, Feb. 5, 1998. But private funding may mean market forces trump safety issues in bringing a technique into use. *Id.* Private funding also means that much research may never be made public.

[13] The Fertility Clinic Success Rate and Certification Act (FCSRA) governs reporting of pregnancy success rates. 42 U.S.C. § 263a-1 (2005). There are no penalties for failure to report under FCSRA. *Id.* According to the CDC, which monitors the program, not all clinics that perform assisted reproductive techniques in the United States report data. The CDC publishes a list of non-reporting clinics on their website. 51(05) Morbidity & Mortality Wkly. Rep. 97 (2002), *available at* http://www.cdc.gov/reproductivehealth/ART01/PDF/ART2001.pdf, at 501. Some additional regulation of IVF clinics has just been added. The FDA has just finalized regulations that will apply to reproductive cells and tissues utilized in IVF centers. Human Tissue Intended for Transplantation, 21 C.F.R. § 1270 (2003).

[14] *See, e.g.*, CDC, *General Recommendations for Quality Assurance Programs for Laboratory Molecular Genetic Tests* (Aug. 31, 1999), http://www.phppo.cdc.gov/dls/pdf/genetics/dyncor.pdf.

[15] *See* Protection of Human Subjects, 45 C.F.R. § 46.101 (1999).

[16] Letter from Kathryn C. Zoon, Director of the FDA's Center for Biologics Evaluation and Research, to Sponsors/Researchers (July 6, 2001), *at* http://www.fda.gov/cber/ltr/cytotrans070601.htm (stating that the FDA "has jurisdiction over human cells used in therapy involving the transfer of genetic material by means other than the union of gamete nuclei," including ooplasm transfer, since it involves the transfer of mitochondrial DNA).

The American Society for Reproductive Medicine (ASRM), whose members comprise researchers and practitioners of reproductive medicine, has issued guidelines covering assisted reproductive technologies that do address some of these ethical and social issues as well as safety concerns,[19] but these guidelines are voluntary even for ASRM members.[20]

In sum, in the United States there is no systematic regulation of reproductive technologies used in medical research or clinical treatment. Existing controls are a patchwork, and most decisions are left to individual providers and their patients. While several blue-ribbon advisory panels have recommended broader regulation, none have ever generated the public or political support necessary to convert that advice into practice. In the next section, we search for explanations for their impotence.

III. THE UNITED STATES' EXPERIENCE WITH BIOETHICS PANELS

In 1978, Michael Yesley, the staff director for the first U.S. bioethics panel, wrote that such entities can serve two very different functions.[21] A blue-ribbon commission may serve to defer or avoid political action or it may provide a method of achieving consensus on issues that require evaluation in light of conflicting values. U.S. bioethics panels have served both functions, sometimes simultaneously. Over time, however, they have been more successful in deferring than inspiring action. This track record in part reflects our political arrangements. The

[17] The FDA has stated that reproductive cloning is subject to the Agency's Investigational New Drug (IND) regulations. The FDA's claim may be supported by the notion that cloning is a form of gene therapy. *See* Gail H. Javitt & Kathy Hudson, *Regulating (for the Benefit of) Future Persons: A Different Perspective on the FDA's Jurisdiction to Regulate Human Reproductive Cloning*, Utah L. Rev. 1201, 1201 (2003). That authority is predicated on the notion that such experiments "involve the administration of unapproved biological drugs subject to the Agency's IND regulations." The FDA's claimed authority for gene therapy is not based on any legislative grant of jurisdiction, but the FDA did submit to a public comment period when it claimed that authority in the early 1990s. No such public comment has occurred with regard to cloning. Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?*, 15 Harv. J.L. & Tech. 85, 118-124 (2001).

[18] Merrill & Rose, *supra* note 17, at 137-139.

[19] *See* ASRM, *Preimplantation Genetic Diagnosis* (June 2001), *at* http://www.asrm.org/Media/Practice/practice.html (available to ASRM members only); The Ethics Committee of the ASRM, *Sex Selection and Preimplantation Genetic Diagnosis,* 72 Fertility & Sterility 595 (1999), *available at* http://www.asrm.org/Media/Ethics/Sex_Selection.pdf (cautioning against the use of PGD for sex selection); The Ethics Committee of the ASRM, *Preconception Gender Selection for Nonmedical Reasons*, 75 Fertility & Sterility 861 (2001), *available at* http://www.asrm.org/Media/Ethics/preconceptiongender.pdf.

[20] The majority of those practicing in this area in the United States are members of ASRM. In addition, ASRM is working closely with its European counterpart, the European Society of Human Reproduction and Embryology (ESHRE). ESHRE is currently working on new comprehensive guidelines. Nonetheless, although most members comply with ASRM rules, they are not compelled to do so since membership is voluntary. Note that ESHRE recently released PGD guidelines. *See* A.R. Thornhill et al., *Best Practice Guidelines for Clinical Preemption Genetic Diagnosis (PGD) and Preimplantation Genetic Screening*, ESHRE PGD Consortium (2004), *available at* http://www.humrep.oupjournals.org/cgi/reprint/deh579v1 (registration required). Similarly, the PGD International Society has issued guidelines. *See* The Preimplantation Genetic Diagnosis International Society (PGDIS), *Guidelines for Good Practice in PGD,* 9 Reproductive Biomedical Online 430 (2004), *available at* http://www.rbmonline.com/4DCGI/Article/2004/1482/RB1481%20PGDguidelines.pdf (registration required).

[21] Michael S. Yesley, *The Use of an Advisory Commission*, 51 S. Cal. L. Rev. 1451, 1452-54 (1978).

President may propose legislation and lobby for its passage but cannot demand enactment. Agreement can be very difficult to achieve when the White House and Congress, or the House and Senate, are controlled by different parties. Even when the political branches are controlled by the same party, party discipline is generally weaker than in parliamentary systems like Great Britain's.

Over the last twenty-five years, moreover, opinions about these technologies have become more sharply divided. As a consequence, bodies created to achieve consensus have been given fewer mechanisms through which to implement their recommendations.[22] This seems entirely intentional. Politicians of all persuasions have become less inclined to compromise and more inclined to challenge any recommendation they find offensive. Neither national party has a clear majority on these issues in Congress. As a consequence, initiatives to address reproductive technologies are rarely enacted.

It is not obvious, though, that this outcome represents failure. It is certainly failure for those who wish to see governmental action, either empowering more rapid scientific progress or restricting technologies that some consider offensive. It is also certainly frustrating for members of commissions. However, Congress's inability to reach consensus may reflect public acceptance of the status quo. Blue-ribbon panels have been "educating" Americans about reproductive genetics and new reproductive technologies since the 1970s. During this time, public attitudes toward reproductive technology have not fundamentally changed.[23] Many people appreciate the options the technology provides for improved treatment of both infertility and disease. Many others fear the technology as threatening religious values and giving humanity too much control over its own future.[24] Some hold both views simultaneously.

[22] The charters of the two early commissions, the National Commission and the Presidential Commission, included "forcing clauses" which created an almost automatic mechanism for the translation of Commission recommendations into regulation. Later commissions were not given anything like that power. *See infra* notes 67 & 105, and accompanying text.

[23] Public opinion polls from 1978 and 2004 are remarkably similar. *See* Louis Harris & Associates, *A Study of the Attitudes of American Women Toward the "Test Tube" Procedure and Related Matters*, Aug. 1978, Parents Magazine, reprinted in *Ethics Advisory Board, Appendix D: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer* (May 1979) [hereinafter EAB Appendix] and Genetics & Public Policy Center, at http://www.dnapolicy.org/research/reproductiveGenetics.jhtml;$sessionid$II4TN3QAABBP4CQBAT3R3KQ.

[24] *See* Genetics & Public Policy Center, *Public Awareness and Attitudes about Reproductive Genetic Technology* (2002), *at* http://www.dnapolicy.org/research/reproductiveGenetics.jhtml; Genetics & Public Policy Center, *Reproductive Genetic Testing: What America Thinks* (2004*), at* http://www.dnapolicy.org/research/reproductiveGenetics2004.jhtml;$sessionid$R5PVXOQAAAVIECQBAT3RNWQ?subSection=rgt2004; R. Timothy Mulcahy, *What has Dolly Wrought? Allow Research Cloning, Ban Reproductive Cloning*, Wis. St. J., Jan. 5, 2003, at Forum B1, *available at* http://www.madison.com/archives/read.php?ref=wsj:2003:01:05:87275:FORUM.

A. *The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978)*

The first national body formed to study biomedical ethics,[25] the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, was created by the National Research Act of 1974 in response to growing public concern about biomedical research.[26] News reports about the Tuskegee Syphilis Study had been published during the summer of 1972.[27] The next year, the Subcommittee on Health of the Senate Committee on Labor and Welfare, chaired by Senator Edward Kennedy, held extensive hearings on the Tuskegee study as well as the unapproved use of approved drugs (Depo-Provera and DES), the use of new psychosurgery techniques, the military's use and testing of drugs, abuses in prison research, the sterilization of the Relf sisters,[28] and other ethical abuses in human research.[29] Several witnesses called for the creation of a commission to study biomedical research. They recommended that it be independent of government entities that supported such research (notably, the National Institutes of Health (NIH)), that it be representative of general public opinion, and that it devote its efforts to educating the public.[30] The Senate report stated:

> [T]he commission should undertake a comprehensive investigation and study in order to identify the basic ethical principles which underlie the conduct of biomedical research involving human subjects. On the basis of those identified principles the committee believes that the commission should develop and implement policies and regulations to assure that such research is carried out according to the highest possible standards. The Committee does not believe that it is the responsibility of the Federal government to develop and establish moral principles. It does believe that the commission should identify those principles

[25] The term "bioethics" or "biomedical ethics" was itself in its infancy at that time. It is believed to have been coined by B. Rensselaer Potter, a cancer researcher in Madison, Wisconsin. U.S. Congress, Office of Technology Assessment, *Biomedical Ethics in U.S. Public Policy—Background Paper,* OTA-BP-BBS-105 (June 1993), at 2 [hereinafter *Background Paper*] (citing W.T. Reich*, How Bioethics Got Its Name*, remarks at the conference The Birth of Bioethics, Seattle, WA, Sept. 1992).

[26] National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974). The act was passed during the last month of the Nixon administration and was implemented in the Ford administration.

[27] The Tuskegee Syphilis Study, conducted by the United States Public Health Service over forty years, sought to understand the natural history of syphilis. Poor African-American men joined the study as a way to obtain treatment. When penicillin became available, it was withheld from the study participants and they were actively dissuaded from seeking effective treatment because to do so would interfere with the natural course of the disease. The study came to public light in 1972. *See* James H. Jones, *Bad Blood* (1981).

[28] The Relf sisters were two young black girls, aged 12 and 14, living in Montgomery, Alabama, who were sterilized in 1973 as part of a federally funded family planning program without their or their parents' actual consent or knowledge. Their mother, who was illiterate, thought that the girls were receiving preventive vaccinations. *See, e.g.*, Meredith Blake, *Welfare and Coerced Contraception: Morality Implications of State Sponsored Reproductive Control*, 34 U. Louisville J. Fam. L. 311, 314 (1995).

[29] S. Rep. No. 93-381 at 27 (1973); Michael S. Yesley, *The Use of an Advisory Commission*, 51 S. Cal. L. Rev. 1451, 1456 (1978).

[30] *Id.*

> and use them as the basis of the rules and regulations that the commission will promulgate.[31]

As envisioned by the Senate report, the commission was to be a permanent regulatory body, whose members were to be appointed by the President with the Chair and Co-Chair subject to Senate confirmation.[32] However, Representative Paul Rogers supported the NIH position that the commission should be only advisory.[33] The final legislation made the commission advisory but required the Department of Health Education and Welfare (DHEW) to convert commission recommendations into regulations or make its reasons for rejection public.[34] The commission was given a two-year life[35] and its members were appointed by the HEW Secretary. Eleven members were chosen: five scientists, three lawyers, two ethicists, and one person in public affairs. The members elected their own chair.[36]

The National Commission is deservedly famous for the Belmont Report, its response to Tuskegee and other research scandals.[37] The Report grew out of a workshop held in February 1976 at the Smithsonian Institution's Belmont Conference Center and was largely drafted by staff member Tom Beauchamp. Remarkable for its brevity as well as its substance, the Belmont

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[31] S. Rep. No. 93-381 at 28.

[32] *Id*. at 48.

[33] The concept of a national bioethics commission was vociferously opposed by some members of the scientific community who were wary of regulations that could hamstring the research enterprise. Robert Cook-Deegan, *The Gene Wars, Science, Politics and the Human Genome* 257 (1993).

[34] National Research Act, Pub. L. No. 93-348, § 202(3)(b) (1974). *See also* Tom Beauchamp, *Origins, Goals and Core Commitments, The Belmont Report and Principles of Biomedical Ethics*, *in The Story of Bioethics* 17, 39 n.7 (Jennifer K. Walter et al. eds., 2003).

[35] Coincidentally, Congress passed the Federal Advisory Committee Act (FACA) in 1972. 5 U.S.C. app. 2 §§ 1-14. FACA mandates that all advisory committees be terminated no later than two years after they are established unless specifically exempted by the entity creating the committee. Advisory committees can, of course, be extended past the two-year limit, and the National Commission was, but FACA eliminates the presumption that a committee will continue to operate. 5 U.S.C. App. 2 §14 (1972).

[36] The commissioners were: Joseph Brady, a biology professor from Johns Hopkins; Robert Cooke, vice-chancellor for Health Sciences at the University of Wisconsin; Dorothy Height, president of the National Council of Negro Women; Albert Jonsen, professor of bioethics from UCSF; Patricia King, a law professor at Georgetown; Karen Lebacz, professor of Christian ethics at the Pacific School of Religion; David Louisell, a law professor at UC Berkeley; Donald Seldin, an internist at the University of Texas; Eliot Stellar, a psychologist and provost of U. Penn; Robert Turtle, an attorney in private practice; and the chair, Kenneth Ryan, an obstetrician and gynecologist and chief of staff at Boston Hospital for Women.

[37] A well-known research scandal involved a study at the Jewish Chronic Disease Hospital wherein debilitated elderly patients were injected with live cancer cells without their fully informed consent. They were merely told that they would be receiving "some cells." In 1966, Henry K. Beecher, a professor of anesthesiology at Harvard Medical School, published an article outlining twenty-two questionable human research studies including the Jewish Chronic Disease Hospital study. *Ethics and Clinical Research*, New Eng. J. of Med., 274, 1354-60 (1966). *See generally, Ethics and Regulatory Aspects of Clinical Research, Readings and Commentary* (Ezekiel Emmanuel et al. eds., 2003).

Report sets out the now commonly accepted principles of human subjects protection: respect for persons, beneficence, and justice.[38]

The history of the Belmont Report illustrates how the National Commission functioned and how its members and staff viewed their roles. The commission had a legislative mandate to identify the ethical principles that should inform human subjects research. At their meeting at the Belmont Center, the commissioners agreed on three basic ethical principles: "respect for persons," "beneficence," and "justice." But when Beauchamp asked the staff director, Michael Yesley, what they meant, he was told that it was his "job to figure out what the commissioners meant—or perhaps what they should have meant." Beauchamp took primary responsibility for the drafting, but the ultimate report was informed by commission discussions and comments from staff and commissioners. The final document more closely reflected the commissioners' views than those of its primary author.[39]

Unlike many such documents, the Belmont Report became shorter with successive revisions. At least one commissioner, Donald Seldin, sought a more philosophical treatise, but the majority favored a more streamlined document.[40] The final report's sparse explanation for its recommendations facilitated consensus; commissioners could agree on the broad principles if not always on their moral underpinnings.

Less well known today, but regarded by several commissioners as their greatest achievement, was the National Commission's first report: "Research on the Fetus." By the time the commission began its work, fetal research had become a major focus for potential regulation in Congress. *Roe v. Wade*,[41] decided in January 1973, brought the treatment of fetuses in research to the forefront. Senator James Buckley proposed an amendment to the National Research Act that would have prohibited HEW from conducting or supporting any non-therapeutic research on a living human fetus before or after elective abortion. The amendment appears to have been prompted by scandal. Press reports of experiments involving the severed heads of twelve fetuses obtained by hysterectomy generated pressure in both Houses to prohibit such research.[42] Rather than resolving the issue by statute, Senator Kennedy argued that the issue should be dealt with by the Commission:

[38] While the principles are well known, what they actually mean may be less clear. Beauchamp notes that much of the drafting of the Belmont Report and the seminal work that he authored with James Childress, *Principles of Biomedical Ethics*, was done simultaneously and each informed the other. They were not identical, however. For example, Beauchamp notes that his conception of the principle "respect for persons" is quite different from that of the commission. Beauchamp and Childress believed that the commission inappropriately combined concepts of respect for autonomy and non-maleficence within respect for persons. Hence, *Principles of Biomedical Ethics* sets out four rather than three principles, and those principles are defined differently. In addition, the Report itself was stripped of voluminous philosophical discussions and underpinnings that were included in the *Principles of Biomedical Ethics* but that did not necessarily reflect the views of the commissioners. Beauchamp, *supra* note 34, at 23-29.

[39] *Id*. at 27.

[40] *Id*. at 20.

[41] 410 U.S. 113 (1973).

[42] Yesley, *supra* note 21, at 1457.

> I do not think we ought to be drawing up those different provisions on the floor of the Senate. That is why we are establishing the Commission, so that they can . . . spend the time to get the people dealing with theology, religion, medicine, and research to sit down and spend hours and days thinking about those various problems . . . . It is difficult to see how we can be expected to write this kind of prohibition here. . . .
> This matter affects the sensibilities and the ethics of the people of this country. It seems to me that, rather than our defining this, it would be much wiser to give the chance to the Commission to examine it and to give it full consideration.[43]

A compromise was reached; fetal research was prohibited by law until the Commission could address the matter,[44] a task it was given four months to complete.[45]

The Commission issued "Research on the Fetus"[46] in May 1975, and by July its recommendations were "translated into federal regulations."[47] The Commission did not address the legal or moral status of the fetus directly, but it did find that some types of research were permissible even though the fetus could not consent.[48] The Commission did demand that fetuses be treated with respect and dignity.[49] For all such research, it stipulated that animal models be used first;[50] that the knowledge sought could not be obtained by other means;[51] that the risks and benefits for both the mother and fetus be fully assessed;[52] that informed consent be obtained from the mother;[53] that, under certain circumstances, the father be given an opportunity to object;[54] and that benefits and risks be distributed equitably among economic, racial, ethnic, and

[43] 119 Cong. Rec., at 29,228 (1973).

[44] *Id*. at 29, 229. Fetal research was not prohibited by statute but by a moratorium imposed by the National Institutes of Health. *See* John C. Fletcher, *The Stem Cell Debate in Historical Context, in The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy*, 27 (Suzanne Holland, et al. eds., 2001).

[45] National Research Act, Pub. L. No. 93-348, § 202(3)(b) (1974).

[46] *Research on the Fetus,* DHEW Pub. No. (OS) 76-127 (Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research 1975) (report and recommendations) [hereinafter *Research on the Fetus*], *available at* http://www.bioethics.gov/reports/past_commissions/research_fetus.pdf. This report considered fetal research and not the embryo research that would be the focus of later commissions like the EAB, HERP and Warnock. Although animal research and indeed research involving human embryos was taking place at this time, it did not become a focus for public concern until after the birth of Louise Brown, the first IVF baby, in 1978.

[47] *Background Paper*, *supra* note 25, at 10-11.

[48] *Research on the Fetus*, *supra* note 46, at 62.

[49] *Id.*

[50] *Id.* at 63.

[51] *Id.* at 64.

[52] *Id.*

[53] *Id.*

social classes.[55] Some fetal research would be permitted under customary review processes but other experiments would be subject to further evaluation by a national review board established to examine individual protocols.

Therapeutic research directed toward the fetus was permissible so long as the mother gave her consent. Therapeutic research directed toward pregnant women was permissible and could include research on abortion techniques permitted by law.[56] Non-therapeutic research directed toward the fetus in utero or toward pregnant women was permissible if it posed no more than minimal risk. This standard applied equally to fetuses slated for abortion and fetuses intended to be carried to term. Recognizing that the standard might be difficult to apply, the Commission's report recommended that these protocols be subject to review by the national review board. Finally research on the fetus during an abortion procedure or on a non-viable fetus ex utero was permissible so long as no interventions were used that could alter the duration of life of the non-viable fetus ex utero; the selection of an abortion procedure, including the method and timing, was kept completely separate from the research decision; and no fetus of greater than twenty weeks gestation was used. Research in this last category, too, would be subject to review by the national review board.

The decision to treat fetuses slated for abortion on the same footing as those expected to reach term represented a major concession to the more conservative members of the Commission. While the Commission thus accorded the same protections to all fetuses,[57] it did provide for exceptions. Research involving more than minimal risk could proceed if approved by the proposed national review board.[58]

Perhaps the most remarkable feature of the Commission's report on fetal research was the lack of controversy that it engendered. Indeed, the report diffused controversy. Senators Kennedy and Buckley each had a hand in choosing commissioners[59] and this may have forestalled complaints that the membership was stacked one way or the other. In addition, the Commission's processes may have dampened controversy. In their early sessions the members avoided possible recommendations and concentrated on information gathering. They learned that the majority of "fetal research involved therapy for the subjects or presented no more than minimal risk."[60] This "narrow[ed] the area of dispute."[61] Ultimately, "what the Commission

[54] *Id.* at 65.

[55] *Id.* at 64.

[56] The recommendation permitting research on abortion techniques was not unanimous. Commissioner David Louiselle argued that such research could not be consistent with the requirement that any therapeutic research involving a pregnant woman had to minimize risk to the fetus. *See Research on the Fetus, supra* note 46, at 77-81 (dissenting statement of Commissioner David W. Louisell).

[57] *See* Fletcher, *supra* note 44, at 28.

[58] The waiver provision was a major worry for the one dissenting member on that provision. To Louisell, it seemed to be a loophole that had no restraint. *See Research on the Fetus, supra* note 46, at 79 (dissenting statement of Commissioner David W. Louisell).

[59] Bradford Gray, *Bioethics Commissions: What Can We Learn from Past Successes and Failures?, in Society's Choices: Social and Ethical Decision Making in Biomedicine* 306 n.4 (Ruth Ellen Bulger, et al. eds., Nat'l Academy Press 1995).

[60] Yesley *supra* note 21, at 1460.

recommended was similar to [legislation] that originally [was] proposed," and its report was greeted with "approval from all sides."[62]

The National Commission issued eight additional reports.[63] The reports on fetuses, prisoners, and children led to HEW regulations that became the foundation for federal oversight of human subjects research.[64] The reports on psychosurgery and research involving the mentally infirm influenced experts in the field but were never implemented.[65] Finally, the Commission's recommendation for a national ethical review board soon led to the creation of the Ethics Advisory Board within DHEW, which existed until 1980.[66]

Several features distinguished the National Commission from the bioethics advisory panels that followed it. Most significant, it had power to drive policy because its chartering statute included the following forcing clause:

> Sec. 205. Within 60 days of the receipt of any recommendation made by the Commission under section 202, the Secretary shall publish it in the Federal Register . . . . The Secretary shall consider the Commission's recommendation and relevant matter submitted with respect to it and, within 180 days of the date of its publication in the Federal Register, the Secretary shall (1) determine whether the administrative action proposed by such recommendation is appropriate to assure the protection of human subjects of biomedical and behavioral research conducted or supported under programs administered by him and (2) if he determines that such action is not so appropriate, publish in the Federal Register such determination together with an adequate statement of the reasons for his determination. If the Secretary determines that administrative action recommended by the Commission should be undertaken by him, he shall undertake such action as expeditiously as is feasible.[67]

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[61] *Id.*

[62] *Background Paper*, *supra* note 25, at 28. In the end, however, this report was not the last word on fetal research. Although the initial compromise was a success, fetal research regulation continues to be debated periodically. For current regulations *see* 45 C.F.R. § 46.204 (2004).

[63] *Research Involving Prisoners*, *Research Involving Children*, *Psychosurgery*, *Disclosure of Research Information Under the Freedom of Information Act (FOIA)*, *Research Involving Institutionalized Mentally Infirm, Institutional Review Boards*, *Ethical Guidelines for Delivery of Health Services by DHEW*, and *Special Study on Implications of Advances in Biomedical and Behavioral Research*.

[64] *See generally* 45 C.F.R. § 46 (regulations regarding the protection of human subjects).

[65] *Background Paper*, *supra* note 25, at 10; Gray, *supra* note 59 at 273. It is possible that at least one factor precluding implementation of the Commission's recommendations on psychosurgery was a continuing reluctance to regulate the clinical practice of medicine. Yesley, *supra* note 21, at 1467. A report on FOIA and a special study on implications of scientific advances that had been requested by Senator Walter Mondale had no obvious impact whatsoever.

[66] By charter, the National Commission was not intended to be a long-term standing advisory commission. However, the commissioners recognized the need for some type of standing advisory panel that would supercede the commission and described what the panel should do. *Summing Up*, Wall St. J., Mar. 28, 1983, at 29. The EAB was created to fill this need.

[67] *Background Paper*, *supra* note 25, at 64.

This clause required the HEW Secretary to accept the National Commission's recommendations or make public the reasons for rejection.[68] The path of least resistance was implementation rather than inaction. In addition, because the Commission was created by statute, it is possible that Congress was more receptive to its recommendations and less likely to interfere with the administrative regulations.

The original commissioners formed a cohesive group even though they represented a wide spectrum of political views. They may have recognized their differences as a potential source of discord; for they worked hard to understand opposing views and find "common ground."[69] The Commission was guided by the members rather than by the staff.[70] Early on, they forced the resignation of the Commission's first executive director, Charles Lowe, M.D., a career NIH employee, in order to achieve independence from the NIH.[71]

Once it began operations, the National Commission was less buffeted from political or public opposition to its recommendations than any of the panels that followed it. Although abortion politics had reached a fever pitch just prior to the decision in *Roe v. Wade*, the Supreme Court's ruling opened a short period of political quiet on this issue.[72] It is hard to believe in 2005, but at that time, *Roe v. Wade* was seen by many as a likely end to a story rather than the beginning of a protracted and divisive battle. The 1974 Congressional elections saw the defeat or retirement of many members who had led the anti-abortion cause.[73] In the following spring, an attempt to limit Medicaid funding for abortion was soundly defeated.[74] It was not until the national election of 1978 that the political landscape really began to change.[75]

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[68] DHEW did not always adhere to this forcing clause. After the National Commission was disbanded, recommendations were not enacted as regulations as required by this clause. *Background Paper*, *supra* note 25, at 10.

[69] Gray, *supra* note 59, at 267. Members of the Commission socialized often. The Friday night of the Commission's two day meetings was usually reserved for a dinner or social occasion.

[70] *Id.*

[71] *Id.* at 267, 292. Michael Yesley, who succeeded Lowe, was a career government lawyer from the Department of Commerce.

[72] David J. Garrow, *Liberty and Sexuality: The Right to Privacy and the Making of Roe v. Wade,* 616-18 (1994).

[73] *Id.* at 618.

[74] *Id.*

[75] *Id.* at 628-31. The election of Ronald Reagan in 1980 cemented the change. Reagan favored a right to abortion when he was Governor of California but opposed it by the time he ran for President. Abortion opponents campaigned hard for Reagan's election, and Reagan established a personal relationship with major pro-life advocates. N.E.H. Hull & Peter C. Hoffer, *Roe v. Wade: The Abortion Rights Controversy in American History* 207 (2001).

B. *Ethics Advisory Board (1978-1980)*

Unlike the National Commission preceding it and the advisory bodies that followed it, the Ethics Advisory Board was a creation of DHEW, not of Congress. It lacked the prestige accorded to the National Commission and the later Presidential Commission. More importantly, neither the President nor Congress had a substantial stake in its success. An invention of the National Commission, the EAB, was intended to be a continuing entity that would not only address recurring ethical issues in biomedical research, but also consult regarding specific protocols.[76] The National Commission anticipated that the EAB would respond to developments in fetal research;[77] new federal regulations made EAB review a condition for federal funding of any IVF research.[78] The EAB was therefore expected to approve each IVF protocol.[79]

In basic structure, the EAB resembled its predecessor and several successors. It had thirteen members. Seven were physicians, and of those seven, six were affiliated with medical schools. Two were lawyers, two were philosophers, one was a business leader, and one was an official of the United Way.[80]

In addition to reviewing individual protocols, the EAB issued four reports before it expired. The first dealt with IVF; the others concerned fetoscopy and exemptions from the requirements of the Freedom of Information Act (FOIA).[81] The EAB's IVF report was unquestionably its most important. In 1979, the Board revisited the role of federal funding for IVF and other embryonic research. Specifically, the Board sought to formulate guidelines that specified the kinds of research permitted and prescribed minimum qualifications for researchers and IVF centers.[82] The EAB's study took place a year after British physicians Steptoe and

[76] *Background Paper*, *supra* note 25, at 11.

[77] *Id.* at 10.

[78] *See* 45 CFR 46.204(d). These regulations actually predated any submission of protocols involving IVF to the NIH. The first was not submitted until 1978. This submission, together with the recommendation of the National Commission, apparently motivated the formation of the EAB.

[79] There is plenty of precedent for such individual review when the experimentation involves vulnerable populations. For example, under current regulations, federally funded protocols involving prisoners require individual approval by the Secretary of Department of Health and Human Services (DHHS) subject to 45 CFR 46.204(d). This, however, does not require a specific entity, e.g. an EAB, to do so. It is not clear why the IVF regulations were written so specifically, although it was most likely coincidence—an EAB existed and it was the best choice for the job. This coincidence, however, meant that federally funded IVF research was in effect halted from the moment the EAB was disbanded. *See infra* notes 84-85 and accompanying text.

[80] The EAB members were Sissela Bok,a philosopher from Harvard University; Jack Conway of the United Way; Henry Foster, Chair of the Department of OB/GYN at Meharry Medical College; James Gaither, a lawyer; David Hamburg, President of the Institute of Medicine; Donald Henderson, Dean of the School of Public Health at Johns Hopkins; Maurice Lazarus of Federated Department Stores; Richard McCormick of the Institute for the Study of Reproduction and Bioethics at Georgetown; Robert Murray, Chief of the division of Medical Genetics at Howard University; Mitchell Spellman, Dean for Medical Services and Surgeon at Harvard University; Daniel Tosteson, Dean of Harvard Medical School; Agnes Williams, a lawyer; and Eugene Zwieback, a surgeon from Omaha, Nebraska.

[81] 5 U.S.C. § 552 (2005).

[82] EAB Appendix, *supra* note 23, Part 1.

Edwards announced the birth of Louise Brown, the first child born through IVF.[83] The study examined not only IVF but embryo research in general. It recognized fears that IVF research might lead to genetic manipulation or casual experimentation with human embryos, as well as stimulation of surrogate mothers, cloning, and genetic hybrids.[84]

The Board's several reports examined contemporary methods of embryonic culture and transfer, methods of assessing risks of embryonic abnormalities, maternal risks, and later embryonic development after transfer.[85] It explored the prospects for future research, not only in fertility but also in areas as diverse as cancer and human evolutionary development. The Board's ethical analysis examined the status of the embryo and the problem of "slippery slopes." It also explored informed consent issues, including the practical implications of an embryo's inability to give informed consent. Further, the board confronted claims that assisted reproduction was "unnatural" by studying its effects on marriage and family life, as well as examining religious perspectives. Finally, it discussed whether infertility was a condition that should be "treated."[86]

The publicity surrounding the birth of Louise Brown created broad public awareness of the IVF procedure,[87] over which public opinion was sharply divided. A Gallup Poll of 1500 U.S. adults found that by two to one, the public approved of the procedure.[88] A Harris poll found similar but more guarded acceptance. Despite widespread sympathy for infertile couples, a plurality of respondents still preferred that couples resort to adoption rather than IVF.[89] Women who anticipated having children displayed more sympathetic acceptance of IVF,[90] as did women with more education.[91]

The EAB wrestled at length with the status of the embryo, arriving at the conclusion that "the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons."[92] The Board's report proposed conditioning research on informed consent of the progenitors, use of embryos no more than fourteen days after fertilization, and an interest in serving a research goal "not reasonably

[83] Steptoe and Edwards began their research on IVF ten years before Louise Brown was born, and a number of others were also engaged in similar research. IVF was anticipated in ethical papers in the early 1970s. *See, e.g.*, Leon Kass, *Babies by Means of in Vitro Fertilization: Unethical Experiments on the Unborn?*, 285 New Eng. J. Med. 1174-79 (1971); M. Lappe, *Risk Taking for the Unborn*, Hastings Ctr. Rep. 1972, at 1-3.

[84] EAB Appendix *supra* note 23, Part 1, at 101.

[85] Members consulted regularly with Steptoe and Edwards and other prominent scientists in the field. *See* EAB Appendix, *supra* note 23, Parts 1, 14-18, 42-46.

[86] These included papers or testimony by LeRoy Walters, Leon Kass, Samuel Gorovitz, Charles Curran, Stanley Hauerwas, Sid Leiman, and Paul Ramsey. *See* EAB Appendix, *supra* note 23, Parts 1, 5-42.

[87] This exceeded 93%. Gallup Poll, *Gallup Poll Index*, Dec. 1978, reprinted in EAB Appendix, *supra* note 23, Part 21.

[88] *Id.*

[89] EAB Appendix, *supra* note 23, Part 22, at 1.

[90] *Id.* at 7.

[91] *Id.* at 5. This was a greater predictor of acceptance than political affiliation.

[92] *Id.* at 101.

attainable by other means. "[93] These recommendations were never endorsed by the DHEW Secretary and so were never subjected to formal public comment. But they did provoke strong public reactions, many of them negative.[94]

The EAB's charter expired in 1979. The Reagan administration did not renew it.[95] It is not altogether clear why. Federal regulations continued for more than a decade to require the Board's approval for IVF research.[96] The expiration of the EAB therefore marked the end of federal funding for such research.

C. *The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1979-1983)*

A new body, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, was created by statute in 1978.[97] The perceived success of the National Commission was the inspiration for the new panel.[98] The legislation had many of the same congressional sponsors and retained the same organizational model. Eleven commissioners were to serve: three in biomedical or behavioral research; three in medicine or provision of health care; and five in ethics, theology, law, natural sciences, the social sciences, the humanities, health administration, government, and public affairs. But the new commission differed in its functioning and its perspective. As a "presidential commission," it operated independently of the Department of Health and Human Services (DHHS), and it had a considerably broader mandate.

Members of the President's Commission were appointed for rotating fixed terms. Thus, while only eleven served at any time, twenty-one individuals served during the life of the commission.[99] The chair, Morris Abram, was appointed by President Carter, who knew Abram

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[93] *Id.* at 106.

[94] Joseph Califano, then secretary of DHEW, published the report for public discussion. More than 13,000 letters were received in response, most of them negative. Many of these appear to have been part of organized protest campaigns. Ronald M. Green, *The Human Embryo Research Debates: Bioethics in the Vortex of Controversy,* 2 (2001). Califano resigned in 1979 and his successor, Patricia Harris, did not pursue the issue. In 1979, DHEW was restructured into the Departments of Health and Human Services (DHHS) and Education.

[95] *Background Paper*, *supra* note 25, at 11.

[96] 45 CFR 204(d) (repealed 1993). The provision was repealed as part of the NIH Revitalization Act of 1993, Pub. L. No. 103-43.

[97] Pub. L. No. 95-622. Background Paper, *supra* note 25, at 12.

[98] Cook-Deegan, *supra* note 33, at 259.

[99] The Commissioners were H. Thomas Ballantine, Jr from Harvard University (8/82-3/83); George Dunlop from the University of Massachusetts (2/82-3/83); Renee Fox from the University of Pennsylvania (7/79-2/82); Mario Garcia-Palmieri from the University of Puerto Rico (7/79-2/82); Frances K. Graham from the University of Wisconsin (5/80-1/82); Bruce Jacobson from Southwestern Medical School (8/82-3/83); Albert Jonsen from the University of California at San Francisco (7/79-8/82); Patricia King from Georgetown University (7/79-5/80); Mathilde Krim from Sloan Kettering Institute (7/79-10/81); Donald Medeiras from Harvard University (7/79-2/82); John Moran, a Texas businessman (8/82-3/83); Arno Motulsky from the University of Washington (7/79-3/83); Daher Rahi, a Michigan doctor of osteopathy (2/82-3/83); Fritz Redlich from the University of California at Los

personally. A prominent civil rights lawyer, Abram had no specific expertise in the biomedical arena.[100] He chose University of Pennsylvania law professor, Alexander Capron, as his staff director, and together they assembled a large and experienced staff.[101] While Abram controlled the tenor of the commission's deliberations, the agenda was largely directed by the staff.

The President's Commission began life dominated by liberal members, supported by a liberal staff, and serving a liberal president. It concluded operations as a group with diverse political affiliations serving a conservative administration. As a result, its early reports differ in tone from later ones as each sought to reflect a consensus of the current members. Most of the Commission's early reports were not politically controversial, so its liberal tilt did not conceal political rifts that might have been exposed when implementation was attempted.

Nonetheless, members of the President's Commission later acknowledged that they never achieved a sense of common purpose.[102] The periodic turnover in membership surely impeded cohesion.[103] The staff's control over the agenda was another source of friction.[104] In turn, staff members felt constrained by the consensus approach expected by the chair. Internal disagreements became more pronounced as the Commission became more diverse.

Although its statutory charter contained a forcing clause, the Commission's members chose to adopt an advisory role.[105] The statute identified several specific topics the Commission was to explore: the requirements of informed consent for participation in research, a uniform definition of death, issues surrounding genetic testing and counseling, availability and access to health services, and procedures designed to safeguard privacy of participants in research and patients generally. The Commission was also authorized to investigate such other areas of biomedical research or medicine as it saw fit.[106] The President's Commission issued ten reports: *Defining Death*, *Protecting Human Subjects*, *Compensating for Research Injuries*, *Making Health Care Decisions*, *Whistleblowing in Biomedical Research*, *Deciding to Forego Life-*

Angeles (7/79-2/80); Anne Scitovsky from the Palo Alto Medical Research Foundation (7/79-8/82); Seymour Siegel from the Jewish Theological Seminary (2/82-3/83); Kay Toma, a physician from California (8/82-3/83); Charles Walker, a physician from Tennessee (7/79-3/83); and Carolyn Williams from the University of North Carolina at Chapel Hill (9/80-8/82). *See* President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Summing Up: The Legal and Ethical Problems in Medicine and Biomedical Research, Final Report on Studies of the Ethical and Legal Problems in Medicine and Biomedical and Behavioral Research* (Mar. 1983), *available at* http://www.bioethics.gov/reports/past_commissions/summing_up.pdf.

[100] Gray, *supra* note 59, at 269.

[101] *Id.* (noting that "[the] President's Commission's staff probably had stronger professional credentials than did the commission itself").

[102] *Id.* at 267.

[103] *See id*. at 268. Only three members, including its chairman, served for the entire life of the Commission.

[104] *Id*. With the notable exceptions of Tom Beauchamp and Stephen Toulman, much of the National Commission's staff was made up of career government professionals, while much of the President's Commission staff were or became prominent scholars in the field.

[105] *Background Paper*, *supra* note 25, at 12.

[106] Community Mental Health Centers Extension Act of 1978, Pub. L. No. 95-622, §§ 1802(1) and (2).

Sustaining Treatment, *Implementing Human Research Regulations*, *Screening and Counseling for Genetic Conditions*, *Securing Access to Health Care*, and *Splicing Life*.

The President's Commission's reports had varying levels of national impact. *Defining Death* laid the foundation for uniform law on that subject and was adopted throughout the United States. *Deciding to Forego Life-Sustaining Treatment* also had a major impact on the law, and is still considered the seminal treatment of the issue.[107] *Splicing Life* led NIH's RAC to expand the scope of its inquiry to consider both technical and ethical aspects of gene therapy.[108] *Securing Access to Health Care* was compromised by rifts among the Commissioners and was regarded as weak by staff.[109] *Screening and Counseling for Genetic Conditions* did not attract attention until several years later, when genetic screening became more viable.[110] The Commission's reports on human subjects research, whistleblowing, and compensating research subjects had little impact.

The National Commission had already addressed the major issues in human subjects research; therefore, the President's Commission's report on the subject focused on the need for uniform regulations throughout federal agencies. This emphasis had an important impact and probably accelerated the ultimate adoption of the "Common Rule" in 1991, but it did not represent an intellectual or political breakthrough. *Compensating Research Subjects* advanced a policy in search of a problem, for the Commission received little evidence of actual research injuries.[111]

Most of the work of the President's Commission was not controversial, and leaders worked hard to make those issues that were controversial seem less so. Many of the Commission's reports served primarily to crystallize policy options that were already in circulation.[112] As the Commission's final report noted, it never confronted such highly charged

[107] Gray, *supra* note 59, at 286.

[108] *Background Paper*, *supra* note 25, at 12. The Recombinant DNA Advisory Committee (RAC) was created by scientists who were worried about biological contamination that could arise from experiments using viruses as vectors to insert DNA sequences from one organism into cells of another. The scientists asked that a panel be convened from the National Academy of Science (NAS) that would review the experiments and evaluate the risks. That panel, in turn, recommended that the NIH create a committee to suggest guidelines. The RAC was formed in 1975 under NIH auspices. Gradually, the RAC's focus shifted from concerns of biological contamination to ethical use of recombinant gene technology. See Joseph M. Rainsbury, *Biotechnology on the RAC--FDA/NIH Regulation of Human Gene Therapy*, 55 Food Drug L.J. 575 (2000).

[109] *See* Gray, *supra* note 59, at 279. *See also Background Paper*, *supra* note 25, at 12; Ronald Bayer, *Ethics Politics and Access to Health Care: A Critical Analysis of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research*, 6 Cardozo L. Rev. 303, 309 (1984).

[110] The report was consulted when cystic fibrosis screening became developed. Gray, *supra* note 59, at 289.

[111] It was not until much later, when the Advisory Commission on Human Radiation Experiments was established to investigate the government's use of human subjects in radiation experiments, that the subject again attracted serious attention.

[112] Gray, *supra* note 59, at 279.

issues as fetal research and psychosurgery, which had been addressed earlier by its predecessor.[113]

As Chairman Abram explained in a contemporaneous article, he believed that the Commission's role was to achieve consensus on the issues it took up:

> A commission such as this one has only the power of persuasion. A group performing ethical analysis, with no coercive powers, cannot be persuasive without internal agreement. Unlike a court or legislature, which is structured to have effect as long as a majority agrees, a commission requires agreement that is as close to unanimity as possible to have any effect at all. Without such virtual unanimity, the commission members simply voice the possible arguments; with it, the commission can persuade.[114]

Abram perhaps took the search for consensus too far. The Commission's reports often mask areas of disagreement that were later exposed when attempts were made to implement their recommendations.

Abram frequently reminded Commission members and staff that their concern was ethics and not politics; in doing so, he gave them an impossible task. For example, the heart of the debate on access to health care was politics, not ethics. Everyone could agree, in principle, that universal access was desirable. But how to achieve that goal in a world of scarce resources was a source of major disagreement.[115] Early discussions of the draft report did not generate much disagreement, but as more Reagan appointees joined the Commission, cracks in the consensus became apparent. These rifts exposed political divisions that had long pervaded American health policy.[116] To achieve consensus, the report was watered down considerably. It left to policy makers to determine what constituted an "adequate" level of care and how to make the "financial impact . . . fall equitably on individuals."[117]

In fashioning several of its reports,[118] the President's Commission faced the puzzle that has continued to trouble later bodies: what was its role? Should it provide leadership by issuing consensus reports, or should its role be to educate the public on the wide and often sharp diversity of views? As the President's Commission demonstrated, it is difficult for the same

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[113] *Summing Up*, *supra* note 66, at 2. The President's Commission did face a politically charged issue in its investigation of access to health care, and the leadership's cautious search for consensus drew very mixed reviews. *See* Bayer, *supra* note 100, at 310; *Background Paper*, *supra* note 25, at 12; Gray, *supra* note 59, at 279.

[114] Morris B. Abram & Susan M. Wolf, *Public Involvement in Medical Ethics: A Model for Government Action*, 310 New Eng. J. Med. 627, 629 (1984).

[115] In many ways, discussion in the Commission foreshadowed the political rifts that became well-known when the Clinton administration attempted health care reform. However, because the public face of the Commission tended to downplay open disagreement, many of these issues did not get much public attention until much later.

[116] Bayer, *supra* note 109, at 309.

[117] *Id.* at 307.

[118] A. J. Weisbard & J. D. Arras, *Commissioning Morality: An Introduction to the Symposium*, 6 Cardozo L. Rev. 223, 231 (1984).

body to do both, and where there are basic political and moral divisions, it is impossible to do both in the same document.

The President's Commission was the first bioethics panel to be directly affected by partisan political divisions.[119] For example, its report on access to health care was portrayed by the media as a critique of Reagan administration cut-backs in Medicaid and other health programs for the poor.[120] Later, revealing that the Reagan administration did not regard the panel as *its* creation, the Commission was ignored when DHHS first issued its "Baby Doe" rule prohibiting hospitals from failing to feed and care for severely handicapped infants.[121] While the Commission criticized the Indiana Supreme Court decision that provoked the regulation, it was also openly critical of the administration's response. Ultimately, the Commission had difficulty getting Congressional funding for the additional three months it required to finish its reports after its designated sunset date of December 31, 1982.[122]

Despite these shortcomings, many bioethicists consider the President's Commission a success. It broadened consensus on a number of issues and cemented research protections for research subjects. While some of its reports were ignored, most had some, and sometimes significant, influence on policy.[123] Albert Jonson has described the body of the Commission's work as a "veritable canon of bioethics."[124] While later panels have contributed significantly to the literature of bioethics and indirectly influenced medical research, the President's Commission was the last blue-ribbon panel to witness concrete regulatory implementation of some of its

[119] Arguably, the demise of the EAB was also politically motivated. However, partisan politics did not actually influence the EAB's reports.

[120] *Health-Care Panel sees 'Ethical' Duty to Provide Access*, Wall St. J., Mar. 28, 1983, at 14. Consonant with its perceived role for consensus building, however, the Commission viewed its work not as advocating a policy but instead providing a framework for policy debates to occur. *Summing Up*, *supra* note 66, at 29.

[121] Baby Doe was born in 1982 in Indiana with Downs Syndrome and a tracheo-esophageal fistula. For the baby to consume nutrition orally, surgery was necessary to repair the fistula. The parents refused to consent to the surgery because the baby had Down Syndrome and the physicians refused to undertake the surgery without parental consent. The Indiana Supreme Court refused to intervene. Baby Doe died six days after his birth. The case immediately drew the attention of a number of right to life groups and advocacy groups for the disabled. The Secretary of HHS issued "emergency regulations" which prohibited hospitals from withholding treatment from newborns and provided for teams of federal inspectors to investigate hospitals that were reported as doing so. The regulations were successfully challenged on the grounds that they had not been subjected to the notice and comment period required by the Administrative Procedures Act. New regulations were implemented that again included use of inspection teams and these were also challenged in the courts. Finally, a compromise was achieved by shifting the codification of the regulations from disability provisions to child abuse prevention funding. The definition of "medical neglect" includes "the withholding of medically indicated treatment from a disabled infant with a life threatening condition." *See* 45 C.F.R. § 1340.15(b)(1) (2005). "Withholding medically indicated treatment is defined as 'failure to respond to the infant's life threatening conditions by providing treatment (including appropriation nutrition, hydration, and medication) which in the treating physicians' . . . reasonable medical judgment will be most likely to be effective in ameliorating or correcting all such conditions." 45 C.F.R. § 1340.15(b)(2) (2005).

[122] Colin Norman, *Ethics Panel Faces the Ax*, 218 Science 456 (Oct. 29, 1982).

[123] *See* Gray, *supra* note 59.

[124] Albert Jonson & Andrew Jametton, *History of Medical Ethics, The Americas, The United States in the Twentieth Century*, *in* Encyclopedia of Bioethics, Vol. 3, 1625, 1625 (Warren T. Reich ed., 1978).

recommendations, specifically, those relating to end of life. Later attempts to exploit this model for eliciting expert advice and exploring the possibilities for policy agreement have fallen short of the achievements of the President's Commission.

D. *Biomedical Ethics Advisory Committee (1985-1986)*

The Health Research Extension Act of 1984[125] proclaimed a new medical ethics entity, this time to be housed within Congress. The Biomedical Ethics Advisory Committee (BEAC) was to be appointed from a Biomedical Ethics Board composed of six senators and six representatives, divided equally by political affiliation. The BEAC was to be a continuing body that would study ethical issues in health care and biomedical research and report directly to Congress. At the outset it was to address three controversial topics: human genetic engineering, fetal research, and withholding nutrition and hydration from dying patients.

The BEAC never got off the ground. A year passed before congressional leaders agreed on the members of the Board and they were not appointed until a week before the Board's designated sunset. The BEAC's collapse is a reflection of abortion politics during the 1980s.[126] Members saw nearly every biomedical problem as implicating the abortion issue and the nascent panel was viewed with suspicion by both sides of the controversy.

E. *The Human Embryo Research Panel (1994)*

The Human Embryo Research Panel (HERP) was not the creation of the President or of Congress, but of an advisory panel appointed by the NIH Director. The Panel reported to the existing Advisory Committee to the Director (ACD). In 1993, the Clinton administration repealed a moratorium on certain fetal tissue research that had been imposed by the first Bush administration.[127] Shortly thereafter, Congress repealed the EAB requirement for IVF.[128] These actions effectively ended the federal ban on fetal research.[129] The new NIH director, Nobel Prize winner Harold Varmus, wanted to see what could be learned from assisted reproductive genetics.[130] Varmus created HERP and chose its panel members.[131] The panel was officially

[125] The Health Research Extension Act of 1985, Pub. L. 99-158 (The legislation was vetoed by President Reagan but the veto was overridden by Congress).

[126] Philip J. Hilts, *Abortion Debate Clouds Research on Fetal Tissue*, N.Y. Times, Oct. 16, 1989, at 19.

[127] Federal Funding of Fetal Transplantation Research, 58 Fed. Reg. 7457 (Jan. 22, 1993).

[128] NIH Revitalization Act of 1993, Pub. L. 103-43. This was done pursuant to the work of another NIH panel, The Human Fetal Tissue Transplantation Panel; *see*, National Institutes of Health, *The Human Fetal Tissue Transplantation Panel Report*, 1988. The new regulations governing fetal tissue research were codified at 45 CFR 46.203. Until the election of 1994, there was a Democratic majority in Congress, thus allowing the administration easier implementation of these regulations.

[129] 45 CFR 204.4 (2005).

[130] *See* Eliot Marshall, *Rules on Embryo Research Due Out; National Institutes of Health to Release Guidelines in Fall 1994*, 265 *Science* 1024, 1024 (1994).

headed by Stephen Muller, president emeritus of Johns Hopkins University, but the real leadership came from the two co-chairs: Brigid Hogan, a cell biologist at Vanderbilt University, and Patricia King, a law professor at Georgetown University.[132]

HERP was given less than eight months to complete its work. That timetable quickly became unrealistic as the panel pursued its deliberations, and the deadline for the panel's report was extended by six months, which made all the difference. Had HERP been able to meet the original deadline, it is possible that its recommendations might have been implemented. But between June 1994 and December 1994, the political landscape changed fundamentally. The fall election produced a majority in Congress that was openly hostile to embryo research, significantly weakening the Clinton administration's ability to advance its policy agenda. In this new environment, HERP's recommendations appeared not just liberal but radical.

HERP enlarged upon the work done by the EAB and Britain's Warnock Commission, which we describe in Part V.[133] Although its final report was written by science writer Kathi Hanna, much of the background analysis was left to the members. With Brigid Hogan as scientific chair, the panel's deliberations reached a high level of sophistication. HERP's report anticipated all of the major scientific developments that came in the following decade.

The Panel's members felt cohesive—at least partially because they soon felt embattled. Soon after their first meeting, members began receiving hate mail, some of it extremely threatening.[134] Even though they appreciated that they were working in a charged atmosphere, they underestimated how politics would influence reactions to their report.

The moral issues addressed by HERP are at the crux of the controversy surrounding embryo research. HERP examined two competing frameworks for assessing the moral status of the embryo. The first holds that there is a single criterion of moral personhood.[135] Those who

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[131] This led to immediate accusations that the committee was "stacked." *See* Stephen Hall, *Merchants of Immortality* at 112 (2003). It probably goes too far to say that the committee was "stacked," but it is true that there was no representation on the committee of the "right to life" views. Even Carol Tauer, a former nun, did not espouse mainstream Catholic doctrine. *See* Ronald M. Green, *The Human Embryo Research Debates: Bioethics in the Vortex of Controversy* 5 (2001). While there were clear moral divisions on the committee, it appears that all members accorded embryos with an intermediate moral status: of the human species but not fully human.

[132] Human Embryo Research Panel, Nat'l. Inst. Health, *Report of the Human Embryo Research Panel*, Vol. I at vii-viii (1994), *available at* http://ospp.od.nih.gov/pdf/VOLUME1_REVISED.PDF [hereinafter *HERP Report*].

The other members were: Diane Aronson, executive director of RESOLVE; Alta Charo, a professor of law and medical ethics at the University of Wisconsin; Patricia Donahoe, chief of pediatric surgery at Massachusetts General; John Eppig, a scientist at the Jackson Laboratory; Ronald Green, a religion and ethics professor at Dartmouth College; Fernando Guerra, director of the department of health, San Antonio, Texas; Andrew Hendrickx, a cell biologist at UC Davis; Mark Hughes, a professor of molecular genetics, cell biology, and medicine at Baylor College of Medicine; Ola Huntley, a director of the Sickle Cell Self-Help Group; Nannerl Keohane, President of Duke University; Bernard Lo, director of medical ethics at UCSF; Mary Martin, Director of the IVF program at UCSF; Thomas Murray, Director of the Center for Biomedical Ethics at Case Western Reserve University; Dorothy Nelkin, a professor of Sociology at NYU; Kenneth Ryan, a professor of OB/GYN at Harvard University and former chair of the National Commission; and Carol Tauer, a philosophy professor at the College of St. Catherine.

[133] The Warnock Report, the report of the committee of inquiry set up to study embryo research in Britain, was issued in 1984. The legislation based on the report, The Human Fertilisation and Embryology Act of 1990 (HFE Act) was passed in 1990. *See* discussion, *infra* Part V.

[134] Hall, *supra* note 131, at 113.

[135] *HERP Report*, *supra* note 132, at 36.

meet that criterion are entitled to full moral respect as humans; those who do not have a lesser status. According to the Panel's account of single criterion views, humanness occurs at a defined point. For some, humanness is determined by a distinctive human genetic identity. For some others, an embryo is human at the moment of conception. Or, humanness may be dependent on reaching a point of human potential; a point reached at or near conception—either at the time of syngamy, when the chromosomes of the male and female gametes join, or at the four to eight cell stage when gene expression begins. Others fix upon a later point in development, sentience or the beginning of brain activity.[136]

In contrast, a pluralistic approach does not recognize a defining moment when moral personhood exists but rather envisions a continuum where the aggregate of several factors, e.g. genetic uniqueness, potential, the onset of a heart beat, sentience, brain activity, compels increasing respect.[137] Respect increases as development progresses, dictating graduated protection for the developing embryo. Thus, an embryo is entitled to more respect than sperm or eggs, but less respect than a developed fetus.

Ultimately HERP embraced the pluralistic approach.[138] It found that although the preimplantation embryo is entitled to respect, this does not rule out well-justified research: "[t]he absence of developmental individuation, the lack of even the possibility of sentience and most other qualities considered relevant to personhood, the very high natural mortality at this stage, and the important human benefits research might achieve all support the conclusion that embryo research may be conducted under strict guidelines."[139]

HERP sought to draw a line between research that should be acceptable for funding and research that should not be funded. It found the following procedures unacceptable:[140] induced twinning, nuclear cloning, research beyond the onset of the closure of the neural tube, research involving fetal oocytes with transfer to a uterus,[141] preimplantation genetic diagnosis for sex-selection unrelated to sex-linked genetic disease, development of human-nonhuman and human-human chimeras, cross-species fertilization,[142] attempted transfer to a uterus of parthenogenetically activated human eggs, attempted transfer of human embryos into nonhuman animals for gestation, and transfer of human embryos for extrauterine or abdominal pregnancy.

HERP found several other procedures presumptively acceptable so long as they met certain threshold criteria.[143] The threshold criteria were that the protocol must be scientifically

[136] *Id.* at 37.

[137] *Id.* at 38.

[138] *Id.* at 40.

[139] *Id.* at 40, 50. Of course, despite the adoption of the pluralistic view, the HERP was still faced with setting a point at which research had to stop. It, like the Warnock committee before it, eventually adopted a fourteen day rule—the point at which the primitive streak would normally form. The HERP was not happy with the arbitrariness of the limit, but found it the best of the choices. *See Id.* at 48-50.

[140] *Id.* at *Executive Summary*, xix-xx.

[141] Such a procedure could theoretically allow the birth of a child from a "parent" who had never been born.

[142] Except for clinical tests of the ability of sperm to penetrate eggs, this is used as a common fertility test. In those tests, the resulting embryo is destroyed at the two cell stage.

[143] *HERP Report*, *supra* note 132, at xvii.

meritorious; must rely on prior adequate animal studies and, where appropriate, studies on human embryos without transfer; must use a minimal number of embryos; must document informed consent from donor sources; must not involve the purchase of gametes or embryos; must not continue beyond 14 days after fertilization; and must pass appropriate review.[144] Acceptable research included protocols aimed at improving the likelihood of a successful outcome for a pregnancy, research on the process of fertilization, studies on egg activation and parthenogenesis without transfer to a uterus, studies in oocyte maturation or freezing followed by fertilization to determine developmental and chromosomal normality, research involving preimplantation genetic diagnosis with and without transfer, research on embryonic stem cells using leftover IVF embryos that had been donated with the consent of the progenitors, and research involving somatic cell nuclear transfer that would not involve transfer to a uterus.

Finally, HERP recognized a third category of research that could, subject to additional review, be acceptable.[145] One example involved the use of existing embryos where one of the progenitors was an anonymous gamete source who received monetary compensation.[146] Another involved the use of embryos created expressly for research. The Panel's report explained that its decision to place use of embryos created for research in this category rather than in the "unacceptable" category reflected the view of a bare majority.[147] It was this recommendation that got HERP into political trouble.

Panel co-chair Patricia King opposed the recommendation, and her prediction that it would damage the panel's credibility proved correct.[148] In August 1994 the *Boston Globe* and *Science* both reported that HERP was about to recommend federal funding for the creation of embryos for research.[149] Anti-abortion groups grew alarmed and the White House became nervous.[150] HERP's draft report was released for public comment in September and was immediately condemned as endorsing the creation of embryos for research.[151] Even the *Washington Post* in an editorial charged that the panel had gone "a step too far."[152] NIH Director

[144] *Id.* This included IRB review, NIH study section review and additional review by an ad hoc review board recommended by the HERP.

[145] Sensitive to the problems that had occurred with the EAB, especially where the demise of the EAB caused the end of federally funded IVF research, the HERP did not recommend that a separate regulatory board be established for this review. Instead, it recommended creation of an ad hoc review board within the existing structure of the NIH. Further, it recommended that this review period sunset after three years. *See HERP Report*, *supra* note 132, at 72-74. *See also* discussion *infra* Part VI.B.

[146] *Id.* at xvii.

[147] *Id.* at xix.

[148] King wrote: "The fertilization of human oocytes for research purposes is unnerving because human life is being created solely for human *use.* I do not believe that this society has developed the conceptual frameworks necessary to guide us down this slope." *HERP Report*, *supra* note 132, app. A, at A-3.

[149] Richard A. Knox, *U.S. Panel May OK Human Embryo Study; Bid to Allow Funding Seen Drawing Fire*, The Boston Globe, Aug. 19, 1994, at A1; Marshall, *supra* note 130, at 1024-26.

[150] Hall, *supra* note 131, at 115.

[151] *Id.*

[152] *Embryos: Drawing the Line*, Wash. Post, Oct. 2, 1994, at C6.

Varmus was summoned to the White House and instructed to repudiate the report.[153] Varmus not only refused, but he did not, at that time, reveal to anyone on the panel that he had been asked to repudiate it, believing that to do so would inappropriately influence their final product.[154]

In November 1994, Democrats suffered a major defeat at the polls. With the "Republican Revolution" came a flock of House freshmen who not only opposed creating embryos for research, but opposed all embryo research. Convinced that Varmus would not repudiate the HERP report, the Clinton White House devised a "strategy of pre-emption."[155] On December 2, the day HERP presented its report to the ADC, the White House issued a statement announcing that the administration would bar funding for the creation of human embryos for research purposes.[156] In the same statement, President Clinton announced the formation of a new National Bioethics Advisory Commission, the next in a growing series.

Given the prevailing political climate, it is hardly surprising that HERP's defense of embryo research was ignored and its report was treated as "political poison." No executive official or member of Congress made any effort to implement any of its recommendations. In August 1995, two Republican House Representatives, Roger F. Wicker of Mississippi and Jay Dickey of Arkansas, successfully pushed through an amendment to the fiscal 1996 DHHS appropriations bill that expressly forbade any department component from funding research for "the creation of a human embryo or embryos for research purposes" as well as "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero [under existing federal regulations.]"[157]

F. *The National Bioethics Advisory Commission (NBAC 1996-2001)*

The new panel that President Clinton promised, the NBAC, was not officially created by executive order until late 1995. The NBAC was to report to the National Science and Technology Council, a cabinet-level committee previously established to coordinate the administration's science, space, and technology policy. The NBAC had broad authority to address bioethical issues affecting the government and the public at large. Harold Shapiro, President of Princeton University, served as chair.[158] Surprisingly, several HERP members

[153] Varmus reported that he was ordered to do so by White House Chief of Staff, Leon Panetta. Hall, *supra* note 131, at 115.

[154] *Id.* at 116. Panel members did not become aware of the extent of the White House displeasure until December.

[155] This statement was made to Stephen Hall by William Galston who served on President Clinton's Domestic Policy Council. Galston maintains that the decision was not political but based on a view that the recommendation was wrong. At the same time, he noted that the White House feared a political backlash. *Id.* at 116.

[156] *Statement by the President*, The White House, Office of the Press Secretary (Dec. 2, 1994).

[157] The Balanced Budged Downpayment Act, I, Pub. L. No. 104-99, 110 Stat. 26 (1996).

[158] NBAC's members were Patricia Backlar, a bioethics professor at Portland State University; Arturo Brito, a professor of pediatrics at the University of Miami School of Medicine; Alexander Capron, a law professor at the

agreed to serve on the new body.[159] Overall, the NBAC members supported abortion rights; the right to life movement had no advocates on the Commission.

The Commission's first order of business was to examine the safeguards for human subjects in medical research, with emphasis on the security of genetic information. Press reports in February 1997 of the cloning of the first adult mammal, a sheep named Dolly, disrupted this plan. Bills to ban human cloning were presented in Congress within days of the announcement. President Clinton immediately asked the NBAC to take up the issue of cloning. When pressure to adopt emergency legislation abated, the Commission was given until June to produce its report.

Because HERP had already addressed the issue of embryo research, the NBAC narrowed its focus to reproductive human cloning.[160] The members divided into three groups - philosophy, biology, and law and policy - each of which was to explore its own area and then report to the Commission as a whole. The full Commission also held public hearings, where it heard from a range of religious leaders[161] and scholars representing widely divergent perspectives.[162] The Commission identified and weighed several "harms" that might come from cloning. A primary concern was the safety of any clone, but other potential harms included the genetic control of cloning, the skewing of family relations, and the narcissism that might perpetuate cloning.

The law and policy group outlined several governmental options: (1) to allow cloning research and permit federal funding, (2) to allow cloning research but withhold federal funding, (3) to allow cloning but with restrictions, and (4) to prohibit cloning. The group observed that federal funding might actually compromise research since it would surely come with significant

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University of Southern California; Eric Cassell, a professor of public health at Cornell University; Alta Charo, a professor of law and medical ethics at Wisconsin; James Childress, a professor of religion and medical education at the University of Virginia; David Cox, a professor of genetics and pediatrics at Stanford University; Rhetuagh Dumas, a professor of nursing at the University of Michigan; Ezekiel Emmanuel, a professor of medical ethics at Harvard University; Laurie Flynn, Executive Director of the National Alliance for the Mentally Ill; Carol Greider, a professor of molecular biology at Johns Hopkins University; Steven Holtzman, Chief Business Officer of Millennium Pharmaceuticals; Bette Kramer, President of the Richmond Bioethics Consortium; Bernard Lo, director of the program in medical ethics at the University of California, San Francisco; Lawrence Miike, Director of the Hawaii State Department of Health; Thomas Murray, Director of the Center for Biomedical Ethics at Case Western Reserve University; and Diane Scott-Jones, a professor of psychology at Temple University. *See* NBAC Roster *in* NBAC, *Cloning Human Beings*: *Report and Recommendations of the National Bioethics Advisory Commission* (June 1997), *available at* http://www.bioethics.gov/reports/past_commissions/nbac_cloning.pdf.

[159] The HERP "alumni" were Alta Charo, Bernard Lo, and Thomas Murray. Kathi Hanna, who had served as a member of HERP's staff, also served on NBAC's staff. The NBAC also included Alexander Capron who was the staff director of the President's Commission.

[160] Harold Shapiro, the chair of the NBAC, was sensitive to the political aspects of embryo research and specifically sought not to "re-engage" the research issue in the cloning debate. *See* Andrea Bonnicksen, *Crafting a Cloning Policy: From Dolly to Stem Cells* 42 (2002).

[161] NBAC has been criticized for not including a spokesman for the Fundamentalist Protestant viewpoint. *See* Green, *supra* note 131, at 116 (Green, however, does not favor giving religious viewpoints a center stage role in the debate.)

[162] The spectrum ran from John Robertson, a leading proponent of "procreational liberty" which starts from a presumption of reproductive liberty, to Leon Kass, who starts from a presumption that cloning is fundamentally wrong and advocates switching "the burden of proof."

regulation. The law and policy group also explored measures short of, or combined with, legislative restrictions. They considered whether the RAC or FDA had the legal authority or institutional resources to exercise appropriate oversight.[163]

The NBAC's final report emphasized the safety concerns raised by human cloning. The Commission concluded that it would be morally irresponsible to attempt to create a child through cloning because of the risks for the fetus and the child once born. Accordingly, it recommended continuation of the current moratorium on federal funding for any procedure designed to clone a child. The report also urged the private sector to comply voluntarily with this recommendation, declaring that any attempt to create a child through cloning would be an "irresponsible, unethical and unprofessional act." The NBAC report also supported the enactment of legislation banning reproductive cloning, but added that such legislation should include a sunset provision to assure that the issue would be revisited.

The NBAC's recommendations did no more than generate wide discussion. None of the recommendations were formally implemented, and the moratorium on federal funding for embryo research continued. However President Clinton shortly thereafter proposed legislation that essentially incorporated the NBAC's recommendations,[164] renewing the Commission's hopes to categorically squelch some research it found unacceptable while allowing funding of other research that did not raise serious safety issues. Clinton's proposed legislation prompted congressional hearings on the NBAC report.[165] Representatives of BIO[166] and the American Society for Reproductive Medicine (ASRM) recommended a voluntary rather than statutory moratorium. By this time, pressure within Congress to do something was abating.[167] The cloning of a human being did not seem to be an immediate possibility. The President's bill did not find a sponsor. A bill banning creation of human embryos produced through cloning[168] was reported out of committee, but got no further.

The NBAC could not avoid the issue of embryo research when it turned to the subject of stem cell research. In 1998, James Thomson, a University of Wisconsin researcher, announced the successful isolation of human embryonic stem cells (ES), the pluripotent cells of the

[163] It appears that NBAC did not consider the FDA to have authority over cloning under current regulations. On the other hand, NBAC never directly considered the issue and its report was issued before FDA announced its assertion of jurisdiction in 1998.

[164] Draft Legislation Entitled the "Cloning Prohibition Act of 1997," H.R. Doc. 105-97 (1997).

[165] *Review of the President's Commission's Recommendations on Cloning*: *Hearing Before the House Comm. on Science Subcomm. on Tech.*, 105th Cong. (1997); *Scientific Discoveries in Cloning: Challenges for Public Policy: Hearing Before Senate Subcomm. on Public Health & Safety of the Comm. on Labor and Human Res.*, 105th Cong. (1997).

[166] BIO, formally known as the Biotechnology Industry Organization, is a trade organization formed in 1993. *Available at* http://www.bio.org/aboutbio/ (last visited Apr. 15, 2005).

[167] Bonnicksen, *supra* note 148, at 53 (Senator Frist noted that "cloning pretty much faded from the mental radar screen of most Americans." 144 Cong. Rec. S320 (daily ed. Feb. 3, 1998) (statement of Sen. Frist)).

[168] Human Cloning Research Prohibition Act, H.R. 922, 105th Cong. (1997).

blastocyst.[169] Contemporaneously, researchers led by John Gearhart at Johns Hopkins announced the isolation of human embryonic germ cells (EG).[170]

These developments caused a shift in views within Congress on the subject of embryo research. For example, Republican Senators Orrin Hatch and Strom Thurmond became supporters of stem cell research and thus supported embryo research that did not involve reproductive cloning. While embryo research had long been portrayed as a promising source of new medical therapies, the techniques involved were no longer theoretical. There were new demands for lifting the ban on federal funding of embryo research.[171]

The NBAC turned its attention to stem cell research in response to President Clinton's specific request. The President said he was "deeply troubled" by reports that scientists at Advanced Cell Technology (ACT), a company in Massachusetts, had created a hybrid cow-human embryo.[172] The original hybrid experiment had actually taken place some time before, but in the fall of 1998, ACT's new president, Michael West, actively pursued the research.[173] West was either unaware, or did not care, that such research had been specifically condemned by HERP in 1994.

In response to President Clinton's request, the NBAC reported that it was unclear (as it still is) how far such a hybrid could develop. To the extent such research was designed to produce an embryo that could develop into a child, even if not immediately feasible, the NBAC condemned it on ethical grounds. However, research involving mixing of cow oocytes and

[169] At the blastocyst stage the embryo consists of about 150 to 200 cells. The blastocyst consists of a sphere made up of an outer layer of cells (the trophectoderm), a fluid-filled cavity (the blastocoel), and a cluster of cells on the interior (the inner cell mass). If the embryo continues to develop, the outer layer of cells will become the placenta. The inner cells are undifferentiated at this point and are a source of embryonic stem (ES) cells. Those cells have the potential to become a wide variety of specialized cell types. Similarly, embryonic germ (EG) cells, which are found in a specific part of the embryo/fetus called the gonadal ridge, normally develop into mature gametes but also have the potential to develop into specialized cell types.

[170] Actually, Gearhard had announced the isolation of EG cells at a meeting in 1997. The discovery, however, did not receive much attention until after the isolation of ES cells and until after both discoveries were covered in print. Hall, *supra* note 131, at 163-64, 167. EG cells, precursors of oocytes and spermatozoa, are derived from six- to nine-week fetuses. Both cell types seem capable of becoming most cell types but not a functioning organism. Of the two types, ES cells seem more versatile. In addition, ES research combined with somatic cell nuclear transfer (SCNT) theoretically makes possible therapies that replace cells and tissues damaged from disease with new cells and tissues derived from a patient's own somatic cell that would thus be genetically (and therefore immunologically) compatible with the patient. ES cells could not (and still cannot) be isolated without destroying the embryo. EG cells raise the issue of using tissue from aborted fetuses. In addition, the use of ES combined with SCNT theoretically would make the possibility of reproductive cloning more likely.

[171] *Stem Cell Research: Hearings Before a Subcommittee of the Senate Committee on Appropriations*, 105th Cong. (1999).

[172] Bonnicksen, *supra* note 160, at 80 (citing Letter from William Clinton, President, United States, to Harold Shapiro, Chair, National Bioethics Advisory Commission (Nov. 14, 1998)).

[173] *See* Eliot Marshall, *Claim of Human-Cow Embryo Greeted with Skepticism*, 282 Science 1390, 1390-91 (1998); Hall, *supra* note 131, at 167, 220.

human material that did not involve creating an embryo did not, in the NBAC's view, raise fundamental ethical issues.[174]

The NBAC's examination of stem cell research[175] led to a number of recommendations. The Commission recommended that federal funding should continue to be available for research on EG cells.[176] It recommended that an exception should be made for the ban on embryo research and that federal funding be made available for carefully regulated ES research from embryos left over from IVF treatment;[177] it also recommended that the government should not fund research involving embryos created expressly for this purpose.[178] The NBAC also opposed federal funding of research involving the derivation or use of human ES cells from embryos made using SCNT into oocytes. It recommended the creation of an oversight committee, to be known as the National Stem Cell Oversight and Review Panel, which would review individual protocols, certify cell lines, maintain public registries and databases and provide sponsoring agencies with social and ethical guidance. Finally, the NBAC recommended that privately funded researchers, whether or not eligible for federal funding, should voluntarily comply with its general recommendations and with the guidelines that would be developed by the proposed panel.

At the core of these recommendations was a consensus within the Commission on the moral status of the embryo. The members examined many perspectives on this issue, including several rooted in religious principles, but eventually endorsed an "intermediate position," which states that "the embryo merits respect as a form of human life, but not the same level of respect accorded persons."[179] In substance, the Commission embraced the same pluralistic approach that had been taken by HERP. It declined to determine when an embryo should be accorded human status, noting that the answer might differ for different people. Instead it sought a position that "respects the moral integrity of different perspectives, but to the extent possible, focuses public policy on ethical values that may be broadly shared."[180] The NBAC concluded that animal research and research involving adult stem cells would not provide an adequate substitute for ES

[174] Bonnicksen, *supra* note 160, at 81 (citing Letter from Harold Shapiro, Chair, National Bioethics Advisory Commission, to William Clinton, President, United States (Nov. 20, 1998)).

[175] Once again, NBAC was distracted from the projects on human research protections that had formed the focus of its original mandate.

[176] Since EG cells do not require the destruction of an embryo, that research has not been affected by the embryo research ban.

[177] Nat'l Bioethics Advisory Comm'n, *Ethical Issues in Human Stem Cell Research* (1999). Recommendations included guidelines on the consent process and use of donor embryos and a requirement that embryos and cadaveric fetal tissue should not be bought or sold.

[178] In this, NBAC was presumably conscious of the results of HERP's decision in the same area.

[179] Nat'l Bioethics Advisory Comm'n, *supra* note 177, at 50.

[180] *Id*. 51-52.

research. Since the research was necessary for medical progress, progress that could benefit millions,[181] moral compromises seemed necessary.

Several scholars have criticized the NBAC for failing to stake out a position on the moral status of the embryo.[182] They contended that the NBAC's decision was political. But the Commission was also criticized for not being pragmatic enough. John Fletcher has argued that the NBAC gave conservatives too little in its attempt to achieve compromise.[183] The NBAC misconstrued promise with reality. In his view, the NBAC asked for too much too soon. Some conservatives could have agreed to federal funding for research using privately-derived cell lines. If the true potential of that research was then demonstrated, justice (and public opinion) would require an expansion of the federal funding framework. Hence, according to Fletcher, the NBAC missed an important opportunity for prudent compromise.

Ultimately, the Clinton Administration opted in favor of a distinction between derivation and use.[184] In January 1999, the NIH general counsel, Harriet Rabb, responded to a request for clarification from Harold Varmus on the applicability of the ban on embryo research on federal funding for ES cells. Rabb concluded that while federal funding could not be made available for derivation of ES cells, it could support use of ES cells that had been derived using private funds.[185] The NBAC issued a draft report in May 1999 that recommended federal funding for derivation as well as use.[186]

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[181] NBAC has been criticized for giving too much credence to projections of medical promise. Much of the medical promise of stem cells is as yet unproven. *See* John C. Fletcher, *NBAC's Arguments on Embryo Research*, *in The Human Embryonic Stem Cell Debate, Science, Ethics and Public Policy*, 65-66 (Holland et al. ed., 2001)

[182] *See, e.g.*, Rolf Ahlers, *Biotech and Theodicy: What Can and What Ought We to Do in Procreative Technology?*, 65 Alb. L. Rev. 679, 686 (2002).

[183] Fletcher, *supra* note 181, at 61-72. The NBAC rejected a "derivation-use" distinction for ES funding. In other words, it rejected the idea of refusing federal funds for the part of research that involved destroying the embryos in order to produce cell lines for research but providing federal funds for research using those cell lines once produced. Under a derivation-use framework, no exception to the ban on embryo research would be necessary; federal funding could be made available for research using cell lines derived from embryos but it could not be used to actually derive the cell lines. The NBAC members rejected that framework because they believed it would hamstring scientific progress. New knowledge could come from the derivation process and scientific progress would require the availability of more cell lines than the private sector would likely produce. *See* Nat'l Bioethics Advisory Comm'n, *supra* note 177, at iv.

Another argument against the derivation-use distinction that is only subtly alluded to in NBAC's report is that there is not much of a moral distinction between using knowledge acquired from a morally wrong act and doing the morally wrong act itself. This, after all, was the dilemma at the birth of bioethics as an academic endeavor - whether the research conducted by Nazi scientists could ethically be used by society. Since NBAC does not find the derivation of cell lines from the destruction of early development embryos morally wrong, it is not caught on the horns of this dilemma. But conservatives who believe that the destruction of embryos is wrong might be.

[184] Indeed, with a significant limitation, it is the path followed by the Bush Administration in 2001. *See, e.g,.* Rick Weiss, *Promising More - and Less; Scientists See Growth in Field, Lament Limits*, Wash. Post, Aug. 10, 2001, at A01.

[185] For a full evaluation of this opinion see Ellen J. Flannery & Gail H. Javitt, *Analysis of Federal Laws Pertaining to Federal Funding of Human Pluripotent Stem Cell Research*, Commissioned Paper, 2 Ethical Issues in Human Stem Cell Research D-1 (Nat'l Bioethics Advisory Comm'n ed. 1999).

[186] Transcripts of NBAC's discussion of the draft report are available at http://www.georgetown.edu/research/nrcbl/nbac/transcripts/may99/day_1.pdf (last visited Mar. 30, 2005).

Soon the Clinton administration again began to distance itself from what it saw as a political problem.[187] In April 1999, Varmus appointed an advisory committee to oversee developing regulations for ES research based on Rabb's opinion.[188] The NBAC issued its final report in October. On the same day, the Clinton administration disavowed its message. President Clinton thanked the commissioners for their hard work but announced that the administration would follow the NIH advisory committee's recommendations which did not include funding for derivation.

It is by no means clear that even the derivation framework NIH endorsed would have attracted consensus. Almost as soon as Rabb's opinion became public, pro-life members of Congress showered DHHS Secretary Donna Shalala with letters condemning it.[189] The advisory committee's report, released for public comment in December 1999, elicited about 50,000 responses.[190] In any event, the issue was soon moot. Before NIH could act on the recommendations of the committee, George W. Bush became President, and the new administration announced that it was submitting the issue of stem cell research for additional review. The election also signaled the imminent demise of the NBAC.[191]

[187] *See White House Statement on Human Stem Cell Research*, U.S. Newswire, July 14, 1999. Members of the Clinton Administration have been rather frank about the decision being a political one. At a meeting in January 2004, Clinton's former chief of staff, John Podesta, candidly noted that the decision taken was political; it was not because NBAC was wrong.

[188] This was a working group of the Advisory Committee to the Director. The group had a public meeting on April 8, 1999. The committee consulted NBAC members. Its report was issued in the Federal Register in December. Draft NIH Guidelines for Research Involving Human Pluripotent Stem Cells, 64 Fed. Reg. 67,576 (Dec. 1999).

[189] *See* Lisa Piercey, *Stem Cell Research in the Cross Hairs of the Abortion Debate*, 14 BioVenture View 12 (Mar. 1999); John J. Miller, *The Hill II: Hard Cell*: *A powerful coalition pushes to subvert the ban on human-embryo research*, Nat'l Rev. (Apr. 5, 1999); Paul Recer, *House Members Protest NIH Stem-Cell Research Plan*, Chattanooga Times Free Press, Feb. 18, 1999, at A4.

[190] NIH Guidelines for Research Using Human Pluripotent Stem Cells**,** 65 Fed. Reg. 51,975, 51,981 (Aug. 25, 2000).

[191] The NBAC's charter was not renewed by the Bush Administration. It continued to work through the end of its charter in September 2001. The NBAC did not end its work with the Stem Cell Report. Several other reports emerged from the Commission's work. *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* was actually issued before the stem cell report, in August 1999. *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* was issued in April 2001 and *Ethical and Policy Issues in Research Involving Human Participants*, the focus of NBAC's original mandate, was issued as NBAC was winding up in August 2001. While these reports were not translated into new regulations, they have exerted some influence. The recommendations in *Research Involving Human Biological Materials* and *Research Involving Human Participants* do not have the force of law, but they do influence institutional review boards and regulatory bodies such as the FDA and the Office of Human Research Protections. *See* Nat'l Bioethics Advisory Comm'n (NBAC), *at* http://www.bioethics.gov/reports/past_commissions/ (last visited Apr. 16, 2005).

G. *President Bush's Council on Bioethics (2002-present)*

In August 2001, in his first major address to the nation, President Bush announced that federal funding could support stem cell research using specified existing cell lines. Research using new cell lines, however, would not qualify for federal funding.

At the same time, President Bush announced the formation of a new President's Council on Bioethics. Professor Leon Kass of the University of Chicago was named chair and he selected most of the members. Reports predicted that the new Council's membership would be stacked with conservatives. While the Council's membership certainly included more conservatives than had served on earlier panels, it would be unfair to call the Council stacked.[192] When the members met for their first meeting in January 2002, several things became clear. First, the Council is more tightly controlled by the chair than any of its predecessors. Dr. Kass guides the discussion with a firm hand. Moreover, most of the investigatory plans and possibly even some Council decisions are determined off-stage by Kass and the staff.[193] Yet, it also became evident that the Council's original membership was sufficiently diverse that consensus on morally complex issues would be elusive.

As of June 2004, the Council had issued four reports. The first, *Human Cloning and Human Dignity: An Ethical Inquiry*,[194] was produced in response to President Bush's request. It examines reproductive and therapeutic cloning and concludes that the former should be banned and, by a closer vote, that the latter should not proceed at this time. The second report, *Beyond*

[192] This is certainly true through February 2004. Members of the PCB were: Elizabeth Blackburn, professor of biochemistry and biophysics at UCSF; Stephen Carter, professor of law at Yale (Stephen Carter did not participate in most of the council's meetings and decisions); Rebecca Dresser, professor of law at Washington University; Daniel Foster, Chairman of the Department of Internal Medicine at the University of Texas Southwestern School of Medicine; Francis Fukuyama, professor of political economy and public policy at Johns Hopkins University; Michael Gazzaniga, professor in Cognitive Neuroscience at Dartmouth; Robert George, professor of jurisprudence at Princeton; Mary Ann Glendon, professor of law at Harvard; Alfonso Gomez-Lobo, professor of philosophy at Georgetown; William Hurlbut, professor of human biology at Stanford; Charles Krauthammer, physician and syndicated columnist, William May, professor emeritus of ethics at SMU, now a fellow of the Institute of Practical Ethics at the University of Virginia; Paul McHugh, Director of the Department of Psychiatry at Johns Hopkins; Gilbert Meilander, professor of Christian ethics at Valparaiso; Janet Rowley, professor of molecular genetics and cell biology at Chicago; Michael Sandel, professor of Government at Harvard; and James Wilson, professor emeritus of management and public policy at UCLA. *See* Council Members, *at* http://www.bioethics.gov/about/former_members.html. In February 2004, Blackburn and May were dismissed and replaced by Benjamin Carson, neurosurgeon at Johns Hopkins; Peter Lawler, professor of government at Berry College; and Diana Schaub, professor of political science at Loyola College in Maryland. *See* Former Council Members, *at* http://www.bioethics.gov/about/former_members.html (last visited Apr. 25, 2005). The dismissals caused considerable discussion in the media that Kass was seeking a more politically conservative group. *See, e.g.*, *Bush Dismisses Members from Bioethics Council*, L.A. Times, Feb. 28, 2004, at 18; Gareth Cook, *President's Panel Skewed Facts, 2 Scientists Say,* Boston Globe, Mar. 6, 2004, at A1.

[193] Interestingly, on its face, the council is the most transparent of all the commissions. It has an excellent website where it provides transcripts and commissioned papers in close to real time. *See generally* The President's Council on Bioethics, *at* http://www.bioethics.gov (last visited Apr. 25, 2005). In many instances, these transcripts reveal meetings that have all the flavor of a graduate seminar, again reflecting the influence of Dr. Kass. In addition, unlike previous chairs of similar panels, Dr. Kass has moved to Washington and devotes most of his time to the Council.

[194] The President's Council on Bioethics, *Human Cloning and Human Dignity: An Ethical Inquiry* (July 2002), *available at* http://www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf.

Therapy: Biotechnology and the Pursuit of Happiness,[195] is a philosophical meditation on the perils of human engineering and control, which makes no formal recommendations. In January 2004, the Council published a report called *Monitoring Stem Cell Research*.[196] It discusses the moral, legal and scientific landscape surrounding stem cell research but likewise makes no formal recommendations. The Council published a fourth report, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, in June 2004, which focuses on assisted reproductive technologies and other aspects of embryo research.[197]

Human Cloning and Human Dignity revisits many of the arguments that have been advanced since the EAB first took a broad look at embryo research and predicted cloning. The report is specifically addressed to cloning, but much of its discussion could apply to other reproductive technologies as well. Yet there is a subtle difference in the Council's approach that changes the landscape. For most of the Council's predecessors, aside from questions of federal funding,[198] the burden of proof has been on those who wanted to regulate scientific inquiry rather than on scientists to show that they should be free from regulation. The President's Council, however, often seems to assume that the burden rests on the research community, that much of this research is so dangerous that every application must be affirmatively justified before it is permitted.

The Council also seems uncertain about its role. At times, the report seeks to supply a moral analysis that provides an answer applicable to both reproductive and therapeutic cloning. At other times, it concentrates on policy and proposes legislative solutions. This dichotomy creates problems when the Council formulates recommendations. Its recommendations regarding therapeutic cloning are illustrative. By a vote of nine to six, the Council members recommended a four-year moratorium on research. This vote required three members who might ultimately accept exploration of therapeutic cloning to join forces with six who seem to oppose

[195] The President's Council on Bioethics, *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (Oct. 2003), *available at* http://www.bioethics.gov/reports/beyondtherapy/beyond_therapy_final_webcorrected.pdf.

[196] The President's Council on Bioethics, *Monitoring Stem Cell Research* (Jan. 2004), *available at* http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf.

[197] The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies* (Mar. 2004), *available at* http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf. *See also infra* note 200 and accompanying text. In many ways this latter report reflects how much of the council's work is that of Kass and staff. More than half of the council's members were absent for the October meetings that discussed some of the material to be included in this report. But news reports state that the final report faces only "minor edits." Nonetheless, the evolution of the report does seem to show a desire to tone down some of the moral rhetoric that was present in earlier drafts and discussion. For example, early drafts did not use the word "embryo" but instead "child to be." Rick Weiss, *Bioethics Panel Calls for Ban on Radical Reproductive Practices*, Wash. Post, Jan. 16, 2004, at A2.

[198] With federal funding, the burden of proof is on science. The concern is that society at large, because it pays for the research, could become morally complicit in activity that a large part of the society may find morally reprehensible. In terms of federal funding, NBAC required science to show that the moral benefit of that science trumped the moral wrong that might occur regarding the embryo. One may argue that NBAC was overly impressed with that science, but nonetheless, NBAC placed the burden on science. However, NBAC and all other previous commissions did not use that calculus with regard to scientific activity that was not federally funded.

the technology under any circumstances. It is noteworthy that all of the scientists on the Council joined in opposing the recommendation for a moratorium.

One must acknowledge that this splintered vote may reflect political realities in the United States. Positions on cloning and embryo research are, if anything, hardening and less susceptible to compromise. The Council's recommendations on cloning have not yet been adopted, or even seriously considered, by Congress. Although the Council's report raised few new arguments, it was not applauded either by those favoring embryo research or by those who want to ban it. President Bush's response was inattentive to the nuances reflected in the report. The White House expressed hope that Congress would rely on the report's findings to ban all types of cloning[199] and the President called for a ban on all forms of human cloning in his 2003 State of the Union address.

The Council's report *Reproduction and Responsibility* has a more measured tone than its report on cloning. It reflects a more sensitive appreciation of legal and political realities and its recommendations are less sweeping and better designed to garner legislative consensus. The report focuses on research techniques or on clinical techniques that arguably are still in a research stage, and much of the discussion centers on techniques that are widely ethically suspect. The report has been criticized for not dealing with issues of more ordinary, and arguably more critical, clinical importance, such as the permissible number of embryos transferred during IVF, sex selection and emerging genetic technologies.[200]

Perhaps the most fundamental difference between the Council's recommendations and those of its predecessors is that instead of focusing on techniques that should be eligible for federal funding, the report focuses on techniques that should be federally prohibited. The Council recommends that the following be prohibited by law: the transfer of a human embryo into the body of a non-human species; the production of a hybrid human-animal embryo; the transfer of a human embryo to a woman's uterus for any purpose other than to produce a live-born embryo; attempts to conceive a child by any means other than the union of egg and sperm; attempts to conceive a child by fusing gametes obtained from a human fetus or derived from human embryonic stem cells; attempts to conceive a child by fusing blastomeres from two or more embryos;[201] use of human embryos in research beyond a designated stage — between ten and fourteen days after fertilization;[202] the buying and selling of human embryos; and finally, patents covering human embryos or fetuses. In addition, the report recommends better federal oversight of reproductive practice through additional study, data collection and monitoring,

[199] Sheryl Gay Stolberg, *Bush's Bioethics Advisory Panel Recommends a Moratorium, Not a Ban, on Cloning Research*, N.Y. Times, July 11, 2002, at A21. Overall, the Bush Administration has largely ignored the Council's work. There is no evidence of any direct communication from the President to the Council since its inception.

[200] Brian Vastag, *Group Calls for Stricter Rules for Assisted Reproduction, Ban of "Extreme" Technologies*, 291 J. Am. Med. Ass'n, 2306, 2306-08 (2004).

[201] These three prohibitions would cover reproductive cloning.

[202] There was a fair amount of dissension on this point; some members opposed any destruction of embryos for research, others favored the longer fourteen-day period after fertilization that had been accepted by earlier bioethics panels, and still others preferred a shorter period of ten days. *See* discussion *supra* notes 199-200 and accompanying text.

particularly through a broadening and strengthening of the Fertility Clinic Success Rate and Certification Act.[203] It also recommends improvements in oversight by professional societies.[204]

For the most part, these recommendations are not particularly politically controversial.[205] Indeed, avoidance of controversy seems to be a goal of the Council. For example, the report avoids morally divisive issues such as the moral worth of an embryo. There is evidence of careful wordsmithing. For example, the ban on attempts to conceive a child by any means other than the union of an egg and sperm carefully focuses the ban on the phase prior to the creation of an embryo thereby avoiding a requirement of destruction of a cloned embryo, which might be abhorrent to some conservatives regardless of the origin of the embryo. In addition, the report dodges the issue of the permissibility of embryonic stem cell research.[206]

But it is not clear that real consensus exists under the veneer of the recommendations or that any such consensus would survive legislative debate. There is some evidence that the Council itself is divided. The report is supplemented by ten personal statements by individual members of the Council. Six members, Robert George, Mary Ann Glendon, Alfonso Gomez-Lobo, William Hurlbut, and Gilbert Meilaender, state that the report does not endorse the destruction of human embryos at any time. At the other end of the spectrum, Michael Gazziniga chafes at the Council's providing human embryos such ethical status.

It is possible that the shift of focus from federal funding to prohibition may provide a sufficient incentive for conservatives to allow legislative compromise in other areas. Nonetheless, reproductive technologies cannot be completely separated from the question of the moral status of the embryo and that issue itself may be inextricably woven into abortion politics in this country. Some bioethicists seek to separate the issues,[207] but it is not so clear that those efforts will be successful in a legislative setting.

IV. HAVE THE U.S. BIOETHICS ADVISORY BODIES BEEN SUCCESSFUL?

It is difficult to evaluate the success of U.S. bioethics panels in part because it is unclear what measures of success one should use. If implementation of recommendations is the principal measure, only the National Commission and the President's Commission could claim

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[203] *See*The President's Council on Bioethics, *Reproduction and Responsibility, supra* note 197, at 208-10.

[204] *Id.* at 215-18.

[205] That is not to say that they might not be legally controversial. Those favoring a broad view of procreative liberty might well find the focus on prohibition to be a fundamental breach of legal rights.

[206] Some commentators have speculated that the report's omission of this issue might be a tacit acceptance of its use. Vastag, *supra* note 200, at 2306-08. Nonetheless, while the report neither endorses nor condemns such research, Dr. Kass specifically notes that the report does not repudiate anything stated in previous reports. Leon R. Kass, Letter of Transmittal to the President, in *Reproduction and Responsibility*, *supra* note 4 at xix. This would appear to mean that the rejection of such research in *Human Cloning and Human Dignity* continues to be the Council's position.

[207] *See, e.g.,* Lori Andrews, Testimony before the President's Council on Bioethics (July 24, 2003), *available at* http://www.bioethics.gov/transcripts/july03/session4.html (stressing the need to separate out the abortion issue from the discussion of reproductive technologies).

to be successful. Later panels have proved largely impotent. By this criterion, the chartering of new panels should cease because they are a waste of public funds.

Such panels may serve other objectives, however. They have provided a forum in which rational public discussion of bioethics can take place. It is important that this conversation not be confined to the academy. Bioethics panels also collect, digest, and disseminate information. Even when members cannot agree on recommendations, they can hold hearings, write reports, and engage in and provoke debate. These activities are usually carried on at a high level of sophistication and at a deliberate pace. A panel can then often produce an instructive picture of the scientific, moral, legal, and political landscape.

These tasks may not need to be repeated every presidential term. As our chronicle demonstrates, successive panels instructed to examine embryo research have revisited the same moral issues. The same questions repeat themselves, because the realization that there is no definitive moral answer may be as important as discovering an answer. It may be as useful to rationalize failure to enact legislation as to make the case for legislative action.

At a more subtle level, bioethics panels may have a political impact that does not require, and indeed may obstruct, implementation of recommendations. This was the outcome, though surely not the aim, of the two commissions over which the Clinton administration presided. Both the HERP and the NBAC were composed of members who stood collectively to the left of the administration on these issues. Nevertheless, the panels arguably served two purposes. First, they reassured the scientific community that important issues were being addressed. Second, because their recommendations fell at the liberal end of the political spectrum, they made the proposals that the Clinton administration advanced seem more moderate.

This account suggests that if the moral or political gulf is not too wide, a blue-ribbon panel can help crystallize public sentiment and even reveal consensus. For example, the reports of the President's Commission on *Defining Death*[208] and *Deciding to Forego Life-Sustaining Treatment*[209] helped crystallize views that had been developing in the bioethics literature and were ripe for implementation. The process the National Commission followed in producing its report on fetal research provided an opportunity for compromise, but it was able to do so only because the abortion controversy had not yet reached the intensity where no compromise was possible. Creation of a panel can sometimes produce a healthy delay that may facilitate compromise or diffuse pressure to enact extreme legislation. For example, the NBAC's study of cloning[210] provided time for public uproar to subside, though of course its report did not resolve the issue.

History suggests that on issues where there is no public consensus, advisory panels cannot resolve moral issues or generate a consensus that leads to political action. In such cases, even if panel members are not themselves divided, they do not reflect the population they are serving. And if they are divided, they are unlikely to achieve a level of consensus firm enough to support a political response.

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[208] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Defining Death: Medical, Legal and Ethical Issues in the Determination of Death* (July 1981), *available at* http://www.bioethics.gov/reports/past_commissions/defining_death.pdf.

[209] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to Forego Life-Sustaining Treatment* (1983).

[210] *See* NBAC Roster in NBAC, Cloning *Human Beings*, *supra* note 158.

It may even be true that panels that are determined to produce political answers must evade important moral questions. For example, the Belmont Report[211] does not articulate many of the moral underpinnings of the principles it espouses. Therefore, a choice must be made at the outset. Is a panel's task to reach a pragmatic compromise? Is it to resolve moral issues? Or is it simply to illuminate the sides of debate? The National Commission and, to a lesser degree, the President's Commission, were explicitly pragmatic. More recent panels, however, have been loath to acknowledge that they have trouble answering all calls.

If a panel hopes to make the case for legislative action, its recommendations must reflect widely shared ethical values. Panel members must seek agreement on recommendations even though they start from different moral premises.[212] Consensus does not require unanimity. While the HERP and the NBAC heard conservative viewpoints in their public sessions, the absence of such voices among the members allowed them to evade compromise and may have blinded them to political reality. If compromise seems unlikely because the moral gulf between factions is wide,[213] bioethics panels can debate, study, and recommend ad nauseum, but their recommendations are not likely to lead to political action. A strong committee report is essential, but it is not enough. Accordingly, if political action is necessary, political leaders must do the hard work. This is the lesson of the British experience, which we describe in Part V.

V. BRITISH REGULATION OF REPRODUCTIVE TECHNOLOGY

While bioethics panels in this country have tried unsuccessfully to catalyze policy on reproductive technologies, Britain has succeeded in doing so. At first, this seems puzzling because, although IVF was pioneered in Britain, both the technology of reproductive genetics and the field of bioethics have advanced more rapidly in the United States.[214] However, neither appreciation of scientific need nor a high-level ethical debate has been able to overcome fundamental political obstacles in the United States. Not only is the abortion issue more divisive here,[215] but differences in governmental structure and medical culture are also at work.

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[211] For a discussion of the Belmont Report, see *supra* notes 37-40 and accompanying text.

[212] John Mendeloff calls this "muddling through." John Mendeloff, *Politics and Bioethical Commissions: 'Muddling Through' and the 'Slippery Slope,'* 10 J. Health Pol. Pol'y. & L. 81 (1985). Mendeloff notes that if the reasons for a decision are not given, it is difficult to assess whether making a decision places us on a slippery slope (i.e. is it one that is very long and very steep, or on one that is a mere bump – the extension of the metaphor is ours).

[213] It is not clear whether the political moral gulf reflects a similar gulf in the general population. Commissions have been poorly suited to really engage the public in debate about these issues.

[214] *See* Jonathan Moreno, *Bioethics is a Naturalism*, *in Pragmatic Bioethics* 5 (Glenn McGee ed., 1999). (arguing that bioethics, as a field of intellectual endeavor, is quintessentially American). PGD, ICSI and ooplasm transfer were pioneered in the United States. Both human embryonic stem cells and germ cells were first isolated in the United States. The United States' pace of innovation may be changing. Recent advances in human cloning and stem cell research have taken place outside the United States and some U.S. scientists have left the country to pursue research.

[215] *See, e.g.*, Parens & Knowles, *supra* note 3, at S10.

The British Human Fertilisation and Embryology Authority (HFEA) was created by the Human Fertilisation and Embryology Act of 1990 (HFE Act).[216] The Act was based on the Report of the Committee of Inquiry into Human Fertilisation and Embryology, commonly known as the Warnock Report.[217] It took six years after the Warnock Report was published for Parliament to act. During that time, there was intense political jockeying primarily focusing on the issue of embryo research. Under the British parliamentary structure, leaders of the Conservative government, who favored allowing embryo research, were able to control the political debate and quickly moved the issue forward. The government was supported by Britain's research community, which recognized that some regulation of such research was inevitable.[218]

A. *History of the HFE Act*

Louise Brown, the first "test tube baby," was born in Britain in 1978. The scientists involved predicted "new horizons in human reproduction" which would contribute "to the benefit of humanity in directions which we do not apprehend today."[219] Louise Brown's birth coincided with popular condemnation of the Abortion Act of 1967,[220] whose critics gained influence with the Conservative victory in the 1979 general election. The Tories, however, were not then, and are not now, fully aligned with anti-abortion forces.

Although the science involved in IVF was not linked to abortion technologically, embryo research soon came to be viewed through the same lens.[221] In addition, assisted reproduction

[216] The United Kingdom is not a single entity for purposes of health law. England and Wales have identical legal systems, but health law in Northern Ireland and Scotland, while largely similar, is not always the same. That being said, the HFE Act applies to the entire United Kingdom although there are some exceptions and differences that apply only to Scotland and Northern Ireland. *See Staff Background Paper: On the British Regulatory System*, a*vailable at* http://www.bioethics.gov/background/background3.html (last visited Apr. 24, 2005).

[217] *Warnock Report*, *supra*, note 1.

[218] Michael Mulkay, *The Embryo Research Debate: Science and the Politics of Reproduction* 25 (Univ. Press, eds., 1997).

[219] *Id.* at 12.

[220] Prior to 1967, abortion was prohibited in Britain pursuant to the Offenses Against the Person Act of 1861. The Abortion Act of 1967 left in place the prohibition on abortion but provided for a number of broadly defined "defenses." These defenses are (1) "social grounds": continuing the pregnancy would involve greater risk of injury to the physical or mental health of the pregnant woman, or to any existing children in her family than if the pregnancy were terminated, (2) "maternal health grounds": termination of the pregnancy is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman or continuance of the pregnancy would involve greater risk to life than if the pregnancy were terminated, and (3) "fetal handicap grounds": two doctors believe in good faith that there is substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped. Social grounds are only available as a defense up to viability and the presumption of viability was lowered from twenty-eight weeks to twenty-four weeks with the HFE Act. All defenses include a very strong presumption in favor of medical judgment.

[221] Mulkay, *supra* note 218, at 12-15. Importantly, it was not viewed through the same lens by all groups that had moral issues with abortion. There was no consistent religious opposition to embryo research. A number of prominent members of the Church of England, e.g. the bishop of Edinburgh and the Archbishop of York, supported

made possible family groupings and relationships that had been impossible before. Some saw IVF as the top of a slippery slope that would open unknown ethical frontiers and threaten traditional family values.[222]

1. The Warnock Commission

Conservative members of the House of Lords called for a commission to study IVF and recommend safeguards to control it.[223] The Thatcher Government[224] responded in 1982 by forming an expert commission to investigate the social, legal and moral implications of assisted reproduction. Led by Dame Mary Warnock, a Cambridge professor of moral philosophy, the commission had sixteen members representing a cross-section of medical practitioners, social workers, legal specialists and ethicists.[225] They were assisted by a legal advisor who exercised significant influence.

Committees of inquiry, including the Warnock Commission, are heavily influenced by the civil service.[226] Most members of committees of inquiry in Britain are appointed from a list called the "central list", used by the British Civil Service for such purposes.[227] Members are

legislation in favor of embryo research. *See* Aurora Plomer, *Beyond the HFE Act 1990: The Regulation of Stem Cell Research in the UK*, 10 Med. L. Rev. 132, 137 (2002).

[222] Mulkay, *supra* note 218, at 15.

[223] 432 Parl. Deb., H.L. (5th ser.) (1982) 1000.

[224] Throughout this paper, as it is in common parlance in Britain, the term "Government" is used as a shorthand for "Her Majesty's Government." The Government includes the Prime Minister and the body of ministers responsible for the conduct of national affairs, which is in some ways roughly equivalent to the executive in the United States. However, there are important differences. Although the Prime Minister is appointed by the Queen, the Prime Minister's authority is derived from majority support in the House of Commons. Therefore, the separation of powers as it exists in the United States is absent. The Government controls the majority in the House of Commons. Moreover, the concept of party discipline is even stronger in Britain than in the United States.

[225] Other members of the Commission were Q. S. Anisuddin, President of the UK Immigrants Advisory Service; T. S. G. Baker, Recorder of the Crown Court; Josephine Barnes, an Ob/Gyn at Charing Cross Hospital; M. M. Carriline, a social worker and former Vice-Chairman of the British Agencies for Adoption and Fostering; D. Davies, Director of the Dartington North Devon Trust; A. O. Dyson, Professor of Social and Pastoral Theology at the University of Manchester; N. L. Edwards, Chairman of the Gwynedd Health Authority; W. Greengross, Chairman of Sexual and Personal Relations of the Disabled; W. G. Irwin, head of the Department of General Practice, Queens University Belfast; J. Marshall, professor of clinical neurology, Institute of Neurology, Queen Square, London; M. C. Macnaughton, professor of Ob/Gyn, University of Glasgow; A. McLaren, Director, Medical Research Council Mammalian Development Unit; D. J. McNeil, solicitor in Edinburgh; K. Rawnsley, professor of psychological medicine, Welsh National School of Medicine; and M. J. Walker, psychiatric social worker. *Warnock Report*, *supra* note 1, at iv-v.

[226] Mary Warnock, Government Commissions in Human Embryos and Research, Proceedings of the European Bioethics Conference in Mainz, 7-9 November 1988, 159-168 (Umberto Bertazzoni et al. eds., Joseph Zacharias trans., 1990).

[227] *Id.* at 160. Warnock jokingly refers to the "central list" as "the list of the Good and Great." She notes that at times those already on the list are asked for names to add. Exactly who gets on the list is a civil service decision, and it is not clear what criteria are used. *Id.*

appointed by the appropriate civil service department. The Warnock Commission reported to the Secretary of State for Social Services, the Lord Chancellor, the Secretary of State for Education and Science, and the Secretaries of State for Wales, Scotland and Northern Ireland.

As Warnock has noted, before the first meeting, the Chair has already worked with the civil servant who will act as secretary to the committee, as well as with the other civil servants who act as liaisons with the Ministers. Often, an introductory paper has been produced by the civil servants, thereby influencing the direction the committee takes.[228]

In Warnock's view, a committee of inquiry is not "the place for profound analyses of moral problems of a philosophical or historical nature."[229] Such analysis should be undertaken only to the extent that it is necessary to the crafting of the law or regulation that is at issue. This viewpoint dictated the procedures used by the Warnock Commission and probably colored the end result.

The Commission began its work believing that "infertility was a malfunction which causes endless misery, and for which treatment should be available to everyone."[230] Over the ensuing two years, the Commission examined all areas of assisted reproduction that were anticipated at the time.[231] It examined artificial insemination, IVF, egg donation, embryo donation, surrogacy, the potential for assisted reproductive techniques outside of infertility,[232] and freezing of gametes and embryos for future use. It reviewed who should be eligible for infertility treatment and how services for infertility should be organized, and it addressed issues of anonymity, counseling and consent. The Commission also attempted to address several future scientific developments that might be the subject of embryo research. These included trans-species fertilization, in vitro use of embryos to test drugs, incubation of an embryo in vitro, gestation of embryos in other species, parthogenesis, prevention of genetic defects, cloning, and "nucleus substitution."[233] After surveying the scientific landscape, the Commission addressed the need for regulation and the legal framework within which regulation should occur.

The Warnock Commission did not address the underlying moral questions and policy recommendations until it had educated itself on the science. When it did move on, its overall approach was utilitarian. There was a recognition that certain techniques or experiments should not be undertaken regardless of the benefits that might accrue, but outside of those questions, and even when weighing them, the Commission focused on the benefits and harms that might accrue.[234] The conviction that colored all of its deliberations was that some regulation was

[228] *Id.* at 160-161.

[229] *Id.* at 161.

[230] *Id.* at 163.

[231] *Warnock Report*, *supra* note 1.

[232] These included avoidance of transmission of hereditary disease and sex selection. *Id.* at 48-52.

[233] *Id.* at 70-74. This discussion anticipated the development of techniques now involving stem cells and cloning to produce histologically identical transplantable organs.

[234] Warnock, *supra* note 226, at 163.

necessary.[235] Therefore, discussion was centered on how to make regulation possible.[236] This forced compromises that may not have occurred had focus been on the moral issues themselves.

Most of the Warnock Commission's recommendations were eventually incorporated into the HFE Act.[237] Most important, the Commission recommended that a new statutory licensing authority should be established to regulate the research and assisted reproduction services that were to be subject to control. Its Report argued that the rules and decisions should be made by an authority that was independent from the government, health authorities, and research institutions.[238] This authority should have a substantial lay membership and its chair should be a lay person. The resulting licensing authority overseeing a specific area of medical practice was, and still is, unique in Britain.[239]

The Warnock Report recommended that any clinical use of assisted reproductive techniques should only be permitted pursuant to licenses issued by the new authority. This would include techniques such as IVF, artificial insemination, egg donation and embryo donation. The authority's jurisdiction would also extend to storage and banking of human gametes and embryos. Sale or purchase of human gametes or embryos could only be done under license. The licensing authority would consider the needs of children born through assisted reproductive technology and determine whether a registry should be maintained. The Report recommended appropriate counseling and specific consent practices for both donors and recipients and other participants in assisted reproductive techniques. The Report recommended limits on duration of storage—after 10 years, right of disposal would pass to the storage authority. In addition, it recommended that rules be established to regulate use or disposal if one or both partners died or could not agree.

Research on in vitro embryos would likewise require licensure. No research would be permitted on any embryo after fourteen days from fertilization.[240] Research could be licensed

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[235] *Id.* at 166.

[236] *Id.*

[237] *Warnock Report*, *supra* note 1, at 80-86. Each recommendation is also discussed in the various chapters that correspond with the technique or issue concerned.

[238] *Id*. at 75.

[239] Connected but separate quasi-governmental entities are often called "quangos" and seem to be a largely British invention, although entities like quangos do exist in the United States. For example, the National Endowment for the Arts might be characterized as a quango, as might NASA. "Quango" stands for "quasi-autonomous nongovernmental organizations" although quangos are often more technically quasi-governmental organizations—or "quaggos." The HFEA is one of these. But the more euphonious term "quango" is more often used. Quangos first appeared in numbers in Britain during the 1970s under the Labour government but were a favorite mechanism of the Conservative government during the 1980s and 1990s. Paul Hirst, *Quangos and Democratic Government*, 48 Parliamentary Affairs 341 (1995).

The Warnock Commission certainly would have been aware of quangos as a way of achieving a semi-independent body.

[240] Three members dissented from the recommendation to permit research on human embryos. They noted that different people would answer the question of when an embryo becomes a "person" different ways. "Scientific observation and philosophical and theological reflection can illuminate the question but they cannot answer it." *Warnock Report*, *supra* note 1, at 90. Both Liberals and Conservatives have called the "14 day" limit arbitrary. *See* Plomer, *supra* note 221, at 137.

regardless of provenance; accordingly, embryos could be created for research so long as licensing requirements were met.[241] The Report recommended that unlicensed research or unlicensed use of trans-species fertilization involving human gametes should be criminal offenses. Similarly, it should be a criminal offense to transfer an embryo that had been used for research into the uterus of a woman, or to place a human embryo into an animal. Although the Report discussed cloning and somatic cell nuclear transfer, as well as techniques involving embryo biopsy for diagnostic purposes, it did not make formal recommendations regarding their permissibility, leaving those decisions to the licensing authority.

The Commission's Report recommended several legal changes to resolve issues of parentage and inheritance rights of children born through assisted reproductive technology. It also recommended that all surrogacy agreements be deemed unenforceable and that recruitment of surrogates should be a criminal offense. Finally, the Report recommended legislation to ensure that there was no right of ownership in any human embryo.

Compared to products of the U.S. panels described in Part III, the Report of the Warnock Commission is remarkably spare. It runs only one hundred pages and does not include or refer to papers or views that may have been considered. While each recommendation is supported, the analysis is often conclusory and frequently glosses over competing values. The Report offers scarcely any philosophical justification for its recommendations.

This approach is quite clearly intentional. From the beginning, the Commission members saw their assignment as designing legislation. In her personal introduction, Dame Mary Warnock quotes Hume: "[morality is] more felt than judg'd of."[242] She notes that neither utilitarianism nor other philosophical principles provide a real answer to the question of the status of the embryo.[243]

> We have been accused of making recommendations which attempt a compromise between incompatible moral positions; of proposing arbitrary limits; or of suggesting that things offensive to numbers of people should be legally permissible. But the law is not, and cannot be, an expression of moral feeling. It must apply to everyone, whatever their feelings; it must be both intelligible and enforceable. We were bound, if we were to fulfill our task, to bear in mind the differences between the law and morality. On the other hand, we had, obviously, to recognize their interconnection.[244]

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[241] Four members of the committee dissented from the determination that embryos could be created for research. *See Warnock Report*, *supra* note 1, at 67-68. They argued that it was inconsistent with the special status afforded to the embryo to permit it to be created with no prospect of implantation. They noted that this might impede scientific progress but that it was morally wrong to do so and moreover that to do so would be to set foot on the "slippery slope" to inappropriate use. They relied on the philosophical argument of "double effect" where an act that would be wrong if chosen for its own sake may be justified if it occurred as a by-product of some other "well intentioned" act. Thus, use of spare embryos created for alleviation of infertility (a well-intentioned act) would be permitted because they would be a necessary by-product of that act. Those members in favor of permitting the creation of embryos for research justified that decision on the belief that otherwise the range and scientific validity of research would be curtailed.

[242] *Id*. at viii.

[243] *Id*. at ix-x.

[244] *Id*. at x.

In short, she argued that the Commission members, like the public at large, could reach agreement on practical recommendations even though they embraced different moral starting points. The Commission members were divided on the moral status of the embryo, but no practical solution could reflect that disagreement; a choice had to be made.

The Commission's ultimate decision on embryo research was pragmatic and utilitarian:

> According to the majority view, the question was not, as is often suggested, whether the embryo was alive and human, or whether, if implanted, it might eventually become a full human being. We conceded that all these things were true. We nevertheless argued that, in practical terms, a collection of four or sixteen cells was so different from a full human being, from a new human baby or a fully formed human foetus, that it might quite legitimately be treated differently. Specifically, we argue that, unlike a full human being, it might legitimately be used as a means to an end that was good for other humans, both now and in the future.[245]

Dame Warnock emphasized that the choice was not between never using embryos in research and allowing any embryo research. Instead, the choice was between prohibition and strict regulation of embryo research.[246] Moreover, she argued, legislation reflecting this choice should apply not only to publicly funded research but to all research conducted in the United Kingdom. She acknowledged that the public regarded assisted reproduction and embryo research with fear. "People generally believe that science may be up to no good, and must not be allowed to proceed without scrutiny, both of its objectives and its methods."[247] The prevailing view had been that regulation of research practices was appropriate if society was funding the research. If funded investigators engaged in morally questionable research, society would thereby become complicit. However, the Warnock Commission moved beyond this concept. The ethical issues surrounding uses of human embryos were serious enough to warrant not just loss of funding, but criminal prosecution, should scientists go beyond the lines drawn.[248]

2. Political Reaction to the Warnock Commission Report

Upon its publication in 1984, the Warnock Report was vociferously condemned by both the scientific community and anti-abortion groups. Abortion opponents were unhappy that the Report not only failed to insist on the fundamental importance of marriage but also would allow assisted reproductive techniques to be available to unmarried couples.[249] Most importantly, they

[245] *Id*. at xiv-xv.

[246] *Id*. at xvi.

[247] *Id*. at xiii.

[248] *Id*. As noted above in the discussion of the committee's recommendations, some of these would include reproductive cloning or the creation of human-animal chimeras.

[249] Mulkay, *supra* note 218, at 17.

were scandalized that the Report recommended a mechanism to continue research on embryos.[250] While scientists did not reject oversight of clinical applications, they did reject the notion that research also required oversight—or that unapproved research could be subject to criminal prosecution.[251]

In early 1985, Conservative ex-Minister Enoch Powell introduced a private bill[252] to ban embryo research in the House of Commons.[253] In February 1985, after the bill's Second Reading, opponents of research scored a decisive victory. In a non-binding vote, Powell's bill received 238 votes with 66 against, with 47% of the Members voting. The only reason the bill did not pass the House was that the Government failed to support it and therefore did not allow time for a formal vote. The bill did, however, serve as a "wake-up" call to those who supported continued embryo research.

In early 1985, Britain's Medical Research Council (MRC) published its response to the Warnock Report. The MRC took issue with certain recommendations, but generally approved the Report. In direct response to the threat of legislation barring embryo research, the Council recommended that an independent licensing agency be set up to supervise embryo research on a voluntary basis pending the passage of formal legislation.[254] Accordingly, the Voluntary Licensing Authority (VLA) was formed by the Medical Research Council and the Royal College of Obstetricians and Gynaecologists[255] in June 1985 and granted its first licenses later that year.[256]

The same year, the scientific community began to develop an organized response to the threatened ban on embryo research. An editorial in *Nature* endorsed the suggestion that a licensing authority should be formed to review protocols for embryo research.[257] In addition, the research community began to shift the focus from the contributions research could make to relieving infertility to its promise of ways to fight genetic disease. Polls had shown that many in the general public who were "undecided" about the appropriateness of embryo research would

[250] *Id.*

[251] *Id.* at 20-21.

[252] Private bills are bills that do not originate with the Government. Since the Government largely controls parliamentary time and procedures, private bills rarely succeed because they are not given adequate time for debate and are not brought to a final vote. But some private bills do succeed—perhaps the most famous private bill was the Abortion Act of 1967.

[253] Mulkay, *supra* note 218, at 24.

[254] *Id.* at 25.

[255] The Medical Research Council is technically not governmental, but is established by Royal Charter and receives most of its funding from the Office of Science and Technology. The Royal College of Obstetricians and Gynaecologists is a professional organization.

[256] Mulkay, *supra* note 218, at 25.

[257] *Id.* The scientific lobby did not endorse all of the Warnock Report—they argued that the types of research that were prohibited under the Warnock Report should also receive individual review rather than wholesale rejection.

respond favorably if it were portrayed as a source of new treatments.[258] In the fall of 1985, scientists, physicians, and like-minded members of Parliament formed a new lobbying organization, "Progress."

In early 1986, another private bill, titled the "Unborn Children (Protection) Bill," was introduced by House of Commons Member Ken Hargreaves. His bill encountered greater opposition than Enoch Powell's earlier bill, but still attracted significant support. Although the Conservative Government withheld support, Hargreaves managed to bring the bill to a vote in the Commons. Although only half of the Members voted, a significant majority supported the bill.[259] Nonetheless, a large number of no votes gave the proponents of embryo research confidence that they were changing Members' minds.[260]

3. Thatcher Supports the HFE Act

In December 1986, the Thatcher Government entered into the debate by issuing a "Discussion Paper,"[261] which reviewed the recommendations in the Warnock Report with an eye to formulating legislation. The paper distinguished between issues on which there seemed general agreement and others, principally surrounding embryo research, on which agreement was lacking. It offered alternative formulas for legislation to facilitate parliamentary debate.[262] Like the Warnock Report, the Government's paper elicited a chorus of criticism. Opponents of embryo research viewed it as a "'delaying tactic' by a morally confused leadership."[263] Progress also lamented the Government's indecision.[264] The result was indeed delay: parliamentary consideration was stalled for much of 1987.

The Thatcher Government continued to move slowly. It next issued a "White Paper," which tracked the Warnock Report closely but again put forward alternative clauses on embryo research.[265] In addition, the White Paper proposed that specific techniques — such as cloning, genetic engineering of embryos and transferring human embryos to other species — should be

[258] *Id*. at 29.

[259] *Id*. at 30-31.

[260] *Id*. Around this time, the scientific community split over terminology. Both Progress and the VLA began calling embryos younger than fourteen days "pre-embryos." Other scientists, including editorial staff at Nature, rejected this maneuver as semantic sophistry. *See also*, Mason and McCall Smith, *Law and Medical Ethics*, at 380 (4th ed. 1994) ("[The term pre-embryo is a] verbal maneuver to establish a 'moral bolt-hole'"); A. Holland, *A Fortnight of My Life is Missing: A Discussion of the Status of the Pre-Embryo,* 7 J. Applied Phil. 25, 35-6 (1990).

[261] Dep't of Health & Soc. Sec., Legislation on Human Infertility Services and Embryo Research (Her Majesty's Stationary Office, 1986).

[262] *Id*.

[263] Mulkay, *supra* note 218, at 32.

[264] *Id*.

[265] Dep't of Health & Soc. Sec., Human Fertilization and Embryology, a Framework for Legislation (Her Majesty's Stationary Office, Nov. 1987).

banned.[266] In an attempt to address concerns of research opponents, it noted: "[o]ne of the greatest causes of public disquiet has been the perceived possibility that newly developed techniques will allow the artificial creation of human beings with certain predetermined characteristics through modification of an early embryo's genetic structure."[267] Active researchers accused the Government of fomenting public fear of embryo research.[268]

In 1988, the Government's White Paper was the subject of debates in both the Commons and the Lords, revealing changes in parliamentary attitudes toward embryo research. The Lords appeared to be roughly evenly divided.[269] A majority in the Commons continued to oppose embryo research, but the margin was shrinking.[270] Undecided members seemed to be strongly influenced by the argument that embryo research might yield treatments for genetic disease.[271]

Many expected the Government to propose legislation, but it remained silent and continued to be heavily lobbied by both sides. Opponents of research questioned the Government's neutrality while proponents chafed at its inaction.[272] In a symbolic gesture, the VLA changed its name to "Interim Licensing Authority," hoping to signal that the Government must act.[273]

Finally, in November 1989, the Conservative leadership was ready to submit a bill.[274] The Government continued to assert its neutrality, promising that the bill would include the alternative options outlined in the White Paper.[275] However, Kenneth Clarke, the Secretary of State for Health, acknowledged that he would vote in favor of continuing embryo research.[276] Prime Minister Thatcher declared that her vote would be based on "the best scientific advice."[277] Notably, the Government decided to introduce the bill in the Lords, where the vote was believed

[266] *Id.* at para. 36-42.

[267] *Id*. at para. 37.

[268] Mulkay, *supra* note 218, at 34. *See Shattered Test Tubes*, 116 New Scientist 21 (Dec. 3, 1987); Simon Hadlington, *British Government Hedges Bets on Embryo Research*, 330 Nature 409 (Dec. 3, 1987).

[269] Mulkay, *supra* note 218, at 35.

[270] *Id*.

[271] *Id*. at 35.

[272] *Id*. at 36.

[273] *Id*. at 36-37.

[274] *Id*. at 37.

[275] *Id*.

[276] *Id*. at 38.

[277] *Id*. (citing *Church Leader Claims Embryo Research Conflicts with Human Rights*, 124 New Scientist 22 (Nov. 11, 1989)).

to be evenly divided, rather than the Commons, where a majority still seemed likely to support a ban on embryo research.[278]

Both sides launched aggressive lobbying efforts. SPUC and LIFE, opponents of research, embarked on a massive letter-writing campaign, equating embryo research with murder.[279] In turn, Progress arranged for families who suffered with genetic disease to visit members of the Lords.[280] The MRC and the British Medical Association lobbied heavily in favor of embryo research.[281] In February 1990, the Lords vote was taken; the tally was 234 to 80 in favor of allowing embryo research to continue.[282]

As the bill moved to the Commons, the Government introduced an amendment reducing the period during which abortion on social grounds could be performed from twenty-eight weeks to twenty-four weeks.[283] Though the Government's motive was not clear, its action served to distract and divide the anti-research lobby. Immediately, there were calls to reduce the period further. Lobbying on the abortion issue took extreme forms. Each MP was sent a life-sized model of a twenty-week old fetus, a gesture that may have backfired, causing many wavering MPs to vote in favor of embryo research.[284] Meanwhile, the proponents of research arranged for each MP to be visited by either an infertile family or one suffering from a congenital abnormality.[285] They scored a media coup by announcing the ability to screen IVF embryos for sex-linked genetic abnormalities.[286] In the end, the Commons vote to continue embryo research was 364 to 193.[287]

4. Why did the HFE Act Pass?

Several factors explain Parliament's adoption of legislation permitting embryo research in the face of what initially seemed majority opposition. First, the scientific community compromised early in the process. Ceding oversight to a licensing agency went against the grain for many scientists, but by surrendering this ground, and then demonstrating though the VLA

[278] *Id.* This was a considerable departure from normal procedures. Most Government bills are first introduced in the House of Commons and move to the House of Lords only after passage in the House of Commons. In addition, if the clause favoring embryo research passed in the House of Lords it could only be reversed in the House of Commons through an amendment that would still have to pass in the House of Lords to be enacted.

[279] *Id.*

[280] *Id.*

[281] *Id.*

[282] *Id.* at 39.

[283] *Id.* at 40.

[284] *Id.*

[285] *Id.* at 41.

[286] *Id.*

[287] *Id.*

that oversight could work, the science lobby was able to quell public fears about unsupervised research. Second, the scientific lobby was successful in combating the perception that embryo research benefited only the infertile and persuading the public that it promised progress in treating genetic disease.

It is noteworthy, too, that the Government's draftsmen did not attempt to resolve the status of the embryo. Dame Warnock recommended that no one should be able to "own" an embryo, but her report recommended that the law should go no further. In the parliamentary debates, one member offered an amendment that provided "for the avoidance of doubt it is hereby declared that the embryo shall have the legal status of a person." The amendment failed, and Lord Hailsham, the former Lord Chancellor, declared:

> An embryo is not a chattel, and to destroy it if it were would be a trespass to someone else's property. A human entity which is living is not a chattel and neither is it a person in the ordinary sense. Most extraordinary results would follow if it were . . . . It would be able to bring an action for personal injury if it were damaged. I suppose the loss of expectation of life might be among the general effects for which general damages could be awarded . . . . It is wrong to try to define a human embryo in terms of existing legal definition which are plainly inapplicable to human embryos. Why must an embryo be one or the other? Why cannot it be just an embryo?[288]

Because the bill did not resolve the status of the embryo, members could vote for it without making a definitive moral choice.

Most important, however, was the fact that Conservative leaders supported continuing embryo research. Had the matter been pushed to a vote in 1985, such research almost certainly would have been outlawed. However, the Thatcher Government moved cautiously, seeking subtly to influence opinion, and acted only when success seemed probable. Remarkably, they also avoided antagonizing a major constituency within the Conservative party.

5. The HFE Act Addresses Cloning and Stem Cell Research

Political will, and perhaps political wiliness, were again evident when cloning and stem cell research came on Parliament's agenda in the late 1990s. By this time, the Labour Party had replaced the Conservatives. With respect to the HFEA, the Blair Government's policy differed little from its predecessor's. The authors of the HFE Act anticipated the possibility of cloning but they assumed that the technique would involve an embryo and thus the statute did not clearly encompass the technology Ian Wilmut used to clone Dolly. Dolly was produced by inserting an adult somatic cell nucleus into an oocyte (Cell Nuclear Replacement or CNR in much British literature),[289] which was then stimulated to behave as though it had been fertilized.

[288] Derek Morgan, *Issues in Medical Law and Ethics* 119 (2001).

[289] This process is more commonly known as Somatic Cell Nuclear Transfer (SCNT) in the United States.

In 1997, the HFEA and the Human Genetics Advisory Commission (HGAC)[290] collaborated to explore the implications of cloning for the agency and for science in general. The HFEA and HGAC formed a working group that developed a paper outlining the major issues.[291] The paper proposed a narrow ban on reproductive cloning that would not affect the technology's potential therapeutic applications. Copies of the paper were distributed; public forums were held; and comments were elicited from experts in religion and bioethics, and from the general public.

The working group reported that the public strongly opposed reproductive cloning. Taking the position that the legislation authorizing HFEA already covered all cloning because the process involved creation of embryos outside the body,[292] the working group proposed that HFEA refuse to license any experiment that involved reproductive cloning. Nonetheless, they also recommended legislation specifically to ban reproductive cloning while at the same time strongly recommending that research into cloning's therapeutic applications be allowed to proceed.

The Blair Government directed Britain's Chief Medical Officer, Liam Donaldson, to form an advisory commission to evaluate the recommendations of the HFEA/HGAC working group. Dr. Donaldson's commission was also encouraged to examine stem cell research and other novel techniques. The commission recognized that CNR and stem cell research could raise ethical concerns that were not considered when the HFE Act was passed, but concluded that those concerns were outweighed by the promise of the research. Rather than endorse new legislation, the commission recommended that the issues be addressed by administrative "regulation."[293] Three months later the Government presented to Parliament a draft regulation that would enlarge the research activities for which the HFEA must issue a license. The draft regulation clarified that therapeutic cloning and stem cell research could take place—but under license.

The Blair Government was criticized for extending the law by regulation rather than by formal amendment after full Parliamentary debate. Criticism grew strong enough that the Government took the unprecedented move of appointing a House of Lords Select Committee to review the regulations *retrospectively*. This novel process was widely deplored, even by friends of the regulation. Baroness Warnock noted:

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[290] The HGAC was formed in 1996 by the Blair government to advise on genetic technologies. It has been subsumed into the Human Genetics Commission (HGC) which serves a somewhat broader function although still limited to genetic technology.

[291] *See* Human Genetics Advisory Comm'n, *Cloning Issues in Reproduction, Science and Medicine* (Dec. 1998), *available at* http://www.advisorybodies.doh.gov.uk/hgac/papers/paperd1.htm.

[292] This conclusion requires some semantic gymnastics. The HFEA does not expressly prohibit CNR, since it only prohibits nuclear substitution of an embryo. But the HFEA does not necessarily cover the technique either—the statutory definition is a "live human embryo where fertilization is complete…." HFEA, §1(1)(a), *available at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_2.htm (last visited Mar. 10, 2005). CNR does not technically involve fertilization. On the other hand, a broad interpretation might include it. *See* Plomer, *supra* note 221, at 141.

[293] Known as "secondary legislation" in the UK. In Britain, secondary legislation, analogous to administrative regulations in the United States, must be approved by Parliament, but it is drafted by the ministries and its details are not debated.

> I deeply wish that there had been time to set up a Select Committee ahead of our having to agree to the regulations. That has been a mistake. We have been bullied and pushed to do things more quickly than we should, which I deplore.[294]

The Government instructed the HFEA to suspend licensing of any cloning experiments pending the House of Lords report.[295] The Pro-Life Alliance then filed a lawsuit challenging the use of secondary legislation to extend the research licensing scheme. The plaintiffs claimed that CNR was not within the definition of an "embryo" under the HFE Act. An initial ruling in their favor was reversed by the Court of Appeal.[296] Conceding that the words of the statute were being strained, the court nonetheless concluded that this was justified because embryos created by CNR fall within the same "genus" as those created by fertilization: "[t]he two are essentially identical as far as structure is concerned, and each is capable of developing into a full grown example of the relevant species."[297] The regulations are thus part of the HFEA today.

The structure of the HFEA is often given credit for the relative ease with which Britain, in contrast to the United States, has been able to devise regulatory solutions to cloning and stem cell research.[298] The HFEA was in a position to respond to the issue immediately and formed a working group to address it. But the Government's success may also be a product of the fact that the larger battle over embryo research had already been fought. Despite complaints that members of Parliament were being railroaded into endorsing regulations, the limited debates that did take place reveal a degree of moral fatigue. There seemed widespread unwillingness to rejoin the battle.

B. *The Structure and Function of the HFEA*

The HFEA is a unique institution, and not only in Britain. The Warnock Report's recommendation that a separate regulatory body be created was a major departure from standard practice. No similar regulatory body has been established, although several advisory committees

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[294] Hansard, 22 January 2001, col. 45, *available at* http://www.parliament.the-stationery-office.co.uk/pa/ld200001/ldhansrd/vo010122/text/10122-06.htm (last visited Mar. 10, 2005).

[295] Plomer, *supra* note 221, at 148.

[296] *Id*. at 150-155.

[297] [2002] 2 All E.R. 625. *Regina v. Secretary of State for Health ex parte Quintavalle*, UKHL 13 (2003).

[298] It may not be entirely accurate to say that there is no administrative agency that can take on some of the role of the HFEA. As we noted at the beginning of the paper, the FDA has claimed jurisdiction over cloning. However, even if that claim is legitimate, which can be questioned, that decision was taken without any public debate, without any clear instruction from the executive, and generally ignoring the discussions taking place with NBAC or elsewhere in the NIH. Indeed, NBAC's stem cell report indicates that it assumed that FDA did *not* have jurisdiction. *See NBAC*, 1 Ethical Issues in Human Stem Cell Research, 93 (1999). *See generally*, Merrill and Rose, *supra* note 17, at 137.

have been created in the Ministry of Health to provide guidance on related issues of public health.[299]

Legally, the HFEA is a statutory corporation that operates as a non-departmental, independent government agency.[300] It functions with significant independence and is housed, at least as a formal matter, outside the Department of Health. However, the members of the HFEA are appointed by the Department and its accounting functions are audited by the Department. Moreover, in 2002-2003, at least half of its funding came from the Department of Health budget.[301]

HFEA members are appointed by the Minister for Health in accordance with guidance from the Commissioner for Public Appointments (The Nolan Guidelines).[302] The HFE Act specifies that the Chair, Deputy Chair, and at least half of the HFEA members shall not be either doctors or scientists involved in human embryo research or in providing fertility treatment. Additionally, it encourages equal representation by men and women.[303] In practice, since the members are appointed by the Minister for Health, the composition of the HFEA reflects the

[299] For example, the Human Genetics Commission operates as an advisory body for the Government on issues involving genetics; the UK National Screening Committee (NSC) advises the Government on screening programs including antenatal and childhood screening; the UK Xenotransplantation Interim Regulatory Authority (UKXIRA) provides advice to the Government on clinical and research aspects of xenotransplantation; the UK Foresight Programme is a broad public health advisory committee which attempts to address future needs by bringing together experts in science, engineering and technology with experts in markets and consumer needs; the Managing Clinical Interventions Group (MCIG) advises the Government on issues pertaining to clinical practice.

[300] HFEA § 5, *available at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_3.htm (last visited Mar. 28, 2005). Schedule 1 states that "[t]he Authority shall not be regarded as the servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown; and its property shall not be regarded as property of, or property held on behalf of, the Crown."

[301] HFEA Twelfth Annual Report, *available at* http://www.hfea.gov.uk/HFEAPublications/AnnualReport/Twelfth%20HFEA%20Annual%20Report.pdf (last visited Mar. 10, 2005). The HFEA's expenditures for the most recent report year were approximately £5.5 million and its expenses are growing. *Id.* at 46. It collects about £2.5 million from licensing fees. *Id.* at 49. The shortfall is covered by the Department of Health. With the growth of assisted reproductive technologies, the agency's staff — and budget — are likely to continue to expand.

[302] HFEA § 4(1), sched. 1.

[303] *Id.* at § 4(2), sched. 1. In determining appointments to HFEA, the Secretary shall "have regard to the desirability of ensuring that proceedings . . . are informed by views of both men and women." The current chair of the HFEA, Suzi Leather, is a political scientist and bioethicist. She succeeded Ruth Deech, a lawyer, who was well-respected and did much of the early groundwork in gaining the HFEA's acceptance. Dr. Leather's deputy is Tom Baldwin, a philosophy professor. Other current members include four physicians with specialties in obstetrics and gynecology and assisted reproduction, a dentist, the director of the National Infertility Support Network, the director of the multiple birth foundation, two law professors, a professor of genetics, an embryologist, a newspaper columnist, the chief ombudsman of the Financial Ombudsman Service, a freelance broadcaster, an Anglican Bishop, and the COO of the BBC New Media and Technology. They are assisted by a professional staff of eighty-four who are responsible for implementing the HFEA's decisions and conducting the HFEA's day to day activities.

views of the Government. That view has not fundamentally changed despite a change in power from Tories to Labour. Thus, the HFEA has frequently been criticized as overly "pro-choice."[304]

The HFE Act regulates assisted reproduction and research using human embryos. However, not all assisted reproduction is covered; instead, only that which involves the creation of embryos outside the human body or storage or donation of embryos or gametes is covered. Thus, there is no blanket prohibition on, or need for licensure for, artificial insemination when the woman is inseminated by her partner's sperm.[305] Similarly, gamete intra-fallopian transfer (GIFT) is not regulated unless it uses stored gametes, because fertilization takes place inside the woman's body.[306] Gamete research that does not involve storage is likewise unregulated.[307]

The statute prohibits all activities relating to ex vivo creation of embryos, storage of embryos and gametes and research involving embryos—except those that are permitted by HFEA license. Certain activities may not be licensed. For instance, licenses may not authorize (1) keeping or using an embryo after the appearance of the primitive streak, (2) placing an embryo in any animal, or (3) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo, or subsequent development of an embryo.[308] In addition, the HFE Act anticipates that this list of forbidden activities may be enlarged by regulation.[309]

The HFE Act provides for three types of licenses: (1) to provide treatment services,[310] (2) to store embryos and gametes,[311] and (3) to carry out research on embryos.[312] If an activity does

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[304] This was especially true during the HFEA's early days. *See, e.g.,* Linda Grant, *Yuk Factor or SPUC Factor*, The Independent (London), July 17, 1994, at 22; Gail Vines, *Pro-lifers Attack Fetal-egg Rules*, New Scientist, July 20, 1994, at 99.

[305] HFEA § 4(1)(b).

[306] If GIFT takes place in a licensed IVF center, the center must observe the rules set out in the HFEA Code of Practice in the same manner as for treatments that require a license.

[307] Ian Kennedy & Andrew Grubb, *Medical Law* 1224, 1246 (2000). Although research using fetal eggs is statutorily unclear, HFEA permits it. It would be illegal to use fetal eggs in treatment since this could involve a child being born from an egg derived from a fetus that was never born.

[308] Human Fertilisation and Embryology Act, 1990, c.37, § 3(3) (Eng.) The last listed prohibition was intended to prevent cloning. It did not actually do so in the case of Dolly, since the procedure involved placing the nuclear material into an oocyte rather than an embryo. While the HFEA maintained that that procedure was "covered" under the HFE Act, regulations were adopted clarifying the issue.

[309] *Id.* at § 3(3)(c).

[310] *Id.* at § 11, sched. 2(1). As of August 31, 2003, HFEA had licensed 110 treatment or research centers. The activities permitted by these licenses included storage of eggs, storage of sperm, storage of embryos, donor insemination, in vitro fertilization, intra-cytoplasmic sperm injection (ICSI), preimplantation genetic diagnosis (PGD), and preimplantation genetic screening for aneuploidy (PGS). By the end of 2000, approximately 50,000 babies had been born in Britain using assisted reproductive technology, a total to which 8,000 babies are added each year.

[311] *Id*. at § 11, sched. 2(2).

[312] *Id*. at. § 11, sched. 2(3). As of August 31, 2003, twenty-eight research projects were licensed by the HFEA, seven of which relate to embryonic stem cells, one to parthenogenesis. In August 2004, the HFEA announced the first license to create human embryonic stem cells using cell nuclear transfer.

not fall within one of these three categories, it may not be licensed.[313] The statute's directions for license use are phrased in general terms, thus conferring significant discretion to the HFEA. For example, the HFEA is authorized to issue research licenses so long as the activity appears necessary or desirable for the purpose of (1) promoting advances in the treatment of infertility, (2) increasing knowledge about the causes of congenital disease, (3) increasing knowledge about the causes of miscarriages, (4) developing more effective techniques of contraception, (5) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation, (6) increasing knowledge about the development of embryos, (7) increasing knowledge about serious disease, or (8) enabling any such knowledge to be applied in developing treatments for serious disease.[314]

HFEA has placed responsibility for issuing licenses in the hands of licensing committees,[315] each consisting of five members. Most licenses are for twelve months but may be shorter if a research plan warrants close monitoring.[316] A license application must identify the individual who has assumed responsibility for supervision. The licensing committee must be satisfied that this individual has the character, qualifications, and experience to hold a license. After an application is filed, a team of inspectors will visit the site of the work.[317] The team will include a clinician, a scientist, a layperson skilled in social or ethical issues, and two members of the HFEA executive staff. They will investigate the qualifications and experience of the project staff and the standards and conditions of the facilities. Where relevant, they will also explore the methods used to assess clients' medical conditions and to determine the welfare of the child, the procedures for screening donors, the information provided participants, provisions for counseling, the handling and storage of embryos and gametes, and the protection of record confidentiality.[318] Following receipt of the inspection team's report, the committee meets to determine whether to grant the license, grant it under conditions, or refuse it.

The HFEA may impose general conditions applicable to a participating unit and specific conditions applicable to specific units or individual researchers involved.[319] The Act prescribes certain conditions. For example, licenses for treatment procedures require that the licensee take

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[313] *Id.* at § 11.

[314] *Id.* at § 11, sched. 2(3)(2)-(3). The latter three are the new regulations designed to encompass stem cell research and therapeutic cloning. HFEA does require that samples of cell lines created for stem cell research be placed in the MRC Stem Cell Bank. In addition, it anticipates adding guidance to the Code of Practice that will closely regulate stem cell research. The primary goal is to ensure that the use of embryos in research is minimized. HFEA Twelfth Annual Report, *supra* note 301.

[315] Human Fertilisation and Embryology Act, 1990, c.37, § 9(1) (Eng.).

[316] Robert G. Lee & Derek Morgan, *Human Fertilisation and Embryology: Regulating the Reproductive Revolution* 115 (2001).

[317] The HFEA employs over eighty inspectors who have expertise in clinical, scientific, embryo biopsy or social and ethical fields. In response to complaints that it is slow in responding to problems, the HFEA is seeking to expand its inspection staff.

[318] Lee & Morgan, *supra* note 316, at 117.

[319] Conditions may be placed on a license where breaches of the Act or Code of Practice have been found during inspections. *Id*. at 114.

account of the welfare of "any child who may be born as a result of the treatment (including the need of that child for a father)."[320] Failure to comply with any license conditions is a violation. Violations are theoretically subject to criminal prosecution,[321] but the much more common sanction is license revocation.

The HFE Act has detailed rules governing consent.[322] Donor consent for the use of gametes and embryos must be in writing. In the case of embryo donation, the consent must specify a purpose (e.g., for treatment but not for research), and may be further conditioned. Consent for storage of gametes or embryos must specify storage duration unless it is for the statutory maximum.[323]

The HFE Act imposes substantial record-keeping obligations on licensees. A licensee must document treatment services for each individual, all gametes or embryos in storage, and each individual born as the result of treatment.[324] The Act also specifies conditions under which individual subjects who may have been born from treatment under the Act may have access to information recorded by the licensee.[325] This right does not extend to the identity of material donors,[326] and can only be invoked by persons over the age of eighteen. Accordingly, the disclosure provisions applicable to children born of assisted reproductive techniques since the Act's passage do not come into play until 2009. Disclosure necessitated by urgent reasons of justice or medical conditions can be secured by court order.[327]

The HFE Act set up a new legal framework for resolving parentage issues.[328] Some rules are automatic; others require court order.[329] Though the Act does not expressly regulate

[320] Human Fertilisation and Embryology Act, 1990, c.37, §13(5) (Eng.). This provision has been interpreted to preclude IVF treatment for lesbians. It has not, however, worked that way in practice. There has been considerable worry in the literature that the provision may work against less "well-off" lesbians. Since NHS clinics are severely strained, HFEA provisions are used to ration services, and NHS clinics deny treatment to lesbians based on § 13(5). However, due to the permissive nature of § 13(5), clinics in the private sector can still treat lesbians. Therefore, the fear is that less well-off lesbians, while lesbians seeking IVF in NHS clinics may be treated less favorably. *See* Margaret Brazier, *Regulating the Reproduction Business?*, 7 Med. L. Rev. 166, 174-78 (1999).

[321] Human Fertilisation and Embryology Act, 1990, c.37, § 41(2) (Eng.).

[322] *Id.* at § 12, sched. 3.

[323] *Id*. The statutory maximum for embryo storage is five years, and ten years for gamete storage. Extensions are permitted for certain reasons, within the discretion of the HFEA. These limits are set by regulation. *See* Human Fertilisation and Embryology Act, 1990, c.37, §§ 14(3)-(5) (Eng.).

[324] Human Fertilisation and Embryology Act, 1990, c.37, §§ 31(1)-(2) (Eng.).

[325] *Id*. at §§ 31(3)-(7).

[326] The rules on donor anonymity have just changed. Children born of donor gametes or embryos after April 2005 will be entitled to find out the identities of the donors.

[327] Human Fertilisation and Embryology Act, 1990, c.37, § 34 (Eng.).

[328] *Id.* at §§ 27-29.

[329] *Id.* at § 30.

surrogacy, it does so implicitly through the HFEA Code of Practice if licensed facilities are involved. The Act does make surrogacy contracts unenforceable.[330]

The Act provides for appeal from refusals to grant or to modify a license. The first step is to "appeal" to the license committee, which is essentially a request for rehearing.[331] Appeal may then be made to the full HFEA.[332] If that fails, the Act allows appeal to the High Court on issues of law.[333] HFEA licensing decisions frequently result in litigation but the Authority generally prevails.

A famous example is the *Blood* case, which is so well known in Britain that discussions in the literature often omit the facts. Diane and Stephen Blood had been married for five years when Stephen died suddenly from meningitis.[334] Just before life support equipment was removed, Diane asked the physicians to recover Stephen's sperm so that she could conceive his child. She claimed that the couple had been planning a child before Stephen's sudden illness. The hospital had an on-staff physician experienced in the technique of electro-ejaculation and the sperm was removed. HFEA was not consulted until after the procedure was completed.

The HFEA later refused permission to allow the sperm to be used or stored because Stephen Blood had not consented in writing. Mrs. Blood then petitioned to have the sperm exported to Belgium where the law would not prevent her use. The HFEA refused. In the ensuing litigation, the Court of Appeal ruled for the HFEA on the issue of written consent but for Mrs. Blood on the issue of exportation, concluding that the HFEA's refusal contravened EC law guaranteeing freedom of movement for goods and medical services. Mrs. Blood went to Belgium some months later and gave birth to a son.[335] Several years later, she had a second son through the same procedure. Mrs. Blood thereafter sued to allow her deceased husband to be named on the boys' birth certificates. Although the HFE Act barred that action, she ultimately prevailed in the High Court, which found the Act incompatible with the European Convention on Human Rights.[336]

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[330] "The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child." *Id.* at § 27(1). *See also id.* at § 36 ("No surrogacy arrangement is enforceable by or against any of the persons making it."). Surrogacy has been the subject of considerable moral debate in Britain. Although the Warnock Report discussed surrogacy, it was considered too hot an issue to wait for the resolution of the HFE legislation. Most surrogacy issues are governed by the 1985 Surrogacy Arrangements Act.

[331] *Id.* at § 19.

[332] *Id.* at § 20.

[333] *Id.* at § 21; Jonathan Montgomery, *Health Care Law* 406 (2d ed. 2003).

[334] The facts and legal disposition of this case are recounted in Ruth Deech, *Assisted Reproductive Techniques and the Law*, 69 Medico-Legal J. 18, 18-20 (2001).

[335] The *Blood* case did stimulate a review of the law regarding consent for gamete removal. In the circumstance where a patient is unconscious but likely to recover and treatment could cause sterility, allowing such removal would be in the patient's best interests. Ian Kennedy & Andrew Grubb, *Medical Law* 1306 (2000) (citing Sheila McLean, *Review of the Common Law Provisions Relating to the Removal of Gametes and of the Consent Provisions in the Human Fertilisation and Embryology Act of 1990* (report to Ministers, July 1998)).

[336] Sky News, *Victory for Diane Blood*, *at* http://www.sky.com/skynews/article/0,,30100-12258362,00.html (last modified Feb. 28, 2003).

The *Blood* case illustrates several important features of the HFEA regime. The case suggests that European law is likely to complicate both agency decision-making and court review. It also suggests that persons thwarted by the HFEA will be tempted to engage in "procreative tourism."[337] A recent example is the Whitaker family's decision to seek treatment in the United States after the HFEA denied them a license to use PGD to determine the HLA compatibility of their embryo with an existing child.[338]

One of the HFEA's most important contributions has been the implementation of a Code of Practice which gives detailed guidance to licensed facilities and individuals. The HFEA declares that the Code rests on the following principles:

> The respect which is due to human life at all stages in its development;
> The right of people seeking assisted reproductive treatment to proper consideration of their request for treatment;[339]
> A concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved; and
> A recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge.

The Code of Practice provides guidance for licensed entities in assessing the welfare of the child and of those seeking treatment; screening of potential donors; disclosure of information; requirements for consent; counseling of subjects; use, storage and handling of gametes and embryos; and responding to complaints. New guidance outlines preimplantation testing procedures, requirements to witness procedures, and ICSI.

An interesting feature of the HFEA Code of Practice is its discussion of the assessment of persons seeking treatment. The Code elaborates this statutory duty in considerable detail. Each treatment center is expected to have written criteria for assessing the welfare of the children who

[337] The term "procreative tourism" was coined by Bartha M. Knoppers and Sonia LeBris in their article *Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues*, 17 Am. J.L. & Med. 329, 333 (1991). The authors noted that modern means of transportation and communication allow people to travel to avoid domestic regulation that denies them a reproductive choice.

[338] Charlie Whitaker suffers from diamond blackfan anemia. The only potential cure for his disease is to receive stem cells from an HLA compatible donor. Charlie's parents sought permission to use PGD to produce an HLA compatible child. But since Charlie's disease is sporadic and not genetic, PGD would only identify HLA compatibility, it would not benefit potential embryos by screening for lethal disease. On those grounds, the HFEA refused permission for PGD. The Whitakers then sought treatment in Chicago and produced an HLA compatible child. It is not yet known whether the treatment will be successful. The Whitaker case has caused considerable consternation in the U.K. and was a primary impetus for a change in the HFEA's PGD policy. *See* BBC News, *Designer Baby is Perfect Match* (July 21, 2003), *available at* http://news.bbc.uk/1/hi/health/3083239.stm; Arlene Klotzko, *Science Matters*, Fin. Times, June 5, 2004, at C1; Iain Murray, *The Return of Scientism*, (Sept. 6, 2002), *at* http://www.techcentralstation.com/090602A.html. For additional discussion of the PGD controversy, see text accompanying *supra* notes 310-14.

[339] This principle was previously stated as the "right of people who are or may be infertile. . . ." With the newer language, HFEA recognizes that assisted reproductive techniques are also used for other reasons than infertility, like pre-implantation genetic diagnosis.

may be produced or affected by treatment.[340] Assessment should take into account the commitment to raise children; the ability to provide a stable and supportive environment; immediate and family medical histories; age, health and ability to provide for the needs of a child; the risk of harm to children including inheritable or transmissible disease; multiple births; problems during pregnancy; neglect or abuse; and the effect of a new baby on any existing child. Licensed centers are required to consult a prospective patient's physician and may make further investigations.

The HFEA has shown itself adept in responding to new scientific developments that affect assisted reproductive practice or research. The HFEA infrastructure facilitates scientific, ethical, and social investigation, and it has assembled an active policy team. While it has no formal rulemaking authority (beyond its own Code of Practice), the HFEA can initiate studies and establish working groups to advise the Secretary of State for Health on needed new regulations which are generally implemented without controversy.

An example is the HFEA's review of sex selection. In 1993, the HFEA determined that parents should be permitted to select the sex of a child conceived through IVF only for medical reasons. However, techniques have since been developed that greatly improve predictability but are largely unregulated since they do not have to involve IVF. After extensive public polling, the HFEA recommended that sex-selection techniques, particularly sperm sorting, should be regulated and that sex selection should continue to be permitted only for medical reasons. The HFEA's report to the health ministers was used to fashion options for legislation.[341] The House of Commons Science and Technology Committee is currently being lobbied by a number of constituencies, both those seeking greater freedom and those seeking continued strict limitations on use of sex-selection technologies.[342]

In December 2000, the HFEA formed a working group with the HGC[343] to develop guidelines for preimplantation genetic diagnosis (PGD). Among the most contentious issues was whether HLA typing would be permitted.[344] HLA typing is sought when parents are using IVF because they are seeking a donor of tissue, such as placental blood, to treat an existing child. The HFEA's original policy allowed HLA typing where the embryo was already being tested for serious disease but not where the embryo was being tested solely for an HLA match with a sibling.[345] After a number of well-publicized cases in which parents were denied PGD/HLA

[340] *See* HFEA Code of Practice 27 (6th ed., 2004), *available at* http://www.hfea.gov.uk/HFEAPublications/CodeofPractice/Code%20of%20Practice%20Sixth%20Edition%20-%20final.pdf.

[341] The full report is available on the HFEA website *at* http://www.hfea.gov.uk/AboutHFEA/Consultations/Final%20sex%20selection%20main%20report.pdf (last visited Mar. 10, 2005).

[342] Tom Martin, *Scots Couple Take the Battle for an IVF Baby Daughter to Commons*, Sunday Express, June 20, 2004, at 8-9.

[343] The advisory body successor to the HGAC.

[344] Simplistically described, HLA typing is done to determine a person's immunity profile — this is done to determine compatibility for certain transplants such as bone marrow. HLA testing is a genetic test.

[345] HFEA Twelfth Annual Report, *supra* note 301. The HFEA website includes a full exposition of the cases involved. *See also* the Whitaker case study discussed *supra* note 338, and the decision on the Hashmi case study, *at* http://www.hfea.gov.uk/PressOffice/Archive/43575468 (last visited Mar. 30, 2005). HFEA's decision to permit

typing to match for an embryo that could potentially save a severely ill child, the HFEA changed its policy in July 2004 to allow the procedure in all such cases.[346]

The statute and the agency have both attracted criticism from different constituencies. Treating physicians and researchers still chafe at the controls imposed by the HFE Act and intrusion into both patient privacy and the doctor-patient relationship. Dr. Robert Edwards, a leading figure in the research that led to the birth of Louise Brown, has described the governmental control of IVF as Nazism and Stalinism in the bedroom.[347] In Britain, most medical research involving human subjects is regulated by the profession and researchers continue to resent that reproductive research has been singled out. From a different perspective, critics complain that the HFEA scheme is too narrow because it covers only fertility and embryo research, while contraception, sterilization, and protection of the fetus go unregulated as do other arguably more dangerous fertility treatments.[348] Others contend that the conditions imposed by the Code of Practice curtail access for already underserved populations and thus effectively limit treatment to those who can afford to go to private clinics.[349] And, unsurprisingly, there are complaints about the delays that the licensing system creates for both treatment and research.

Right-to-life advocates have levied quite different charges. Comment on Reproductive Ethics (CORE), which was formed soon after the scheme went into effect, argues that the HFEA is unduly influenced by scientists and allows its licensees too much discretion. Although the Code of Practice theoretically requires that clinics assess the "welfare of the child," oversight of this requirement is buried among the HFEA's other responsibilities and the HFEA never questions clinics' discretion. CORE charges that the HFEA's membership does not include people who are opposed to the "reproductive revolution." Finally, CORE contends that the HFEA has assumed authority to resolve fundamental ethical issues on which there is no societal agreement.[350]

In January 2004, the Public Health Minister, Melanie Johnson, on behalf of the Blair Government, announced that the HFE Act would be fully reviewed.[351] Ms. Johnson stated that

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HLA typing has been challenged in the courts but so far unsuccessfully. That action was brought by CORE, a right-to-life group created soon after passage of the HFE Act. *See* Susan M. Wolf et al., *Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines & Limits*, 31 J. L. Med. & Ethics 327, 328-29 (2003).

[346] *HFEA Agrees to Extend Policy on Tissue Typing*, *at* http://www.hfea.gov.uk/PressOffice/Archive/1090427358 (last visited Mar. 30, 2005).

[347] Ruth Deech, *Assisted Reproductive Techniques and the Law*, 69(1) Medico-Legal J. 13, 14 (2001). Edwards was at a conference in Canada where the legislature has been in a protracted struggle to produce its own ART legislation. That legislation failed to pass once again in 2003 but did pass in 2004. Assisted Human Reproduction Act, ch. C-6 (2004) (Can.).

[348] Brazier, *supra* note 320, at 170. Professor Brazier points out that the risk of multiple pregnancy is slightly higher in the U.K. with GIFT than with IVF. In addition, misuse of fertility drugs, which do not come into the purview of HFEA and which can be prescribed by non-specialists, carries the highest risks of multiple pregnancy.

[349] *Id*. at 171.

[350] Lee & Morgan, *supra* note 316, at 8.

[351] Kirsty Horsey, *HFE Act to Be Fully Reviewed*, BioNews, Jan. 24, 2004, *at* http://www.bionews.org.uk/new.lasso?storyid=1956.

recent technological advances, changes in public perception of ethical issues, questions surrounding use of information, and activity in the European Parliament, particularly the European tissue directive, made comprehensive review necessary. She assured supporters of the HFEA regime, however, that this review would not "open the whole thing up" for reconsideration.

VI. ARE THERE LESSONS FOR THE UNITED STATES IN THE BRITISH MODEL?

A. *Why has Britain Succeeded in Regulating Reproductive Technologies?*

The U.S. Congress has not yet enacted legislation regulating reproductive technology and administrative action has not resulted in systematic oversight of the technology. Why has Britain managed to create a regulatory regime? Any answer is necessarily speculative but several factors seem important. First, the Warnock Commission adopted the pragmatic approach used by the U.S. bioethics panels that were most successful getting their recommendations implemented. Second, although the Warnock Commission did not include representatives of the anti-abortion lobby, it was successful in producing recommendations for regulation that all sides could view as better than the status quo. Third, abortion politics are less partisan in Britain than in the United States. Fourth, the commission was the creation of the government in power, which then had a political stake in its success. Fifth, Britain's parliamentary system ensures that the government can control what the legislature addresses and passes. Sixth, the Conservative Party remained in power long enough to see the legislation through and was relatively untroubled by election pressures. Finally, it is possible that the British polity may be more receptive to such regulation than that of the United States.

1. A Pragmatic Approach

In adopting a utilitarian approach, the Warnock Commission enlisted many of the techniques that proved successful for the United States' National Commission.[352] Both panels recognized that consensus on moral issues was unlikely. Instead, they focused on the design of regulation rather than on its moral underpinnings. It proved possible to achieve consensus on this level so long as agreement on the justifications for regulation was not required.

2. A Comprehensive Approach

The Warnock Report's recommendations for regulation of reproductive technologies are in many ways similar to those endorsed by the HERP a decade later. Many of the procedures that the HERP said should not be eligible for federal funding are those the Warnock Report recommended should be prohibited. This is not surprising since the U.S. panel was aware of Dame Warnock's work. Three differences, however, may be important.

[352] As discussed *supra* notes 59 & 211, this approach was used by the National Commission both in its Report on Fetal Research and in its formulation of the Belmont Report.

First, the Warnock Commission recommended the establishment of a new independent body, the HFEA, to oversee regulation. The HFEA's separate status may be more important than its independence. Lines of jurisdiction are clearer, which provide greater confidence in the clarity and enforcement of regulations that are put in place. The HERP resisted creation of a separate body, which it believed would hamstring research,[353] but the ironic result is that research may be stifled by a lack of federal funding.

Second, and possibly more important, the focus of the Warnock Commission was not just embryo research, but all uses of reproductive technology. This means that although the line between research and clinical practice is often blurred, practice nonetheless remains subject to regulation. This focus is directly related to the third difference. The Warnock Commission was not content to only control practice that would be funded by the government; it called for licensure of all reproductive technologies, regardless of funding. This comprehensive approach was not endorsed by any U.S. panel until the President's Council's reports on cloning and use of reproductive technologies. That approach could raise constitutional and cultural difficulties in the United States, but more comprehensive regulation may be necessary to satisfy those who worry about the direction science may take.

3. Direct Government Support

As Dame Warnock has made clear, there was a strong link between her Commission and the civil service apparatus that appointed it. As a result, the ensuing report was regarded by the Government as "its report," which surely strengthened the Government's support for its recommendations. U.S. bioethics panels have generally operated independently from the incumbent administration. And while there are good reasons for such independence, it has political costs. For example, the Clinton administration clearly had no political stake in the HERP report or in any of the NBAC's reports. Those reports were treated by the administration as "outsider" advice. The National Commission may initially have had more political support because it was created by legislation, but in the U.S., congressional consensus is often short-lived. The Presidential Commission was created by Congress and appointed by the executive, but it was never embraced by either branch.

4. Tepid Abortion Politics

It has been stated that abortion politics is not as intense in Britain as in the United States,[354] perhaps another reason that Britain has regulated reproductive technologies while the U.S. has not. The anti-abortion and pro-choice lobbies are very active in Britain, but abortion politics is not as partisan there as it has become in the United States. While the Warnock Report was being debated in Parliament, several Tory "back-benchers" were aligned with the anti-abortion movement, but neither Prime Minister Thatcher nor her Minister for Health, Kenneth

[353] *HERP Report*, *supra* note 132, at 72.

[354] *See* Parens & Knowles, *supra* note 3, at S16.

Clarke, were so aligned, so the Government did not need to satisfy the anti-abortion part of its constituency to retain political power.

5. Advantages of a Parliamentary Structure

Parliamentary governments give the party in power substantial control over the process of enacting legislation. In Britain, the executive controls the legislative agenda. The executive determines not only what matters will come before the Commons, but also the time provided for debate, and whether the issue will come to a vote. In the United States, even when the President's party controls Congress, the administration lacks the kind of control enjoyed by British Prime Ministers. Thus, Margaret Thatcher was able to control the legislative timing and tenor of the debate in addition to keeping a politically controversial issue alive. Although the main opposition to legislation was within her own party, the issue was not so divisive within the Conservative Party that it ever threatened her governance.

6. Government Stability

Six years passed between the Warnock Commission's report and final passage of the HFE Act, and ultimate passage was never certain. But Margaret Thatcher's majority was substantially secure, thus permitting the government to not rush the legislation. It also allowed the dialogue to progress so that the debate evolved rather than starting from scratch with each legislative session.

7. Acceptance of Regulation of Medical Practice

Britain and the United States exhibit many similarities — both have common-law systems and both distinguish between legislation and administrative regulation — but the economic and legal differences between the countries are substantial. The British government provides and pays for most medical care. The United States has a stronger free-market tradition, which extends to medical care. Control over every aspect of treatment, even in a defined arena like assisted reproduction, would not be easily surrendered to government here. Moreover, our national legislature does not exercise exclusive, possibly not even significant, authority to legislate with respect to doctor-patient and family relationships. Here, issues of surrogacy and parental status have historically been governed by state law. Some areas of research and possibly some reproductive procedures might be beyond the reach of Congress.[355]

The United States and British legal cultures also differ in their views of rule and discretion. British statutes often speak in broad terms, conveying wide powers to a designated

[355] To regulate in this area, the federal government must ordinarily show a nexus with interstate commerce. *See United States v. Lopez*, 514 U.S. 549 (1995); *United States v. Morrison*, 529 U.S. 598 (2000). It is possible that some uses of reproductive technology could not be regulated at the federal level because that nexus would be insufficient. The states, rather than the federal government, have traditional sovereignty over issues involving professional medical practice. *Linder v. United States*, 268 U.S. 5, 18 (1925); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954).

administrative bureaucracy.[356] Keith Hawkins once described American regulation as "rigid and rule oriented" while British regulation is "flexible and informal."[357] On its face, the HFEA turns this comparison on its head. Britain has imposed regulation where the United States has none, and the authorizing legislation is quite specific. In operation, however, the HFEA exercises a degree of discretion that is rarely granted in the United States. Moreover, in Britain, public policy is made in a less transparent fashion—often evolving from internal discussions within a regulatory agency.[358] Finally, American enforcement relies on legal sanctions with frequent resort to the courts, while in Britain enforcement is imposed through negotiation to correct violations rather than punishing the wrongdoer.[359]

The creators of the HFEA regime had the advantage of entering an empty landscape when they set about designing a system for regulating reproductive research. Most medical research on human subjects in Britain is not officially regulated, though medical practice is influenced by Department of Health guidance and by professional organizations. The United States operates a substantial research oversight infrastructure at the national level. Most medical research is already overseen by one or both of two federal agencies—the Food and Drug Administration (FDA) and DHHS's Office of Human Research Protection (OHRP).

Finally, the physician-patient relationship displays a different character in the two nations. Although Britain has a stronger tradition of doctor discretion, it has a weaker tradition of patient choice. Indeed, years of NHS medical care have confirmed that most Britons have little choice, at least outside private hospitals. In comparison, failed attempts at health care reform in this country indicate that Americans do not willingly cede critical personal choices.

B. *Advantages and Disadvantages of the HFEA Structure*

One strength of the HFEA is that it is a standing body that possesses the expertise and the ability to formulate policy that is coherent and predictable. The agency's formal authority is defined by statute, but it has sufficient discretion to deal with novel situations. And, because the HFEA' authority is delineated, it does not act in competition with other agencies. U.S. governmental bodies, such as the FDA and OHRP, have less latitude than the HFEA to fashion and implement regulations, and it is unlikely that any new entity would be given wider authority.

The HFEA enjoys another advantage: its licensing authority yields a steady stream of revenue that is separate from its public appropriations and thus insulates it from government belt-tightening. This authority also provides a mechanism for sanctioning inappropriate action without resorting to penal enforcement. It is questionable whether comparable authority would

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[356] Keith Hawkins, *Rule and Discretion in Comparative Perspective: The Case of Social Regulation*, 50 Ohio St. L. J. 663, 666 (1989).

[357] *Id*.

[358] *Id*. at 667. It is easy to overstate this difference—indeed one of the major criticisms of the FDA's assertion of jurisdiction over cloning, was the "back room" nature of the rule-making. However, in so doing, the FDA was acting outside traditional American notions of rule-making, and indeed possibly violating the Administrative Procedures Act. *See* Merrill & Rose, *supra* note 17, at 124.

[359] Hawkins, *supra* note 356, at 668.

be conferred on a new U.S. entity. FDA's new drug approval process[360] and the OHRP "institutional assurance process"[361] are forms of licensing schemes, but neither requires licensure of individual research procedures.

The HFEA licenses both research activities and clinical practice. This would be unprecedented in the United States.[362] Indeed, although the FDA approves drugs, biological products, and many devices, the law is clear on the point that once a product is approved, its use in treatment is left to the physician's judgment. This explains why IVF has been essentially unregulated in this country since its inception. By contrast, in Britain the VLA was created almost as soon as IVF entered a clinical practice. The American Society for Reproductive Medicine (ASRM) has adopted guidelines for assisted reproductive procedures, but these guidelines were designed to avoid, rather than to become the basis for, regulation. While this difference may be chiefly psychological, it is likely to have political ramifications. It would be extremely difficult—politically, scientifically, and ethically—for either Congress or the executive to select the clinical uses of reproductive technology to be overseen. Yet, if clinical practice were to be exempted, activities that warrant ethical scrutiny could go unregulated.

Creation of an HFEA-like entity here would add layers of administrative oversight to an already burdened research enterprise. This realization was one reason the HERP rejected a recommendation to form a new EAB to deal with types of research and specific protocols that might cause public anxiety or fall outside an IRB's expertise.[363]

VII. CONCLUSION

We have chronicled the attempts to establish a foundation for the regulation of reproductive technologies in the United States and examined the very different experience in Britain. These technologies hold promise for treatment of major illness as well as advancing scientific understanding, but they also present profound ethical dilemmas. Britain has developed a successful model for such regulation, but the two countries' political, legal, and medical cultures differ enough that importation of the British model would be difficult and perhaps unwise. Notwithstanding that conclusion, British experience merits close study by U.S. policy makers who must confront calls for expanded public oversight and control of human reproduction. In the final analysis, however, the U.S. will have to chart its own course.

[360] 21 C.F.R. § 312 (2005).

[361] 45 C.F.R. § 46.103 (2005).

[362] As noted earlier, there are some isolated examples of regulation of clinical practice. For example, the partial birth abortion statute regulates clinical rather than research practices. 18 U.S.C. § 1531 (2004). The legal challenges to that statute have not yet run their course; but one aspect of a challenge centers on the fact that physicians' clinical judgment is denied. A comprehensive regulation of a given area of clinical medical practice would be unique.

[363] It is also likely that the HERP was concerned about what happened with the original EAB, because ultimately it was disbanded, leaving a whole segment of research out of bounds since statutorily required review by the EAB could not take place. Protocols involving recombinant DNA require RAC review, as well as FDA review, and OHRP oversight when federally funded.