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Appendix B – The Synthetic Human Growth Hormone (hGH)

Medical Indications

Since their introduction in 1985, the list of FDA-approved indications for synthetic human growth hormone has been expanded from classical human growth hormone deficiency in children to include, among other things, renal failure and Turner Syndrome. Pediatric endocrinologists have used synthetic hGH for several other off-label indications such as intrauterine growth restriction (IUGR) and Prader-Willi Syndrome.¹ Chronic renal insufficiency causes kidneys to fail, leading to an accumulation in the child's blood of toxins that hamper the normal growth process. As such, chronic renal insufficiency does not affect the production of hGH, yet treatments with this hormone have proven effective. Approximately 3,000 children yearly are affected by chronic renal insufficiency.² IUGR is also a clear case of a physiological dysfunction. IUGR is associated with abnormal growth in the uterus. (Affected children are said to be small for gestational age.) Just like chronic renal insufficiency, IUGR does not impair the production of the hGH; nevertheless, administering this hormone has been shown to help. Turner Syndrome is caused by a genetic defect that affects only girls. Symptoms include shortness and a failure to fully develop ovaries. Girls are on average only 4'8" tall, versus 5'5" for the average female.³ Girls with Turner Syndrome do not have an hGH deficiency, yet when treated with hGH, they too display a faster growth rate. Prader-Willi Syndrome is another genetic defect that stunts growth. It is rare, affecting only 1 in 10,000 to 12,000 newborn babies. Children with the Prader-Willi Syndrome tend to be obese and of short stature, and have small hands, small feet, a small mouth, and small genitals. In these children, hGH treatment can add several inches to their stature, reduce their body fat, and even improve their physical activity.

The FDA decision to approve the use of synthetic hGH for idiopathic shortness represents a significant departure from earlier practice in that this condition may be described as a cosmetic use of hGH. Idiopathic short stature (ISS) has no clear or obvious physiological cause. The pharmaceutical industry has been trying to identify the causes of idiopathic shortness for many years, without success. Many ISS children have levels of hGH well above what is considered normal. On the other end, some children of normal stature have been shown to have growth hormone levels at or below the norm. This shows that the relationship between levels of hGH

¹ Hormone Foundation, "Get the Facts: Growth Hormone Issues in Children and Adults," (Chevy Chase, MD: The Hormone Foundation, 2003); Mary Lee Vance and Nelly Mauras, "Growth Hormone Therapy in Adults and Children," *New England Journal of Medicine* 341, no. 16 (1999).

² Dieter Haffner et al., "Effect of Growth Hormone Treatment on the Adult Height of Children with Chronic Renal Failure," *New England Journal of Medicine* 343, no. 13 (2004).

³ Paul Saenger, "Turner's Syndrome," *New England Journal of Medicine* 335, no. 23 (1996).

secretion and height is far more complex than normally assumed. To complicate matters further, there is no agreed-upon definition of short stature. In some studies, children in the third percentile for their age and sex are considered short; in others, the threshold is the fifth or tenth percentile; in still others, all children below two standard deviations from the mean are characterize as short.

That one should be careful in diagnosing idiopathic shortness was demonstrated by a recently conducted study in which approximately one-third of both idiopathic short boys and girls eventually reached a normal stature.⁴ This result indicates that growth velocity may vary considerably over time: In other words, a significant fraction of ISS children are simply growing at a speed slower than average for their age at the time of the measure, but their developmental velocity could accelerate significantly at a later point in time. These so-called ISS children not only are healthy, they are also not short. In sum, it is quite possible that ISS children are perfectly healthy, and often their shortness is only temporary.

Safety and Efficacy

Two key aspects of the debate over the use of synthetic hGH are safety and efficacy. The hormone may be effective, could critics argue, but should it be used to treat healthy children if there are any doubts about its safety? Alternatively, one may argue that it is not sufficient for this treatment to be safe. In order to justify the exorbitant costs of an hGH treatment, a treatment that usually lasts several years, the pharmaceutical company must be able to show clear and unambiguous evidence of effectiveness.

With regard to safety, there is very little evidence of risks or adverse effects associated with hGH treatments; very few adverse effects have been documented. Recently, the Growth Hormone Research Society reviewed approximately 200 peer-reviewed articles on this subject and concluded that the use of HGH for approved indications is safe.⁵ The safety of synthetic hGH is not a concern for the FDA, which – at its June 10, 2003, meeting convened to review the pharmaceutical manufacturer’s application for the non-medical uses of synthetic hGH – concluded with few reservations that hGH in general and Humatrope in particular are safe.⁶

Assessing the efficacy of synthetic hGH to treat ISS children is considerably more difficult. hGH treatments for children with a discernible physiological condition generally are considered very effective and can add several inches to these individuals’ adult height, though these treatments usually do not entirely compensate for their shortness. Nevertheless, there is agreement in the medical community that hGH treatments are quite effective, if not in

⁴ Luigi Greco, Chris Power, and Catherine Peckham, "Adult Outcome of Normal Children Who Are Short or Underweight at Age 7 Years," *British Medical Journal* 310 (1995).

⁵ Michael O. Thorner, "Critical Evaluation of the Safety of Recombinant Human Growth Hormone Administration: Statement from the Growth Hormone Research Society," *The Journal of Clinical Endocrinology & Metabolism* 86, no. 5 (2001).

⁶ Briefings materials are available at <http://www.fda.gov/ohrms/dockets/ac/03/briefing/3957b1.htm>.

completely treating then at least in significantly mitigating the negative consequences of severe hGH deficiency. We were surprised to discover that the same treatment is far less effective in treating ISS children. In this case, the evidence is mixed. Opponents of the use of hGH for non-medical reasons have claimed that the efficacy of this treatment has not been demonstrated. Several recent studies seem to support this view.⁷ Not surprisingly, supporters of legalizing hGH⁸ for treating ISS children point to other studies that seem to demonstrate precisely the opposite. The literature on this issue is simply too large and too technical for us to offer an independent assessment, but it should be mentioned that researchers funded by the leading manufacturers of synthetic hGH tend to produce supportive studies, while the FDA, in reviewing the extant literature, including the studies conducted by pharmaceutical companies, is much less sanguine about the effectiveness of the treatment.

There are several reasons for these conflicting results. First, and perhaps most importantly, the non-therapeutic use of hGH remains controversial among medical practitioners. Medical doctors and scientists may read the available empirical evidence differently depending on their personal inclinations. Second, it is much easier to evaluate the efficacy of hGH treatments for traditional, medical indications, as these indications have been treated for a much longer period of time and the available empirical evidence is sizeable. Third, it is also important to recognize that a thorough evaluation of the efficacy of hGH treatments on final height requires conducting lengthy and costly longitudinal studies. Many studies on the efficacy of hGH for ISS children started in the mid-1990s and have not yet been concluded.

In sum, while the safety and efficacy of hGH treatments for traditional medical indications is not in dispute, the efficacy of these treatments for ISS children is debatable at best and inadequate at worst.

Social-Psychological Pathologies

In this section, we examine the possible negative psychological and social effects of shortness. We start by offering an obvious but important observation: The ethical questions raised by individuals of normal stature trying to gain a few inches are quite different from the concerns associated with parents trying to help their short children grow taller. Much of the debate surrounding the use of synthetic growth hormone is centered on treating short stature, but the abuse of synthetic hGH in individuals of normal stature is just as relevant to our discussion.

⁷ C.G.D. Brooks, "Growth Hormone: Panacea or Punishment for Short Stature?," *British Medical Journal* 315 (1997); Sharon E. Oberfield, "Growth Hormone Use in Normal, Short Children – a Plea for Reason," *New England Journal of Medicine* 340, no. 7 (1999).

⁸ John G. Buchlis et al., "Comparison of Final Heights of Growth Hormone-Treated Vs. Untreated Children with Idiopathic Growth Failure," *Journal of Clinical Endocrinology and Metabolism* 83, no. 4 (1998); Beth S. Finkelstein et al., "Effect of Growth Hormone Therapy on Height in Children with Idiopathic Short Stature," *Archives of Pediatric & Adolescent Medicine* 156 (2002); Raymond L. Hintz et al., "Effect of Growth Hormone Treatment on Adult Height of Children with Idiopathic Short Stature," *New England Journal of Medicine* 340, no. 7 (1999).

Accordingly, one should distinguish between the (mostly positive) effects of above-average stature on individuals (mostly men), and the (largely) negative effects of shortness on children and adults well below normal height.

Tallness – a Requisite for Success?

Popular wisdom holds that taller-than-average individuals – especially men – are more successful than the average population. Surprisingly perhaps, in this case popular wisdom seems indeed to be correct. A recent study of the relationship between stature and socioeconomic status in the former West Germany – defined as a composite of educational level, occupational types and of occupation and income – has shown that men of average social status are 1.7 cm (0.67 inches) taller, and men enjoying a higher status are 3.9 cm (1.54 inches) taller than men of a lower social status. A similar pattern emerges for citizens of the former East Germany and for women.⁹ Two factors that could explain these results – limited access to health care and poor nutritional habits – are most likely not responsible for the study results, as Germany has an excellent health care system and high standards of living.

Height is not only associated with status and income. It also affects the reproductive chances of males. According to a recently conducted survey, taller men are much more likely to have children, even after controlling for residence (compared to the urban population, the rural population is shorter), health (hGH deficiency and other conditions can have a dramatic impact on final height), and education – all factors that have been shown to affect stature.¹⁰ The size of the sample – 3,000 individuals – does not leave any doubts about the robustness of this conclusion. Height has also been shown to account for the differences between males and females in status and income.¹¹ According to another study, career chances seem to be considerably higher for taller-than-average individuals.¹² The study analyzed homogenous groups of professionals (nurses, individuals in clerical positions, and craftsmen) and found that height correlates with seniority – even after controlling for education level and socioeconomic background.

It doesn't stop here. It is a well-documented empirical fact that there is a significant – albeit weak – correlation between height and IQ. One may have serious doubts about the adequacy of IQ tests as indicators of cognitive performance, but it would be hard to ignore available empirical evidence. In one study, the authors assembled a very large, representative sample of the entire U.S. population.¹³ These children were examined twice, between 1963 and 1965, and again

⁹ J. Komlos and P. Kriwy, "Social Status and Adult Height in the Two Germanies," *Annals of Human Biology* 29, no. 6 (2002).

¹⁰ B. Pawlowski, R.I.M. Dunbar, and A. Lipowicz, "Tall Men Have More Reproductive Success," *Nature* 403 (2000).

¹¹ Paul V. Crosbie, "The Effects of Sex and Size on Status Ranking," *Social Psychology Quarterly* 42, no. 4 (1979).

¹² A. Schumacher, "On the Significance of Stature in Human Society," *Journal of Human Evolution* 11 (1982).

¹³ Darrell M. Wilson et al., "Growth and Intellectual Development," *Pediatrics* 78, no. 4 (1986).

between 1966 and 1970. The longitudinal sample consisted of more than 2,000 children ages 8 to 11. Each sample included approximately 14,000 children. The study found a small but significant correlation between height and IQ in both cases. The correlation persisted even after controlling for socioeconomic status (i.e., family income), and race (black versus white).

These findings have been repeatedly replicated, suggesting that the relationship between stature and IQ, while not strong, is indeed real. For example, a recently completed study of physical, psychological, and cognitive aptitudes of a nearly complete cohort of more than 38,000 18-year-old Swedish young men showed that taller men perform significantly better than average on a variety of cognitive tests and are psychologically more stable.¹⁴ A Danish study of 76,000 young men confirmed these results.¹⁵ However one decides to account for this evidence, it is hard to ignore the fact that on the whole, taller and good-looking men (for women tallness is often a handicap) seem to be considerably more successful than their average peers.

Shortness as a Psychological and Social Impairment?

The question of whether short individuals are at a disadvantage compared to individuals of normal height is analytically distinct from the question we have discussed in the preceding section, i.e., whether individuals taller than average enjoy (undeserved) benefits. One can easily imagine passing a ban on the use of synthetic hGH for individuals of normal height on the ground that the ubiquitous use of hGH in this case could trigger a costly arms race with no discernible benefits for the participants. The rationale for administering synthetic hGH to extremely short children is rather different. In this case, it is presumed – and parents have argued to the FDA – that children of idiopathic short stature suffer from low self-esteem and are at a significant disadvantage compared to their peers. Determining whether these claims are justified is therefore of some import to this discussion.

The prevailing wisdom until the late 1980s was that short children are indeed at a disadvantage. According to some studies, they frequently experience teasing and bullying, they have poor social skills, they are isolated, they are plagued by low self-esteem, and their academic performance is poor.¹⁶ Similar conclusions were reached for adult short individuals. Among the most frequently cited concerns are education,¹⁷ employment, romantic relationships, and friendships.¹⁸ In more recent times, however, the prevailing view has begun to shift. New,

¹⁴ Torsten Tuvemo, Björn Jonsson, and Ingemar Persson, "Intellectual and Physical Performance and Morbidity in Relation to Height in a Cohort of 18-Year-Old Swedish Conscripts," *Hormone Research* 52 (1999).

¹⁵ T.W. Teasdale, David R. Owen, and T.I.A. Sørensen, "Intelligence and Educational Level in Adult Males at the Extremes of Stature," *Human Biology* 63, no. 1 (1991).

¹⁶ David E. Sandberg, Amy E. Brook, and Susana P. Campos, "Short Stature: A Psychosocial Burden Requiring Growth Hormone Therapy?," *Pediatrics* 94, no. 6 (1994), p.832.

¹⁷ Teasdale, Owen, and Sørensen, "Intelligence and Educational Level in Adult Males at the Extremes of Stature.": Melissa Wake, David Coghlan, and Kyle Hesketh, "Does Height Influence Progression through Primary School Grades?," *Archives of Disease in Childhood* 82 (2000).

¹⁸ F. Ulph et al., "Personality Functioning: The Influence of Stature," *Archives of Disease in Childhood* 89 (2004), p.17.

methodologically more rigorous studies and larger samples suggest that short children do indeed experience stress as a result of teasing and bullying, but that these experiences have very little impact on their psychological well-being and on their ability to cope with these problems. Studies conducted in the UK¹⁹ and in the United States²⁰ found that boys of idiopathic short stature differed only moderately from peers in the control groups on a variety of psychological tests such as self-esteem, self-perception, and behavior. Girls of idiopathic short stature, for their part, were nearly indistinguishable from their normal counterparts.

These results have been corroborated by other studies. A Dutch group analyzed the impact of short stature on the quality of life of five different groups of short individuals: individuals affected by classic hGH deficiency, individuals suffering from renal failure, women with Turner Syndrome, individuals of idiopathic short stature, and individuals presumed to be idiopathically short. (The latter group is a reference group of short individuals who had not been referred to an endocrinologist.)²¹ According to the study, all participants experienced difficulty in finding a partner. In other respects, however, the picture is far more nuanced. Only women with Turner Syndrome reported problems with job applications, and normal short individuals did not report any reduction in their quality of life.

Surprisingly, individuals of idiopathic short stature who were referred to an endocrinologist did report reductions in their quality of life. They also reported a range of psychological and social problems.²² This result has been confirmed by other studies²³ and has been attributed to the failure of the hGH treatment to produce the expected results. It is not entirely clear whether the failure should be interpreted in physiological terms, i.e., as an ineffective treatment, or whether it should be attributed to the realization by the subjects in question that increased stature alone was unlikely to have a significant impact on their quality of life. Either way, this finding suggests that the medical treatment of what is ultimately a psychological and a social problem could exacerbate rather than mitigate the problem.

In sum, the available empirical evidence suggests that there is no basis for the claim that children of idiopathic short stature are psychologically impaired, that their chances of success in life are limited, or that their quality of life is poor. Short children do report experiencing bullying and teasing, but this does not seem to have a significant impact on their well-being.

¹⁹ Bruce A. Dowdney et al., "Are Short Normal Children at a Disadvantage? The Wessex Growth Study," *British Medical Journal* 514 (1997); A.B. Downie et al., "Psychological Response to Growth Hormone Treatment in Short Normal Children," *Archives of Disease in Childhood* 75 (1996); Ulph et al., "Personality Functioning: The Influence of Stature."

²⁰ Sandberg, Brook, and Campos, "Short Stature: A Psychosocial Burden Requiring Growth Hormone Therapy?."

²¹ J.J.V. Busschbach et al., "Quality of Life in Short Adults," *Hormone Research* 49 (1998).

²² H.-C. Steinhausen et al., "The Behavior Profile of Children and Adolescents with Short Stature," *Journal of Behavioral Pediatrics* 21 (2000); L.E. Underwood, "The Social Costs of Being Short: Societal Perceptions and Biases," *Acta Paediatrica Scandinavica*, no. 377 (1991).

²³ Sandberg, Brook, and Campos, "Short Stature: A Psychosocial Burden Requiring Growth Hormone Therapy?."

Patterns of Use

Could the medical profession contribute to discourage parental demands for treatments with synthetic hGH, or is it more likely that it will actually support and amplify questionable parental desires? Should the government trust the medical profession not to indulge demands for what may be cures of dubious effectiveness? To explore this question, in this section we examine prescription patterns for synthetic hGH among medical specialists.

A fairly recent, comprehensive survey of prescription practices among pediatric endocrinologists and their views on numerous questions pertaining to the prescription of synthetic hGH provides several important insights.²⁴ The survey was sent to the members of the Lawson Wilkins Pediatric Endocrine Society, the largest professional organization of pediatric endocrinologists. The response rate was very high: 81 percent, or 434 out of 534 physicians, returned the survey. A first important conclusion emerging from this survey is that pediatric endocrinologists do not treat ISS children very often. According to this survey, 58 percent of the patients were treated for classical hGH deficiency, 15 percent for Turner Syndrome, 11 percent for neurosecretory disorders, and 2 percent for renal insufficiency. Of the remaining 14 percent, 5 percent were treated for other, non-endocrine medical conditions and 9 percent for familial, constitutional, or unknown causes of short stature. In other words, only approximately one out of 10 treated patients were ISS children.

Based on this initial observation, one might conclude that pediatric endocrinologists are generally cautious in prescribing hGH for the treatment of idiopathic short stature. This conclusion would be premature. Asked whether short children in the third to fifth percentile for their age are likely to be psychologically impaired, 83 percent of pediatric endocrinologists answered that this is either “sometimes” or “often” the case. This percentage rises to 91.5 percent for children in the third percentile. An analogous pattern emerges for adults in the same height intervals. The survey also shows that pediatric endocrinologists are more likely to recommend a treatment the shorter the child is, the slower his or her growth rate is, and the more advanced bone age is.²⁵ These patterns of prescription again are inconsistent with the medical literature: Shortness is a poor indicator of responsiveness to treatment, and so are slow growth and bone age.²⁶ This data suggests that the decision to recommend treatment is based on two equally unwarranted perceptions – that shortness causes psychological impairment, and that shorter children are more likely to respond well to a human GH treatment.

These observations indicate that if an increasing number of ISS children were to be referred to pediatric endocrinologists, the total number of prescriptions for hGH treatment would increase significantly. We do not have recent data on this question, but the aforementioned study offers

²⁴ Leona Cuttler et al., "Short Stature and Growth Hormone Therapy: A National Study of Physician Recommendation Patterns," *Journal of the American Medical Association* 276, no. 7 (1996).

²⁵ Bone age is a measure of skeletal maturation, and its used to evaluate a child's remaining potential for growth.

²⁶ Cuttler et al., "Short Stature and Growth Hormone Therapy: A National Study of Physician Recommendation Patterns," p.535.

some clues. The survey reports that 68 percent of respondents believed that the rate of prescription for ISS children had increased either “somewhat” or “significantly” in recent years.²⁷ Anecdotal evidence indicates that parents are indeed likely to refer their short but otherwise healthy children to an endocrinologist,²⁸ so much so that insurance companies have found it necessary to clamp down on prescriptions for hGH.²⁹

Perhaps the strongest evidence that making idiopathic short stature a medical condition would lead to an unprecedented increase in the non-therapeutic use of hGH comes from Australia. In 1988, the Australian government decided to eliminate mandatory testing for hGH deficiency as a condition for the prescription of hGH. The number of children receiving hGH treatment increased by a factor of four, and the annual cost for these prescriptions went from \$1 million to \$45 million in three years. Alarmed by this trend, the Australian government decided to reverse its decision, and in 1995, the total cost was reduced to \$16 million.³⁰ The situation in the United States differs from the Australian case in that the FDA has merely included idiopathic shortness in the list of approved medical uses. A prescription by a pediatric endocrinologist is still required. Nevertheless, the Australian experience clearly suggests that regulatory agencies should be very cautious in indulging societal tendencies that may be both ethically questionable and very costly.

The admittedly limited data demonstrates that pediatric endocrinologists are likely to share with parents and children inaccurate and misleading views of the relationship between shortness and psychological impairment. These views may translate into supportive attitudes toward parents demanding costly cures for non-existent conditions. More importantly, they also facilitate the creation of a powerful coalition of medical professionals, pharmaceutical companies, and patient groups dedicated to advancing what ultimately are the narrow interests of a few societal groups.

The Market for Human Growth Hormone

Reliable figures about the size and growth of the market for synthetic hGH are very difficult to come by. Repeated inquiries with the leading pharmaceutical manufacturers such as Pfizer, Genentech, and Ely Lilly produced very limited results. The lack of reliable data notwithstanding, there is no doubt that this market is both lucrative and rapidly expanding. In 1996, a group of medical practitioners estimated the cost of an hGH treatment at \$13,000 to

²⁷ Remember that the survey was conducted in 1996, so this trend might well have accelerated since then.

²⁸ Rick Weiss, "Growth Hormone's Downside; Use on Healthy Children Raises Ethical Concerns," *The Washington Post*, May 10, 1995.

²⁹ Rick Weiss, "Are Short Kids 'Sick'? Doctors and Drug Makers May Be Overpromoting a Profitable Hormone That Makes Children Taller," *The Washington Post*, March 15, 1994.

³⁰ G.A. Werther, "Growth Hormone Measurements Versus Auxology in Treatment Decisions. The Australian Experience," *Journal of Pediatrics* 128, no. 5 (1996).

\$16,000 per year, for several years.³¹ More recent figures range between \$20,000 and \$30,000 per year. The aforementioned study estimates the number of children in the United States affected by severe hGH deficiency at approximately 14,000. Based on this number, in the mid-1990s, market size was between \$182 and \$224 million – a sizeable but not a huge market.

Every new therapeutic use of synthetic hGH approved by the FDA has of course expanded the size of this market. With the recent decision by the FDA to add idiopathic short stature to the list of approved indications, the potential size of the synthetic hGH market has grown dramatically. Estimates of the number of ISS children range from 400,000 to 1.7 million.³² The lower estimate, by Eli Lilly, can be attributed to a more conservative definition of short stature, in this case below 2.5 standard deviations. Leona Cuttler, by contrast, defined ISS children as those in the third percentile for their sex and age. In the latter case, the market for hGH would expand to a very attractive \$22 billion. Another way to appreciate the economic significance of the FDA decision to declare idiopathic short stature a medical condition is to note that children with classical hGH deficiency constitute only between 0.82 and 3.5 percent of the population of ISS children, depending on how idiopathic short stature is defined.

The actual market size for synthetic hGH is even larger if one includes off-label prescriptions and illegal uses of hGH. Anecdotal evidence suggests that aging baby-boomers are beginning to rely on hGH treatments to combat age-related symptoms.³³ It appears that in modest amounts, hGH can indeed be beneficial, and the side effects are minimal. A new, more recent trend has been observed among women seeking “eternal youth.”³⁴ It is also well-known that some athletes have used hGH to boost their performance.³⁵ Finally, there is some evidence that adolescents are abusing hGH.³⁶ In sum, the synthetic hGH is on its way to becoming a major source of revenue for several large pharmaceutical companies – a point that federal regulators and most bioethicists have failed to adequately acknowledge.

³¹ Cuttler et al., "Short Stature and Growth Hormone Therapy: A National Study of Physician Recommendation Patterns."

³² Ibid.

³³ Sabin Russell, "Aging Baby Boomers Turn to Hormone: Some Doctors Concerned About Growing 'Off-Label' Use of Drug," *The San Francisco Chronicle*, November 17, 2003.

³⁴ Katrina Beikoff, "New Body-Drugs Shock Seeking Beauty in Bottle," *Hobart Mercury*, February 12, 2000.

³⁵ Sabin Russell, "Growth Hormone an Expensive Garnish: Drug Used to Treat Dwarfism in Young Appeals to Athletes," *The San Francisco Chronicle*, October 22, 2003.

³⁶ Jeannette M. Smith, "Human Growth Hormone: A New Substance of Abuse among Adolescents?," *Journal of the American Medical Association* 269, no. 11 (1993).

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Appendix C – IVF Health and Safety Risks: Some Illustrations

Major Birth Defects

In early 2002, a study published in the *New England Journal of Medicine* found that children conceived through IVF (in vitro fertilization) and ICSI (intracytoplasmic sperm injection) were twice as likely (9 versus 4.5 percent) to be born with at least one major congenital defect than children conceived naturally.¹

The study sets itself apart from other, similar studies in several respects. Unlike earlier studies, it used a single definition of birth defect and applied it consistently to both ART children and to the children in the general population.² It used a fairly restrictive definition of major birth defect. It documented congenital defects not only at birth but also at one year of age, by which most birth defects become apparent. The authors took steps to minimize a differential diagnosis based on the mode of conception. Finally, they compiled a reasonably large sample that enabled them to control for several confounding factors.

The study's main result – a doubling of major birth defects among children conceived through IVF and ICSI – seems quite robust. It is not affected by whether one analyzes the original samples or focuses exclusively on singletons or on-term singletons. Furthermore, the result is not affected if one controls for maternal age and parity, the sex of the infant, and correlation between siblings.³

As the correspondence in the *New England Journal of Medicine* between the study authors and their critics shows, these findings came as a major surprise to ART practitioners. The study was criticized on several grounds. In our view, nothing offered by the critics seriously undermines the study's credibility. On the other end, the rather vicious tone taken by these critics could lead one to conclude that the critics have a vested interest in undermining any suggestion that either IVF or ICSI are anything short of perfectly safe methods of assisted reproduction.⁴

The present study certainly does not exhaust the debate about the safety of ART treatments. As a recently published meta-analysis of the incidence of major congenital defects in ART

¹ Hansen et al., "The Risk of Major Birth Defects after Intracytoplasmic Sperm Injection and in Vitro Fertilization."

² Jennifer J. Kurinczuk and Carol Bower, "Birth Defects in Infants Conceived by Intracytoplasmic Sperm Injection: An Alternative Interpretation," *British Medical Journal* 315, no. 1260-1265 (1997).

³ Hansen et al., "The Risk of Major Birth Defects after Intracytoplasmic Sperm Injection and in Vitro Fertilization," p.728.

⁴ Maryse Bonduelle et al., "Developmental Outcome at 2 Years of Age for Children Born after ICSI Compared with Children Born after IVF," *Human Reproduction* 18, no. 2 (2003); Jennifer R. Bowen et al., "Medical and Developmental Outcome at 1 Year for Children Conceived by Intracytoplasmic Sperm Injection," *Lancet* 351 (1998); Jennifer J. Kurinczuk, "Safety Issues in Assisted Reproduction Technology," *Human Reproduction* 18,

children shows, many other epidemiological studies on this matter exist and should be included in the present discussion.⁵ The sheer number of these studies and their differing methodologies would make it very difficult for anyone to draw firm conclusions from this mass of evidence. It would also require a major commitment of time and resources well beyond our budgetary constraints.

Low Birth Weight

An obvious and quite familiar risk associated with an IVF treatment is a multiple pregnancy. Dramatic imagery notwithstanding, reproductive specialists consider twins and higher-order pregnancies an “adverse outcome,” and for good reasons. Multiple pregnancies suffer from a higher number of perinatal deaths, i.e., death during pregnancy or shortly thereafter, and are at a much higher risk of obstetric complications.⁶ In addition, twins are at an increased risk of short- and long-term disabilities. They may also suffer from low birth weight. Finally, multiple pregnancies often force prospective parents to perform what is politely referred to as “selective reduction” – i.e., the abortion of one of more fetuses. Selective reduction increases the chances that at least one baby will be born alive and reduces the health risks to the prospective mother.

Multiple gestations have been shown to be associated with low birth weight, but until recently it was unclear whether assisted reproduction is also associated with lower birth weight in singletons. A research group at the Centers for Disease Control (CDC) in Atlanta, Georgia, compared the incidence of low birth weight (2,500 grams, i.e., 5.5 pounds or less) among 42,000 ART children born between 1996 and 1997 and in more than 3 million children born spontaneously in 1997 in the United States. Among children born after a normal pregnancy (37 weeks or later), the risk of low birth weight in singleton ART children was 2.6 times higher than in the control group.⁷ Interestingly, the study did not find significant differences between ART twins and twins conceived naturally.

There are straightforward reasons for a much higher rate of twins and multiple pregnancies among ART patients. To increase the likelihood of a pregnancy, reproductive specialists routinely transfer several embryos to a woman’s uterus. This has especially been the case in the United States, where the decision as to how many embryos should be transferred is made by the reproductive specialist and the patient, and is partly dictated by cost considerations and by

no. 5 (2003); Alastair G. Sutcliffe, "Health Risks in Babies Born after Assisted Reproduction," *British Medical Journal* 325 (2002).

⁵ Jennifer J. Kurinczuk, Michèle Hansen, and Carol Bower, "The Risk of Birth Defects in Children Born after Assisted Reproductive Technologies," *Current Opinion in Obstetrics and Gynecology* 16 (2004).

⁶ Pierpaolo Mastroiacovo et al., "Congenital Malformations in Twins: An International Study," *American Journal of Medical Genetics* 83 (1999); François Olivennes, "Avoiding Multiple Pregnancies in ART," *Human Reproduction* 15, no. 8 (2000).

⁷ Laura A. Schieve et al., "Low and Very Low Birth Weight in Infants Conceived with Use of Assisted Reproductive Technology," *New England Journal of Medicine* 346, no. 10 (2002).

parental desires. By contrast, the British Human Fertilisation and Embryology Authority limits the maximum number of embryos that can be transferred to three.⁸

Neurological disorders

In 2002, a group of Swedish scientists published one of the most comprehensive studies on neurological disorders in IVF children.⁹ The authors conducted a retrospective analysis of 5,680 IVF children born between 1982 and 1995. The age of the children in the sample ranged from 18 months to 14 years. Every IVF child was matched with two children in the control group. To compensate for the high incidence of twins in the population of IVF children, the researchers matched each twin with two additional controls, also twins. Thus, the control group consisted of 15,397 children.

The Swedish group identified 138 distinct disorders and grouped them in 20 categories. These included mental retardation, infantile autism, behavioral disorders, speech disorders, suspected developmental delay, cerebral palsy, congenital malformations, chromosomal aberrations, neuromuscular disorders, torticollis, brachial plexus injury, disorder of the joints, disorders of the eye, hearing loss, hydrocephalus, habitual tip-toeing, accidents, seizures, other neurological disorders, and other disorders.

Among the most common diagnoses were cerebral palsy, suspected developmental delay, congenital malformation, mental retardation, chromosomal aberration, and behavioral disorders.¹⁰ IVF children face a risk of cerebral palsy that is almost four times higher and a risk of congenital malformations that is almost twice as high than children conceived naturally. These rather disturbing results can partly be explained by the large incidence of twins and higher-order pregnancies and associated problems, in particular low gestational age and low birth weight. For IVF singletons, the risk of cerebral palsy is nearly three times higher and the risk of congenital malformations remains twice that of the control population.

Ectopic Pregnancies

It has long been standard practice in the ART industry to cryopreserve embryos produced during IVF. Different reasons have been offered for cryopreserving an embryo. Some parents wish to preserve excess embryos for later use; others find it ethically unacceptable to authorize the destruction of their embryos; still others are simply unclear about what to do with their excess embryos. According to a survey conducted in 2003 by the American Society for

⁸ K. Duckitt, "Infertility and Subfertility," *Clinical Evidence* 9 (2003).

⁹ David L. Healy and Kerry Saunders, "Follow-up of Children Born after in-Vitro Fertilisation," *The Lancet* 359, no. 9305 (2002); B. Strömberg et al., "Neurological Sequelae in Children Born after in-Vitro Fertilisation: A Population-Based Study," *The Lancet* 359 (2002).

¹⁰ Strömberg et al., "Neurological Sequelae in Children Born after in-Vitro Fertilisation: A Population-Based Study," p.463.

Reproductive Medicine (ASRM), approximately 400,000 embryos are currently cryopreserved at U.S. fertility clinics.¹¹

As for most other standard treatments in the ART industry, cryopreservation has long been deemed safe, yet an actual assessment of its safety has never been conducted. It was therefore with considerable surprise that in 2003 ART practitioners learned that frozen embryos seemed to be associated with a higher risk of ectopic pregnancies. An ectopic pregnancy is a pregnancy that takes place outside the womb, typically in the fallopian tube, ovary, abdomen, or cervix rather than in the lining of the uterus. The condition is potentially life-threatening both for the prospective mother and the child, and often leads to an abortion. Ectopic pregnancies affect approximately 1 percent of pregnant women.

Researchers at Brown University analyzed 490 pregnancies achieved with fresh embryos and found that only nine (1.8 percent) were ectopic. By contrast, six out of 19 pregnancies achieved with frozen embryos resulted in ectopic pregnancies.¹² According to the leading author, this is the first time that an association between frozen embryos and safety has been shown. Given the small size of the sample, researchers have been cautious in drawing firm conclusions, yet these results are suggestive enough to be taken seriously.

Craniosynostosis

Craniosynostosis is a rare birth defect that causes the premature closure of the cranium in small children. Between three and five babies in 10,000 are affected by this condition, recognizable by the abnormal shape of the cranium. The condition is not fatal but may require surgery to reduce pressure within the cranium. While the precise causes of premature cranial closure are unknown, craniosynostosis has been associated with several risk factors, including advanced maternal age and maternal smoking.

In a recently published study, a group of researchers with the CDC studied the association between three ART treatments (ovarian stimulation, IVF, and artificial insemination) and the incidence of craniosynostosis. Data was collected from four regions – San Francisco and Santa Clara counties in California, metropolitan Atlanta in Georgia, and the entire state of Iowa. The study authors were able to identify 99 cases of craniosynostosis, a significant number given the very low incidence of this birth defect. The authors matched these cases with 777 control mothers.

The study showed that babies conceived through ovarian stimulation, IVF, and artificial insemination face a risk three to four times higher of developing craniosynostosis than children

¹¹ Hoffman et al., "Cryopreserved Embryos in the United States and Their Availability for Research."

¹² Shaoni Bhattacharya, *Frozen IVF Embryos Linked to Ectopic Pregnancy* (New Scientist, October 15, 2003 [cited April 26, 2006]); available from <http://www.newscientist.com/news/news.jsp?id=ns99994277>; "Frozen Embryos: Higher Ectopic Pregnancies," *The Washington Times*, October 15, 2003.

conceived naturally.¹³ In the discussion of their results, the study authors were careful to examine several alternative factors that may explain a four-fold increase in the incidence of this birth defect. It is possible that an unrecognized medical indication, rather than the reproductive technology itself, is associated with this birth defect, though the study authors observed a similar increase in all three types of fertility treatments. Other factors such as smoking could also be associated with both infertility and craniosynostosis. In this study, however, smoking was not associated with this condition.

Beckwith-Wiedemann Syndrome

Recent studies suggest that ART technologies might affect the epigenetics of early embryogenesis and might cause birth defects. Beckwith-Wiedemann Syndrome (BWS) is a congenital defect characterized by excessive body growth. Primary symptoms include macrosomia (the excessive growth of the body), macroglossia (enlarged tongue), predisposition to embryonal cancer, and abdominal wall defects. Beckwith-Wiedemann Syndrome apparently is caused by an imprinting disorder on gene 15. In the general population, BWS accounts for approximately 1.3 cases per 100,000 liveborn babies; in other words, it is an extremely rare congenital defect.

The association between this disorder and assisted reproduction has been documented only very recently. There have been three unrelated studies showing an association between ARTs and BWS. Michael DeBaun and associates have been tracking cases of BWS in the United States since 1994. More recently, they have begun to include in their registry information about the method of conception (natural versus IVF) and the type of IVF procedure. The data shows that children conceived through IVF are six times more likely (4.6 percent versus 0.76 percent in the general population) to be born with BWS than naturally conceived children.¹⁴ A French study based on 149 cases of BWS found that six of these children were born after IVF. According to the author, this figure is three times higher than in the French general population and is highly significant.¹⁵ Finally, a similar study conducted in Britain and based on the same number of BWS cases (149) found the exact same number of children conceived through ART.¹⁶

¹³ Jennita Reefhuis et al., "Fertility Treatments and Craniosynostosis: California, Georgia, and Iowa, 1993-1997," *Pediatrics* 111, no. 5 (2003), p.1164-65.

¹⁴ Michael R. DeBaun, Emily L. Niemitz, and Andrew P. Feinberg, "Association of in Vitro Fertilization with Beckwith-Wiedemann Syndrome and Epigenetic Alterations of *Lit1* and *H19*," *American Journal of Human Genetics* 72 (2003).

¹⁵ Christine Gicquel et al., "In Vitro Fertilization May Increase the Risk of Beckwith-Wiedemann Syndrome Related to the Abnormal Imprinting of the *Kcnq1ot* Gene," *American Journal of Human Genetics* 72 (2003).

¹⁶ E.R. Maher et al., "Beckwith-Wiedemann Syndrome and Assisted Reproduction Technology (ART)," *Journal of Medical Genetics* 40 (2003).

Angelman Syndrome

Two recent studies have reported on cases of Angelman Syndrome.¹⁷ This disorder is characterized by severe mental retardation, delayed motor development, poor balance, and absence of speech, among other things. Angelman Syndrome is rare: It affects only one in 15,000 live births. The cases of Angelman Syndrome observed in these two studies were due to sporadic imprinting defects, which are considered extremely rare (one in 300,000 live births).

Given the small size of the sample under consideration – only three cases – it would certainly be premature to draw any firm conclusions based on this evidence. However, after excluding a variety of possible alternative explanations for the onset of this condition, both authors attribute it to ICSI. The ASRM panel of experts also identified Angelman Syndrome as a risk associated with assisted reproductive treatments, but was not prepared to make a causal connection between this birth defect and reproductive treatments.

The Cloacal-Bladder Exstrophy-Epispadias Complex

The cloacal-bladder exstrophy-epispadias complex identifies a combination of birth defects that include cloacal and bladder exstrophy and epispadias. Simply put, babies with this set of conditions are born with their bladder and/or their rectum outside their bodies. Epispadias is a congenital defect resulting in the urethral opening on the dorsum of the penis.

The cloacal-bladder exstrophy-epispadias complex is extremely rare. Bladder exstrophy accounts for 3.3 cases per 100,000 live births; cloacal exstrophy and male epispadias occur in only one in 300,000 and one in 117,000 births, respectively. Since IVF accounts for only 0.7 to 0.8 percent of live births in the United States, it would normally take years and an extensive monitoring system to detect a case. It is thus surprising to learn that recently, a group of researchers at Johns Hopkins University was able to identify four IVF children with the cloacal-bladder exstrophy-epispadias complex simply by reviewing all cases of this birth defect, 78 cases in total, referred to the university hospital and born between 1998 and 2001.¹⁸

Statistical analysis shows that IVF children are seven times more likely to be born with these malformations than children conceived naturally. Admittedly, the sample size is small, but considering the extremely low probability of this condition, the fact that the study authors were able to easily identify four cases is disturbing. This is a condition that, given the extremely small odds, should remain all but undetected. The fact that IVF children might be exposed to a much

¹⁷ Gerald F. Cox et al., "Intracytoplasmic Sperm Injection May Increase the Risk of Imprinting Defects," *American Journal of Human Genetics* 71 (2002); K.H. Ørstavik et al., "Another Case of Imprinting Defect in a Girl with Angelman Syndrome Who Was Conceived by Intracytoplasmic Sperm Injection," *American Journal of Human Genetics* 72 (2003).

¹⁸ *In Vitro Fertilization May Be Linked to Bladder Defects* (ScienceDaily, 2003 [cited August 2, 2005]); available from <http://www.sciencedaily.com/releases/2003/03/030319082147.htm>; Hadley M. Wood, Bruce J. Trock, and John P. Gearhart, "In Vitro Fertilization and the Cloacal-Bladder Exstrophy-Epispadias Complex: Is There an Association?," *The Journal of Urology* 169 (2003).

greater risk of contracting what can only be described as a dreadful condition gives reason for pause.

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Appendix D – Congressional Legislative Activities 2001-2004

CONGRESS	BILL	TITLE	SPONSOR	STATUS
105th	H.R.3133	Human Cloning Research Prohibition Act	Rep. Stearns, Cliff [FL-6]	2/11/1998 Referred to House Subcommittee on Health and Environment.
Prohibits the expenditure of federal funds to conduct or support any research on reproductive cloning involving humans, but allows for the use of somatic cell nuclear transfer for therapeutic purposes not involving human embryos or tissues.				
105th	H.R.922	Human Cloning Research Prohibition Act	Rep. Ehlers, Vernon J. [MI-3]	Reported (Amended) by the Committee on Science.
Prohibits the expenditure of federal funds to conduct or support any research on reproductive cloning involving humans, but allows for the use of somatic cell nuclear transfer for therapeutic purposes not involving human embryos or tissues. Also allows its use for cloning animals.				
105th	H.R.923	Human Cloning Prohibition Act	Rep. Ehlers, Vernon J. [MI-3]	3/14/1997 Referred to House Subcommittee on Health and Environment.
Makes it unlawful for any person to use a human somatic cell for the process of producing a human clone. Sets forth a civil money penalty.				
105th	S.1574	Human Cloning Prohibition Act	Sen. Campbell, Ben Nighthorse [CO]	1/27/1998 Referred to Senate Committee on Labor and Human Resources.
Makes it unlawful for any person to clone a human being, conduct research for such purposes, or otherwise create a human embryo. Prohibits federal funds from being used for such research. Sets forth a civil money penalty.				
105th	S.1595	Bill solely intended to establish a Commission to Promote a National Dialogue on Bioethics	Sen. Frist, Bill [TN]	2/2/1998 Referred to Senate Committee on Labor and Human Resources.
The Commission would provide an independent forum for broad public participation and discourse concerning important bioethical issues including cloning, and report to the Congress its recommendations concerning federal policy and possible congressional act.				
105th	S.1599	Human Cloning Prohibition Act of 1998	Sen. Bond, Christopher S. [MO]	2/3/1998 Referred to Senate Committee on Judiciary.
Criminalizes the use of human somatic cell nuclear transfer technology, and importing an embryo produced through such technology. Sets penalties of up to 10 years in prison, a fine, or both.				
105th	S.1601	Human Cloning Prohibition Act	Sen. Lott, Trent [MS]	2/11/1998 Made it to the Senate floor, but was met by a filibuster and the cloture vote failed. Vote. 42-54. Record Vote No: 10.
Criminalizes the use of human somatic cell nuclear transfer technology, and importing an embryo produced through such technology. Sets penalties of up to 10 years in prison, a fine, or both.				

105th	S.1602	Prohibition on Cloning of Human Beings Act of 1998	Sen. Feinstein, Dianne [CA]	2/3/1998 Referred to Senate† Committee on Labor and Human Resources.
Makes reproductive cloning of humans unlawful while allowing for therapeutic cloning.				
105th	S.1611	Prohibition on Cloning of Human Beings Act of 1998	Sen. Feinstein, Dianne [CA]	2/5/1998 Senate preparation for floor. Status: Read the second time. Placed on Senate Legislative Calendar under General Orders. Calendar No. 305.
Makes reproductive cloning of humans unlawful while allowing for therapeutic cloning. Sets forth, with respect to violations of the cloning prohibition, requirements for: (1) civil penalties; (2) civil actions; and (3) the forfeiture of certain property.				
105th	S.368	†	Sen. Bond, Christopher S. [MO]	2/27/1997 Referred to Senate Committee on Labor and Human Resources.
Prohibits the use of federal funds for research regarding the cloning of a human individual.				
106th	H.R.2326	Human Cloning Research Prohibition Act	Rep. Stearns, Cliff [FL-6]	7/7/1999 Referred to House Subcommittee on Health and the Environment
Prohibits the expenditure of federal funds to conduct or support any research on reproductive cloning involving humans, but allows for the use of somatic cell nuclear transfer for therapeutic purposes not involving human embryos or tissues. Also allows its use for cloning animals.				
106th	H.R.571	Human Cloning Prevention Act of 1999	Ron Paul [TX-14]	2/16/1999 Referred to House Subcommittee on Health and the Environment
Bans federal funds from being received by any business, institution, or organization that either engages in or is associated with human cloning.				
106th	S.2015	Stem Cell Research Act of 2000	Sen. Specter, Arlen [PA]	1/31/2000 Read twice and Referred to Senate Committee on Health, Education, Labor and Pensions
Bans reproductive cloning while allowing for the derivation of embryonic stem cells under a specific set of guidelines.				
107th	H.R.1260	Ban on Human Cloning Act	Rep. Kerns, Brian D. [IN-7]	8/3/2001 Referred to the House Subcommittee on Crime.
Prohibits any person from engaging in a human cloning procedure (the transfer of a nucleus of a human somatic cell into an egg cell from which the nucleus has been removed) with the intent of implanting the resulting cellular product into a uterus. Sets forth criminal penalties.				
107th	H.R.1372	Human Cloning Research Prohibition Act	Rep. Stearns, Cliff [FL-6]	4/16/2001 Referred to House Subcommittee on Health.
Bans reproductive cloning while allowing for the use of somatic cell nuclear transfer and other cloning technologies for therapeutic purposes.				
107th	H.R.1608	Human Cloning Prohibition Act of 2001	Rep. Ehlers, Vernon J. [MI-3]	6/14/2001 Referred to House Subcommittee on Crime.
Bans the use of somatic nuclear transfer unless the nucleus of the clonal cell has been modified to prevent it from fully developing.				
107th	H.R.1644	Human Cloning Prohibition Act of 2001	Rep. Weldon, Dave [FL-15]	6/20/2001 Hearings Held by the House Subcommittee on Health.
Prohibits any person or entity, in or affecting interstate commerce, from: (1) performing or attempting to perform human cloning; (2) participating in such an attempt; (3) shipping or receiving the product of human cloning; or (4) importing such a product.				
107th	H.R.2059	Stem Cell Research Act of 2001	Rep. McDermott, Jim [WA-7]	6/18/2001 Referred to House Subcommittee on Health.
Bans reproductive cloning while allowing for the derivation of embryonic stem cells under a specific set of guidelines.				

107th	H.R.2172	Cloning Prohibition Act of 2001	Rep. Greenwood, James C. [PA-8]	6/25/2001 Referred to House Subcommittee on Health.
Amends the Federal Food, Drug, and Cosmetic Act to prohibit reproductive cloning, while allowing for further study on the potential of embryonic stem cells. Sets forth registration requirements for individuals who intend to perform human somatic cell nuclear transfer technology, including attesting that prohibitions will not be violated.				
107th	H.R.2505	Human Cloning Prohibition Act of 2001	Rep. Weldon, Dave [FL-15]	7/31/2001 Passed House by recorded vote: 265 - 162 (Roll no. 304).
Prohibits any person or entity, in or affecting interstate commerce, from: (1) performing or attempting to perform human cloning; (2) participating in such an attempt; (3) shipping or receiving the product of human cloning; or (4) importing such a product.				
107th	H.AMDT. 284 to H.R.2505	Amendment to Human Cloning Prohibition Act of 2001	Rep. Scott, Robert C. [VA-3]	7/31/2001 Agreed to by voice vote.
Requires the General Accounting Office to conduct a study within four years of enactment of H.R.2505 to assess the need (if any) for amendment of the prohibition on human cloning.				
107th	H.AMDT. 285 to H.R.2505	Amendment to Human Cloning Prohibition Act of 2001	Rep. Greenwood, James C. [PA-8]	7/31/2001 Failed by the Yeas and Nays: 178 - 249 (Roll no. 302).
Amendment in the nature of a substitute sought to ban the use of human somatic cell nuclear transfer technology to initiate a pregnancy but allow the use of somatic cell nuclear transfer technology to clone molecules, DNA, cells, or tissues.				
107th	H.R.2608	Cloning Prohibition Act of 2001	Rep. Greenwood, James C. [PA-8]	7/31/2001 Referred to House Subcommittee on Health.
Amends the Federal Food, Drug, and Cosmetic Act to prohibit reproductive cloning, while allowing for further study on the potential of embryonic stem cells. Sets forth registration requirements for individuals who intend to perform human somatic cell nuclear transfer technology, including attesting that prohibitions will not be violated.				
107th	H.R.2747	Stem Cell Research for Patient Benefit Act of 2001	Rep. DeGette, Diana [CO-1]	8/10/2001 Referred to House Subcommittee on Health.
Requires the director of NIH to conduct or support research using human embryonic and fetal tissue stem cells in accordance with the National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells.				
107th	H.R.2863	To direct the Secretary of Health and Human Services to establish and maintain a panel to provide expert scientific recommendations in the field of cell development.		9/17/2001 Referred to House subcommittee. Status: Referred to the Subcommittee on Health.
107th	H.R.3495	Human Cloning Prevention Act of 2001	Rep. Paul, Ron [TX-14]	12/28/2001 Referred to House Subcommittee on Health.
Bans federal funds from being received by any business, institution, or organization that either engages in or is associated with human cloning.				
107th	H.RES.21 4	Resolution urging the consideration of HR2505	Rep. Myrick, Sue [NC-9]	7/31/2001 Passed/agreed to in House. Status: On agreeing to the resolution Agreed to by the Yeas and Nays: 239 - 188 (Roll no. 300).
Sets forth the rule (modified closed) for the consideration of H.R. 2505 (human cloning prohibition).				

107th	S.1758	Human Cloning Prohibition Act of 2001	Sen. Feinstein, Dianne [CA]	12/3/2001 Referred to Senate Committee on the Judiciary.
Bans human cloning, but explicitly allows for therapeutic cloning and reproductive cloning of animals.				
107th	S.1893	Human Cloning Ban and Stem Cell Research Protection Act of 2001	Sen. Harkin, Tom [IA]	3/5/2002 Referred to Senate Committee on Health, Education, Labor, and Pensions. Hearings held.
Bans human reproductive cloning, but allows cloning for the purposes of biomedical research – therapeutic cloning.				
107th	S.1899	Human Cloning Prohibition Act of 2001	Sen. Brownback, Sam [KS]	1/28/2002 Referred to Senate Committee on the Judiciary.
Prohibits any person or entity, in or affecting interstate commerce, from: (1) performing or attempting to perform human cloning; (2) participating in such an attempt; (3) shipping or receiving the product of human cloning; or (4) importing such a product.				
107th	S.2076	Human Cloning Prohibition Act	Sen. Dorgan, Byron L. [ND]	4/9/2002 Referred to Senate Committee on the Judiciary.
Prohibits any person from conducting or attempting to conduct human cloning (defined as implanting the product of somatic cell nuclear transfer or any other cloning technique into a uterus or the functional equivalent of a uterus).				
107th	S.2439	Human Cloning Prohibition Act of 2002	Sen. Specter, Arlen [PA]	5/1/2002 Referred to Senate Committee on the Judiciary.
Amends the federal criminal code to prohibit human cloning, while amending the Public Health Service Act to require research involving nuclear transplantation to be conducted in accordance with certain federal standards for the protection of human subjects.				
107th	S.704	Human Cloning Prohibition Act	Sen. Campbell, Ben Nighthorse [CO]	4/5/2001 Referred to Senate Committee on Health, Education, Labor, and Pensions.
Makes it unlawful for any person to engage in a human cloning procedure. Prohibits the expenditure of any federal funds related to human cloning research. Sets civil and criminal penalties for violators.				
107th	S.723	Stem Cell Research Act of 2001	Sen. Specter, Arlen [PA]	4/5/2001 Referred to Committee on Health, Education, Labor, and Pensions.
Would amend the Public Health Service Act to allow the Secretary of Health and Human Services to conduct, support, or fund research on human embryos for the purpose of generating embryonic stem cells under stipulated guidelines.				
107th	S.790	Human Cloning Prohibition Act of 2001	Sen. Brownback, Sam [KS]	4/26/2001 Referred to Senate Committee on the Judiciary.
Prohibits any person or entity, in or affecting interstate commerce, from: (1) performing or attempting to perform human cloning; (2) participating in such an attempt; (3) shipping or receiving the product of human cloning; or (4) importing such a product.				
108th	H.R.234	Human Cloning Prohibition Act of 2003	Rep. Weldon, Dave [FL-15]	3/6/2003 Referred to House Subcommittee on Crime, Terrorism, and Homeland Security.
Prohibits any person or entity, in or affecting interstate commerce, from: (1) performing or attempting to perform human cloning; (2) participating in such an attempt; (3) shipping or receiving the product of human cloning; or (4) importing such a product. Sets forth criminal penalties.				
108th	H.R.534	Human Cloning Prohibition Act of 2003	Rep. Weldon, Dave [FL-15]	2/27/2003 Passed House by the Yeas and Nays: 241 - 155 (Roll no. 39).
Bans the use of somatic nuclear transfer for both reproductive and therapeutic purposes, while allowing the techniques use in animal research and human cells other than human embryo cells or tissues.				
108th	H.AMDT.	Amendment to Human Cloning Prohibition	Rep. Scott, Robert C. [VA-3]	2/27/2003 3:25pm:On agreeing to the Scott (VA) amendment

	4 to HR534	Act of 2003		(A001) as modified Agreed to by voice vote.
Requires the General Accounting Office, after consultation with the National Academy of Sciences, to conduct a study to assess the need (if any) for amendment of the prohibition on human cloning contained in the bill.				
108th	H.RES.10 5	Providing for consideration of the Human Cloning Prohibition Act of 2003	Rep. Myrick, Sue [NC-9]	2/27/2003 Passed/agreed to in House.
Sets forth the rule for consideration of H.R. 534.				
108th	H.R.801	Cloning Prohibition Act of 2003	Rep. Greenwood, James C. [PA-8]	2/26/2003 Referred to House Subcommittee on Health.
Amends the Federal Food, Drug, and Cosmetic Act to prohibit reproductive cloning, while allowing for further study on the potential of embryonic stem cells. Sets forth registration requirements for individuals who intend to perform human somatic cell nuclear transfer technology, including attesting that prohibitions will not be violated.				
108th	H.R.916	Human Cloning Research Prohibition Act	Rep. Stearns, Cliff [FL-6]	3/10/2003 Referred to House Subcommittee on Health.
Prohibits the expenditure of federal funds to conduct or support any research on the cloning of humans, while allowing federal funding for cloning animals and human cells other than human embryo cells or tissues.				
108th	H.R.938	Human Cloning Prevention Act of 2003	Rep. Paul, Ron [TX-14]	3/10/2003 Referred to House Subcommittee on Health.
Bans federal funds from being received by any business, institution, or organization that either engages in or is associated with human cloning.				
108th	S.245	Human Cloning Prohibition Act of 2003	Sen. Brownback, Sam [KS]	1/29/2003 Referred to Senate Committee on Health, Education, Labor, and Pensions.
Amends the Public Health Service Act to prohibit any person or entity, in or affecting interstate commerce, from knowingly: (1) performing or attempting to perform human cloning; (2) participating in such an attempt; (3) shipping or receiving an embryo produced by human cloning or any product derived from such an embryo; or (4) importing such an embryo. Sets criminal and civil penalties for violators.				
108th	S.303	Human Cloning Ban and Stem Cell Research Protection Act of 2003	Sen. Hatch, Orrin G. [UT]	2/5/2003 Referred to Senate Committee on the Judiciary.
Amends the Federal criminal code to prohibit human cloning, while amending the Public Health Service Act to require research involving nuclear transplantation to be conducted in accordance with certain federal standards for the protection of human subjects.				

Source: The Center for Public Integrity (<http://www.publicintegrity.org/genetics/report.aspx?aid=193&sid=200>).

Appendix E – Committee Opinions

A committee opinion offers consensus-based (or evidence-based, when there is sufficient evidence available) guidance relative to a given practice activity. This guidance, in addition to scientific and clinical information, may take into account issues of ethical and financial concerns.

Guidelines

- American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Position Statement on West Nile Virus
released February 2005 (*Fertility & Sterility* 2005;83:527-8)
- Ovarian Tissue and Oocyte Cryopreservation
released October 2004 (*Fertility & Sterility* 2004;82:993-8)
- Society for Assisted Reproductive Technology Position Statement On Donor Suitability of Recipients of Smallpox Vaccine (vaccinia virus)
released April 2004 (*Fertility & Sterility* 2004;81:1172-3)
- Estrogen and Progestogen Therapy in Postmenopausal Women
released October 2003 (*Fertility & Sterility* 2004;81:231-41)
- Round Spermatid Nucleus Injection (ROSNI)
released September 2003 (*Fertility & Sterility* 2003;80:687-9)
- Use of Clomiphene Citrate in Women
released June 2003 (*Fertility & Sterility* 2003;80:1302-8)
- Salpingectomy for Hydrosalpinx Prior to IVF
reviewed May 2003; released July 2001
- Blastocyst Production and Transfer in Clinical Assisted Reproduction
reviewed May 2003; released January 2001
- Does Intracytoplasmic Sperm Injection (ICSI) Carry Inherent Genetic Risks?
reviewed May 2003, under revision; released November 2000
- Repetitive Oocyte Donation
reviewed May 2003; released November 2000
- The Role of Assisted Hatching in IVF: A Review of the Literature
reviewed May 2003, under revision; released August 2000
- Optimal Evaluation of the Infertile Female
reviewed May 2003; released June 2000
- Use of Insulin Sensitizing Agents in the Treatment of Polycystic Ovary Syndrome
reviewed May 2003; released April 2000
- Aging and Infertility in Women

- released January 2002
- The Menopausal Transition
 - released December 2001
- Pre-implantation Genetic Diagnosis
 - released June 2001
- Antiphospholipid Antibodies Do Not Affect IVF Success
 - revised and released October 1999
- Intravenous Immunoglobulin (IVIG) and Recurrent Spontaneous Pregnancy Loss
 - released October 1998 (*Fertility & Sterility* 2004;82:S199-200, Suppl 1)
- Position Statement on Nurses Performing Limited Ultrasound in a Gyn/Infertility Setting
 - released June 1998
- Elements To Be Considered In Obtaining Informed Consent For ART
 - released January 1998
- Electroejaculation (EEJ)
 - released August 18, 1995
- Intracytoplasmic Sperm Injection (ICSI)
 - released November 5, 1994
- Definition of "Infertility"
 - released July 17, 1993
- Definition of "Experimental"
 - released May 17, 1993

Technical Bulletins

A technical bulletin is a brief (six to eight page) presentation of a diagnostic or therapeutic procedure, with selected references from the literature.

- Early Diagnosis and Management of Ectopic Pregnancy
 - released March 2001
- The Evaluation and Treatment of Androgen Excess
 - released April 2000
- New Techniques for Sperm Acquisition in Obstructive Azoospermia
 - released August 1999
- Vasectomy Reversal
 - released August 1999

Educational Bulletins

An educational bulletin is a review of the literature on a subject of clinical importance. It differs from the evidence-based guideline in that it is utilized when inadequate data of high quality prohibits objective comparisons and clinical recommendations.

- Increased Maternal Cardiovascular Mortality Associated With Pregnancy in Women with Turner Syndrome
released April 2005 (*Fertility & Sterility* 2005;83:1074-5)
- Hepatitis and Reproduction
released December 2004 (*Fertility & Sterility* 2004;82:1754-64)
- Hormonal Contraception: Recent Advances and Controversies
released August 2004 (*Fertility & Sterility* 2004;82:520-6)
- Current Evaluation of Amenorrhea
released July 2004 (*Fertility & Sterility* 2004;82:266-72)
- Endometriosis and Infertility
released May 2004 (*Fertility & Sterility* 2004;81:1441-6)
- Treatment of Androgen Deficiency in the Aging Male
released May 2004 (*Fertility & Sterility* 2004;81:1437-40)
- Correct Coding for Laboratory Procedures During Assisted Reproductive Technology Cycles
released April 2004 (*Fertility & Sterility* 2004;81:1168-71)
- Smoking and Infertility
released April 2004 (*Fertility & Sterility* 2004;81:1181-6)
- Interpretation of Clinical Trials
released April 2004 (*Fertility & Sterility* 2004;81:1174-80)
- Ovarian Hyperstimulation Syndrome
released November 2003 (*Fertility & Sterility* 2003;80:1309-14)
- Myomas and Reproductive Function
reviewed May 2003; released November 2001
- Multiple Pregnancy Associated with Infertility Therapy
reviewed May 2003; released November 2000
- Effectiveness and Treatment for Unexplained Infertility
reviewed May 2003; released September 2000
- Status of Environmental and Dietary Estrogens – Are They Significant Estrogens?
reviewed May 2003; released August 2000
- Information on Commonly Asked Questions about Genetic Evaluation and Counseling for Infertile Couples
released February 2002

Guidelines and Minimum Standards

- Revised Guidelines for Human Embryology and Andrology Laboratories
published December 2004; approved August 2004 (*Fertility & Sterility* 2004; 82:1736-53)
- Guidelines on Number of Embryos Transferred
published September 2004; approved June 2004 (*Fertility & Sterility* 2004;82:773-4)
- Guidelines for Advertising by ART Programs
published August 2004; approved May 2004 (*Fertility & Sterility* 2004;82:527-8)
- Revised Minimum Standards for Practices Offering Assisted Reproductive Technologies
published September 2003; approved May 2003 (*Fertility & Sterility* 2003;80:1556-9)
- 2002 Guidelines for Gamete and Embryo Donation
released June 2002
- Guidelines for the Provision of Infertility Services
released July 1996 (*Fertility & Sterility* 2004;82:S24-5, Suppl 1)

Joint Reports

Joint reports are collaborations between the ASRM and other medical societies to create documents of importance to the field of reproductive medicine. These reports are intended to provide medical practitioners with a consensus of principles and strategies for the care of couples, and are based on current professional literature, clinical experience, and expert opinion.

- Report on Varicocele and Infertility
written with the American Urological Association, April 2001
- Report on Optimal Evaluation of the Infertile Male
written with the American Urological Association, April 2001
- Report on Management of Obstructive Azoospermia
written with the American Urological Association, April 2001
- Report on Evaluation of the Azoospermic Male
written with the American Urological Association, April 2001

Appendix F – ASRM Ethics Committee Reports and Statements

- [Fertility treatment when the prognosis is very poor or futile \(PDF format\)](#)
(released October 2004)
Fertility & Sterility 2004; 82: 806-10
- [Child-rearing ability and the provision of fertility services \(PDF format\)](#)
(released September 2004)
Fertility & Sterility 2004; 82: 564-7
- [Informing offspring of their conception by gamete donation \(PDF format\)](#)
(released March 2004)
Fertility & Sterility 2004; 81: 527-531
- [Family members as gamete donors and surrogates \(PDF format\)](#)
(released November 2003, reviewed January 2004)
Fertility & Sterility 2003; 80: 1124-30
- [Donating spare embryos for embryonic stem-cell research \(PDF format\)](#)
(released November 2002, reviewed January 2004)
Fertility & Sterility 2002; 78: 957-60
- [Human immunodeficiency virus and infertility treatment \(PDF format\)](#)
(released February 2002, reviewed January 2004)
Fertility & Sterility 2002; 77: 218-22
- [Preconception gender selection for nonmedical reasons \(PDF format\)](#)
(released May 2001, reviewed January 2004)
Fertility & Sterility 2001; 75: 861-4
- [Human somatic cell nuclear transfer - cloning \(PDF format\)](#)
(released November 2000, reviewed January 2004)
Fertility & Sterility 2000; 74: 873-6

- [Financial incentives in recruitment of oocyte donors \(PDF format\)](#)
(released August 2000, under review January 2004)
Fertility & Sterility 2000; 74: 216-20
- [Sex selection and preimplantation genetic diagnosis \(PDF format\)](#)
(released October 1999, under review January 2004)
Fertility & Sterility 1999; 72: 595-8
- [Shared-Risk Or Refund Programs in Assisted Reproduction](#)
(released September 1998, reviewed January 2004)
Fertility & Sterility 1998; 70: 414-5
- [Informed Consent and the use of Gametes and Embryos for Research](#)
(released November 1997, under review January 2004)
Fertility & Sterility 1997; 68: 780-1
- 1997 Report *Fertility & Sterility* 1997; 67: Suppl 1
 - [Foreward](#)
 - [Disposition of abandoned embryos](#)
(reviewed January 2004)
 - [Oocyte donation to postmenopausal women](#)
(under review January 2004)
 - [Embryo splitting for infertility treatment](#)
(reviewed January 2004)
 - [The use of fetal oocytes in assisted reproduction](#)
(reviewed January 2004)
 - [Posthumous reproduction](#)
(under review January 2004)
- [1994 Report](#)
(complete statements on more than 29 topics)
Fertility & Sterility 1994; 62: Supplement 1

Appendix G – State-Level Legislative Initiatives

Enacted Legislation

Reproductive cloning

<i>State</i>	<i>Prohibited/ Allowed</i>	<i>Legislative Info</i>	<i>Year</i>	<i>Comments</i>
Arkansas	Prohibited	SB 185	2003	
California	Prohibited	Health and Safety Code: §24185, §24187, § 24189, §125115-17		
Iowa	Prohibited	707B.1 to 4	2002	
Michigan	Prohibited	§§ 333.26401-06	1998	
New Jersey	Prohibited	SB 1909 / HB 2480	2002	
North Dakota	Prohibited	HB 1424	2003	
Rhode Island	Prohibited	§ 23-16.4-1 to 4-4		Expires July 7, 2010
South Dakota	Prohibited	SB 184	2004	
Virginia	Prohibited	§ 32.1-162.21-22	2001	

Research (Therapeutic) Cloning

<i>State</i>	<i>Prohibited/ Allowed</i>	<i>Legislative Info</i>	<i>Year</i>	<i>Comments</i>
Arkansas	Prohibited	SB 185	2003	
California	Allowed	Business, Professions § 16004, §16105 Health and Safety § 24185, § 24187, § 24189, § 12115-17		
Iowa	Prohibited	707B.1 to 4	2002	
Michigan	Prohibited	§§ 333.26401-06	1998	
Missouri	Allowed	§ 1.217	2003	
New Jersey	Allowed	SB 1909 – HB 2480	2002	
North Dakota	Prohibited	HB 1424	2003	
Rhode Island	Protected	§ 23-16.4-1 to 4-4		Expires July 7, 2010
South Dakota	Prohibited	SB 184	2004	
Virginia	Protected	§ 32.1-162.21-22	2001	

Stem Cell Research (explicitly)

<i>State</i>	<i>Prohibited/ Allowed</i>	<i>Legislative Info</i>	<i>Year</i>	<i>Comments</i>
California	Allowed	Health and Safety § 125300-320		Under the supervision of an institutional review board, registry for embryos to be established

Iowa	Prohibited	§§ 707B.1-4	2002	Prohibits research on human embryos or cells
Minnesota	Prohibited	§§ 145.421, 422	1973/ 2003	Prohibits any experimentation or sale of "human conceptus," artificial or natural, from fertilization through first 265 days
Nebraska	Allowed	§§ 28-342, 346, 71-7606	1977/ 2000	Prohibits research on premature infants aborted alive, prohibits use of state funds for research involving human embryonic stem cells
New Hampshire	Allowed	§§ 168-B-1, 15	1991	Pre-embryo may not be maintained ex utero past 14 days after fertilization, donated pre-embryos for research must not be implanted
New Jersey	Allowed	SB 1909/ AB 2840	2002	Explicitly permits stem cell research, subject to supervision by a review board
South Dakota	Prohibited	§§ 34-14-16, 17, 20; 34-23A-17	2000	Prohibits non-therapeutic research on embryo which destroys or threatens to destroy it (from single-cell stage onward), prohibits research on aborted child

Embryonic Research (in general)

<i>State</i>	<i>Legislative Info</i>	<i>Year</i>	<i>Comments</i>
Arizona	§§ 36-2302, 2303		Prohibits use of embryos (or parts) from abortion
Arkansas	§§ 20-17-802, 20-161001 to 1004		Prohibits research on cloned embryos
California	§§ 123440, 24185, 12115-7		Prohibits research on live fetuses, reproductive cloning, specifically permits embryonic research (by donation, IVF)
Florida	§ 390.0111		Abortion Law Prohibits research on aborted live fetus
Illinois	720 ILCS 510/6, 510/12.1	1975	Abortion Law Prohibits research on fertilized embryo, Allows research on dead material
Indiana	§ 35-46-5-1	2004	Prohibits human tissue trafficking
Kentucky	§ 436.026	1992	Prohibits use/ transfer of dead or aborted child
Louisiana	§ 14: 87.2		Prohibits research on embryo or fetus in utero, in vitro fertilized embryo
Maine	22 § 1593	1989/ 2003	Prohibits research on any live product of conception, intra- and extra-uterine
Massachusetts	112 § 12J		Prohibits research on aborted embryo/ live fetus
Michigan	§§ 333.2685, 2687	1978	Prohibits non-therapeutic research on aborted embryo/ live fetus
Missouri	§§ 188.036, 037	2003	Prohibits any type of research on fetus or aborted child, or sale of tissue
Montana	§ 50-20-108(3)	1987	Prohibits research on premature infant born alive
New Mexico	§ 24-9A-1, 3, 5		Prohibits research on embryo/ fetus after implantation
North Dakota	§ 14-02.2-01, 2; HB 1424	2003	Prohibits research on live human fetus or embryo, or use of tissue or organs from an aborted one.

Ohio	§ 2919.14	1974	Prohibits research on product of human conception which is aborted
Oklahoma	63 § 1-735		Prohibits experimentation, sale, etc. on an unborn child which is resulting from or intended for abortion
Pennsylvania	18 §§ 3203, 3216	1997	Prohibits non-therapeutic research (= other than for health of) unborn live child
Rhode Island	§11-54-1		Prohibits any kind of experimentation on live human fetus or embryo, before or after implantation
Tennessee	§ 39-15-208	1989	Consent of mother required for research, sale etc. on aborted fetus
Texas	Penal Code § 48.02	1994	Prohibits purchase/ sale of human organs or tissue
Utah	§§ 76-7-301, 310	1976/ 2004	Prohibits research on live unborn children
Virginia	§ 32.1-162.32-2	1979/ 2002	Human research prohibited unless by informed consent of the "subject" to it, establishes Human Research Review Committee
Wyoming	§ 35-6-115		Prohibits sale/ transfer/ distribution of human embryo or fetus for any experimentation

Pending Legislation

<i>State</i>	<i>Title</i>	<i>Legislative Info</i>	<i>Year</i>	<i>Scope</i>
California		AB 3012, AB 267	2004, 2003	Allows stem cell research, calls for establishment of advisory committee, Allows therapeutic cloning
Illinois	Stem Cell Research Act	HB 3589	2004	Allows stem cell research under supervision of a committee yet to be created, prohibits sale or purchase of material, "unused embryos" decided upon by individual
Illinois	Human Cloning and Adult Stem Cell Act	HB 6693/ SB 2934	2004	Prohibits reproductive and research cloning, allows cloning techniques for reproduction of tissues
Massachusetts		HB 2052/ SB 515, SB 1917, HB 1280, HB 2048	2004 2003 2003 2003	Allows stem cell research under supervision of a committee yet to be created, calls for research fund, prohibits sale or purchase, prohibits reproductive and research cloning
Michigan		SB 249	2003	Prohibition of non-therapeutic research on embryos or tissue, if life is jeopardized
Michigan		HB 4507, HB 606	2003	Prohibits sale, transfer of embryos, tissues and cells and use of such illegally obtained material
New Jersey		AB 160	2004	Regulates disclosure of genetic information, protects individual rights
New Jersey		AB 2388	2004	Prohibits human reproductive and research cloning, prohibits reprogramming of DNA, etc. back to

New York		AB 1819, SB 7064, SB 7524,	2003/ 2004	initial stage of human being Allows stem cell research, subject to review by institutional review board, embryo must not develop beyond 14 days, regulates storage and disposition, prohibits sale of stem cells and tissue, prohibits human cloning
New York	Reproductive Cloning Prohibition and Research Protection Act	AB 6249, AB 3295	2003	Prohibits reproductive cloning while allowing stem cell research and therapeutic cloning, creates legislative commission on cloning
New York		AB 4533, AB 10256	2003 2004	Prohibits human cloning, no differentiation reproductive/therapeutic
Pennsylvania	Stem Cell Research Act	HB 422	2003	Allows research on embryonic stem cell, subject to review by DOH
Pennsylvania	Stem Cell Research Authorization Act	HB 945	2003	Source of embryonic stem cells can only be public or private fertility clinics (“unused”), written consent required, research must not have reproductive purposes

Legislation that Has Died or Was Withdrawn

<i>State</i>	<i>Title</i>	<i>Legislative Info</i>	<i>Year</i>	<i>Scope</i>
Alabama		HB 282		Limits stem cell research
Arizona		HB 2685		Limits stem cell research
Connecticut		HB 5536		Allows stem cell research
Delaware	Cloning Prohibition and Research Protection Bill	SB 55	2004	Prohibits reproductive cloning (purpose is actual birth), allows cloning techniques for biomedical research
Florida		SB 2558		Limits stem cell research
Indiana		SB 162		Limits stem cell research
Iowa		HB 2032, SB 2013		Limit stem cell research
Kansas		HB 2647		Limits stem cell research
Kentucky		HB 170, HB 171		Limit stem cell research
Louisiana	Human Cloning Ban and Adult Stem Cell Research Promotion Act	HB 557, SB 74 HB 803/ SB 873	2004	Very explicitly prohibits any kind of cloning, establishes harsh penalties
Maryland		HB 1021, HB 482		Allows stem cell research
Maryland		SB 472		Limits stem cell research
Minnesota		HB 2049, SB 2077 SB 2635		Allows stem cell research
Minnesota		HB 2026, SB 2129		Limit stem cell research
Mississippi		HB 727		Limits stem cell research
Missouri		HB 1136, HB 1151		Regulates disposition of fetal remains, right of mother to determine
Nebraska		LB 566, LB 602,		Limit stem cell research

Oklahoma	LB 512		Limit stem cell research
Rhode Island	HB 1130, SB 1607		Allows stem cell research
South Carolina	SB 266, SB 2318		Limits stem cell research
Tennessee	HB 3819		Limit stem cell research
Tennessee	HB 1075, SB 1515		Allow stem cell research
Washington	HB 945, SB 1654		Allow stem cell research
	HB 2336, HB 1461,		
	SB 5466		
West Virginia	HB 4487, SB 426,		Limit stem cell research
	HB 2832, SB 25,		
	SB 78		
Wisconsin	AB 104/	2003	Prohibits human cloning and parthenogenesis, for reproductive or research purposes, Specifically prohibits non-therapeutic cloning
	SB 45,		
	AB 246		

Appendix H – Legislative Initiatives at the International Level

Statutes

Countries	<i>Relevant Statutes</i>	<i>Administering Agencies</i>
United States	<ul style="list-style-type: none"> - 1992 Fertility Clinic Success Rate and Certification Act - 2001 Presidential directive on hESC research - FDA "Dear Colleague" letter of 2001 - Dickey-Wicker Amendment of 1996 	<ul style="list-style-type: none"> - Centers for Disease Control and Prevention (CDC) - Food and Drug Administration (FDA)
Canada	Bill C-6: An Act Respecting Assisted Human Reproduction and Related Research (2004)	Assisted Human Reproductive Agency of Canada
Australia	<ul style="list-style-type: none"> - Prohibition of Human Cloning Act 2002 - Research Involving Human Embryos Act of 2002 - Ethical guidelines on the use of assisted reproductive technology in clinical practice and research of 2004 - Code of Practice for Centres Using Assisted Reproductive Technology of 2002 	<ul style="list-style-type: none"> - Fertility Society of Australia - Australian Health Ethics Committee of the National Health and Medical Research Council - Embryo Research Licensing Committee (ERLC)
Germany	<ul style="list-style-type: none"> - Embryonenschutz-Gesetz (1991 Embryo Protection Act) - Stammzellgesetz (2002 Stem Cell Act) 	<ul style="list-style-type: none"> - Bundesministerium fuer Gesundheit und Soziale Sicherung (Federal Ministry of Health) - Zentralen Ethik-Kommission für Stammzellenforschung (Central Ethics Commission on Stem Cell Research)
UK	<ul style="list-style-type: none"> - 1990 Human Fertilisation and Embryology Act - 2001 Human Reproductive Cloning Act - The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 	<ul style="list-style-type: none"> - Human Fertilisation and Embryology Authority (HFEA) - Ministry of Health
France	Loi n° 2004-800 du 6 août 2004 relative à la bioéthique	<ul style="list-style-type: none"> - Ministère de Santé Public - Agence de la biomédecine - Le Comité consultatif national d'éthique
Italy	Norme in materia di procreazione medicalmente assistita no. 40, 2004 (2004 Norms Regarding Medically Assisted Reproduction)	Ministry of Health

Countries	<i>Relevant Statutes</i>	<i>Administering Agencies</i>
Spain	<ul style="list-style-type: none"> - Law 35/1988 – Assisted Reproduction Techniques Act - Law 42/1988 – Donation and Use of the Embryos and Fetus, or Their Cells or Organs Act - Law 41/2002 – Patients’ Rights and Obligations Act - Law 45/2003 National Health System Act Organic Law 	<ul style="list-style-type: none"> - Ministry of Health - Ethics Advisory Committee for Scientific and Technological Research - National Commission of Assisted Reproduction (CNRA)
Sweden		National Board of Health and Welfare issues permits
Japan	<ul style="list-style-type: none"> - 2000 The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques - No legislation governing the ART industry [check] 	Ministry of Education and Science
China	<ul style="list-style-type: none"> - 2004 Ethical Guidance on Human Embryonic Stem Cell Research - 2003 Guidelines on Human Assisted Reproductive Technologies - 2003 Ethical Principles of Human ARTs - 2000 The Human Reproductive Technology Ordinance (Hong Kong) 	Ministry of Health/Ministry of Science and Technology
Singapore		Bioethics Advisory Committee (BAC)
S. Korea	2004 Life Ethics Law	Ministry of Health and Welfare

Table 16: Governing statutes.

Key Provisions

	<i>Embryo Research</i>	<i>Reproductive Cloning</i>	<i>Research Cloning</i>	<i>Stem Cell Research</i>	<i>PGD¹</i>	<i>Creation of Chimeras</i>	<i>Creation of Hybrids</i>	<i>Germ-line Genetic modifications</i>	<i>Surrogacy</i>	<i>Trade/Sale of Gametes and Embryos</i>
United States	Unregulated	Prohibited ²	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated	Unregulated
Canada	Regulated	Prohibited	Prohibited	Regulated ³	Regulated ⁴	Prohibited	Prohibited	Prohibited	Regulated ⁵	Regulated ⁶
Australia	Regulated	Prohibited	Prohibited	Regulated ⁷	Regulated ⁸	Prohibited ⁹	Prohibited	Prohibited ¹⁰	Regulated	Regulated ¹¹
Germany	Prohibited	Prohibited	Prohibited	Regulated ¹²	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Regulated ¹³
UK	Regulated	Prohibited	Regulated	Regulated ¹⁴	Regulated ¹⁵	[check]	Regulated	Prohibited	Regulated ¹⁶	Regulated ¹⁷

¹ Pre-implantation genetic diagnosis.

² De facto.

³ Permitted on donated, supernumerary embryos.

⁴ Exclusively for therapeutic applications.

⁵ Non-commercial services allowed.

⁶ Commercial sale of gametes and embryos prohibited.

⁷ Allowed on donated, supernumerary embryos.

⁸ Therapeutic applications recommended.

⁹ Creation of chimeric animals allowed.

¹⁰ Creation of transgenic animals allowed.

¹¹ Commercial trade of gametes and embryos prohibited.

¹² Stem cell lines can be imported if derivation consistent with German provisions and research is deemed important.

¹³ Oocyte donation prohibited, sperm donation permitted.

¹⁴ Allowed on donated, supernumerary embryos.

¹⁵ Some therapeutic uses permitted.

¹⁶ Commercial offerings prohibited.

¹⁷ Commercial trade of gametes and embryos prohibited.

	<i>Embryo Research</i>	<i>Reproductive Cloning</i>	<i>Research Cloning</i>	<i>Stem Cell Research</i>	<i>PGD¹</i>	<i>Creation of Chimeras</i>	<i>Creation of Hybrids</i>	<i>Germ-line Genetic modifications</i>	<i>Surrogacy</i>	<i>Trade/Sale of Gametes and Embryos</i>
France	Regulated ¹⁸	Prohibited	Prohibited	Regulated ¹⁹	Regulated ²⁰	Prohibited	Prohibited	Prohibited	[check]	Regulated ²¹
Italy	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited
Spain	Regulated ²²	Prohibited	Regulated ²³	Regulated ²⁴	Regulated ²⁵			Prohibited	Prohibited	Regulated ²⁶
Sweden		Prohibited ²⁷	Prohibited ²⁸	Regulated ²⁹	Regulated ³⁰			Prohibited		Regulated ³¹
Japan		Permitted	Permitted	Unregulated ³²		Regulated ³³	Regulated ³⁴		Unregulated	

¹⁸ Research on in vitro embryos prohibited, however studies permitted where research does not harm the embryo.

¹⁹ Donation of embryos for research purposes allowed, provided the research contributes to therapeutic progress – provision valid for the next five years.

²⁰ Allowed only to prevent serious inheritable disease.

²¹ Commercial sale of gametes and embryos prohibited.

²² Research on excess in vitro embryos at least five years old permitted – assuming they are no longer viable.

²³ Permitted on surplus embryos that have passed their legal date for implantation.

²⁴ Research on excess in vitro embryos at least five years old permitted – assuming they are no longer viable.

²⁵ Permitted to diagnose and prevent hereditary diseases

²⁶ Gamete and embryo donation permitted.

²⁷ Ban on implantation effectively precludes human cloning for either reproductive or research purposes

²⁸ (Ban on implantation effectively precludes human cloning for either reproductive or research purposes.

²⁹ Non-therapeutic research allowed on embryos of up to fourteen days development.

³⁰ Allowed for prevention of sex-linked hereditary diseases.

³¹ Consent is required of egg and sperm donors

³² Does not address development of human embryonic stem cells

³³ Embryo creation permitted, but implantation prohibited.

³⁴ Embryo creation permitted, but implantation prohibited

	<i>Embryo Research</i>	<i>Reproductive Cloning</i>	<i>Research Cloning</i>	<i>Stem Cell Research</i>	<i>PGD¹</i>	<i>Creation of Chimeras</i>	<i>Creation of Hybrids</i>	<i>Germ-line Genetic modifications</i>	<i>Surrogacy</i>	<i>Trade/Sale of Gametes and Embryos</i>
China	Regulated ³⁵	Prohibited	Permitted	Regulated ³⁶	Regulated ³⁷	Prohibited ³⁸	Prohibited	Prohibited	Prohibited	Regulated ³⁹
Singapore	Unregulated	Prohibited	Permitted	Regulated ⁴⁰	Unregulated					Unregulated
S. Korea	Regulated	Prohibited	Permitted	Regulated ⁴¹	Regulated ⁴²	Prohibited	Prohibited	Prohibited		

Table 17: Key statutory provisions.

³⁵ Research allowed with informed consent

³⁶ Research allowed on supernumerary IVF embryos, aborted fetal tissue, donated germ cells. Creation of embryos for research prohibited. 14-day limit for embryo research.

³⁷ Prohibits sex selection without medical indications.

³⁸ Research on human chimeric embryos prohibited.

³⁹ Purchase or sale of human gametes, embryos or fetal tissue prohibited.

⁴⁰ Creation of embryos for research prohibited.

⁴¹ Creation of embryos for research prohibited. Research on supernumerary embryos permitted.

⁴² Restricted to treatment of hereditary diseases.

Appendix I – Select Supreme Court Cases

Meyer v. Nebraska (1923)

Meyer v. Nebraska of 1923 involved the constitutionality of a ban enacted by the state legislature of Nebraska on teaching children below eighth grade in any language other than English.¹

In striking down this law, the Court noted that while it had not tried to precisely define which liberties are protected by the due process clause of the Fourteenth Amendment, it had identified some of them, including “not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.”² The Court singled out two liberties restricted by this law – the right of some teachers to freely pursue their profession, and the right of parents to select what they believe is the best education for their children.

Pierce v. Society of Sisters (1925)

Two years later, in 1925 the Court was called upon to rule on a case involving school choice. In Pierce v. Society of Sisters, the Court determined that a law that would have required all children of the state of Oregon to be educated in a public school was a clear violation of the parents’ right to educate their children as they see fit.³ The law would have made it illegal for parents to send their children to private schools run by the Society of Sisters, a non-profit organization with a long history of providing educational services in the state. The Court found that this law was inconsistent with the 1923 ruling in Meyer v. Nebraska.

Skinner v. Oklahoma (1942)

The only ruling that specifically recognizes a right to procreation is Skinner v. Oklahoma.⁴ At issue in this case was an Oklahoma statute that required compulsory sterilization of individuals who had committed two or more felonies. In dictum, the Court noted: “We are dealing here with legislation which involves *one of the basic civil rights of man. Marriage and*

¹ See 262 U.S. 390 (1923).

² See 262 U.S. 390, 399 (1923).

³ See 268 U.S. 510 (1925).

⁴ See 316 U.S. 535 (1942).

procreation are fundamental to the very existence and survival of the race.”⁵ Its rhetoric notwithstanding, the Court struck down this statute on equal protection, not on substantive due process grounds. The Court pointed out that under this statute, individuals who had committed grand larceny three times would have been sterilized, whereas repeated embezzlement for the same sum of money would go entirely unpunished. In this sense, the ruling is not centered on reproductive rights per se, though the nature of the punishment is clearly a central consideration in this ruling. Moreover, the ruling only establishes a right to preserve one’s procreative capacity; it does not focus procreation per se.

Griswold v. Connecticut (1965)

Until the early 1960s, the Court had ruled narrowly on the merits of specific privacy-related cases and avoided any generalization that would have suggested the existence of a broad right to privacy. A right to privacy existed, but only for those familial choices identified by the Court as deserving constitutional protection. Obviously, this approach leaves very little room for generalizations to other familial choices. If a right to privacy existed at all, it was a highly fragmented and narrowly circumscribed right. This situation changed dramatically in 1965 when the Court, for the first time, ruled that privacy was indeed a right protected by the Constitution.

Griswold v. Connecticut involved the executive director of Planned Parenthood who, by advising married couples on means of preventing pregnancy, was arrested for violating a Connecticut statute that prohibited both the use of and any assistance in using contraceptives.⁶

The Court found that the case involved the substantive due process clause of the Fourteenth Amendment,⁷ but pointed out that in the past this clause had been invoked in conjunction with business affairs,⁸ whereas the present law “operates directly on an *intimate relation of husband and wife* and their physician’s role in one aspect of that relation.”⁹ Noting that this case touched on “a *relationship* lying within the zone of privacy created by several fundamental constitutional guarantees,”¹⁰ the Court asked rhetorically, “[w]ould we allow the police to search the sacred

⁵ See 316 U.S. 535, 541 (1942), emphasis added.

⁶ See 381 U.S. 479 (1965).

⁷ Ever since *Mugler v. Kansas* (1887) [123 U.S. 623, 660-661], the Court has recognized that due process includes two components – a procedural and a substantive element. Thus, the state cannot deprive citizens of life, liberty, or property without following certain procedures designed to ensure fairness. But the state cannot simply invoke procedural fairness as the basis for imposing arbitrary legislation. To infringe upon these liberties, the state not only must provide a “compelling interest,” but it must also demonstrate a “rational relationship” between state interests and legislative means.

⁸ After *Lochner v. New York* (1905) [198 U.S. 45], substantive due process had come to be seen as synonymous with judicial overreach.

⁹ See 381 U.S. 479, 482 (1965).

¹⁰ See 381 U.S. 479, 485 (1965).

precincts of *marital bedrooms* for telltale signs of the use of contraceptives? The [...] very idea is repulsive to the notions of privacy surrounding the *marriage relationship*.”¹¹

Critical to the Court opinion was the determination that marriage is protected by the “penumbras” of several articles of the Bill of Rights. For example, the right of association is contained in the penumbra of the First Amendment; the penumbra of the Third Amendment protects “against the quartering of soldiers ‘in any house’ in time of peace without the consent of the owner”; and the Fourth Amendment explicitly establishes “right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures.” The Fifth Amendment, in its self-incrimination clause, creates a “*zone of privacy* which government may not force him to surrender to his detriment.” The Court also found that the Ninth Amendment – “The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.” – suggests that a fundamental right to privacy exists even though it is not explicitly mentioned in the Constitution.

Much has been said about this landmark legal opinion. Strict constructionists have criticized this ruling as a classic example of the Court discovering a fundamental right that is nowhere to be found in the Constitution or the Bill of Rights. Others have argued that this opinion did not simply create a new fundamental right, but that it was based on numerous Court precedents. The controversy was exacerbated by the fact that the Court established a right to privacy without elaborating on the nature of the activities protected by this right. Using contraceptives, along with the rights enumerated in this opinion (marriage, raising and educating children, and so on), does enjoy constitutional protection, but since the Court did not specify the outer boundaries of the right to privacy, it is unclear whether and to what extent other activities – activities that would most likely be regarded as private – do deserve constitutional protection. Here, we simply note that this ruling can be read in both narrow and broad ways. Narrowly, it establishes a right for married couples to use contraceptives; more broadly, it identifies marital relationships as a private area that the state can intrude on only by demonstrating a compelling interest.

Eisenstadt v. Baird (1972)

In *Eisenstadt v. Baird*, the Court was called upon to determine the constitutionality of a Massachusetts statute that proscribed the distribution of contraceptives to unmarried individuals.¹² The Court found that the Massachusetts statute violated the equal protection clause of the Fourteenth Amendment. The Court noted that the Fourteenth Amendment does not deny the state the power to treat different classes of citizens differently, but it found that the reasons offered by the state of Massachusetts for discriminating between married and unmarried individuals were wholly unrelated to the purported intentions of this law. The Court observed that if “[...] under *Griswold* the distribution of contraceptives to married persons cannot be prohibited, a ban on distribution to *unmarried persons* would be equally impermissible. It is true

¹¹ See 381 U.S. 479, 485-486 (1965).

¹² See 405 U.S. 438 (1972).

that in *Griswold* the right of privacy in question inhered in the marital relationship. Yet the marital couple is not an independent entity with a mind and heart of its own, but an association of two individuals each with a separate intellectual and emotional makeup. If the right of privacy means anything, it is the right of the *individual, married or single*, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether *to bear or beget a child.*¹³

Eisenstadt v. Baird is often mentioned as a Court ruling reaffirming *Griswold* and the right to privacy, but it should be pointed out that the Court struck down the Massachusetts statute specifically on equal protection grounds. One may wonder if the “decision whether to bear or beget a child” also encompasses the right to have a child by whatever technical means. The substantive context of this ruling – the use of contraceptives by unmarried persons – suggests that the Court had mainly the right not to have children in mind. A right to privacy would clearly protect this right, but how far the Court would go in protecting the opposite choice remains a matter of speculation.

Stanley v. Illinois (1972)

Stanley v. Illinois called on the Court to rule on the constitutionality of an Illinois statute that assigned the custody of an unmarried father’s children to the state after the death of the mother, without granting the father an opportunity to demonstrate his fitness as a parent.¹⁴ Noting that the Court has frequently recognized the importance of the family and that the “rights to conceive and to raise one’s children have been deemed essential,”¹⁵ the Court determined that the Illinois statute violated the Fourteenth Amendment’s due process and equal protection clauses. The Court recognized the state interest in protecting the well-being and the health of children, but questioned the means of pursuing these legitimate state interests. Once again, the Court focused on family matters as one area that deserves special constitutional protection, but whether the “rights to conceive and to raise one’s children” should be taken to include a positive procreative right is unclear.

Roe v. Wade (1973)

A milestone in the constitutionality of reproductive choices was the 1973 *Roe v. Wade* ruling.¹⁶ In this case, the Court was called upon to decide the constitutionality of a Texas law that allowed interrupting a pregnancy based solely on previous medical advice. *Roe*, a single pregnant woman whose health was not threatened by her pregnancy, argued that the Texas abortion law was unconstitutionally vague and it infringed upon her right to privacy. The Court

¹³ See 405 U.S. 438, 453 (1972).

¹⁴ See 405 U.S. 645 (1972).

¹⁵ See 405 U.S. 645, 651 (1972).

¹⁶ See 410 U.S. 113 (1973).

acknowledged that a right to privacy is not explicitly mentioned in the Constitution, but it went on to point out that a long line of rulings going as far back as 1891 had established the existence of such a right. These rulings involve “fundamental rights” to personal privacy, a right that “has some extension to activities relating to *marriage*, *Loving v. Virginia*, 388 U.S. 1, 12 (1967); *procreation*, *Skinner v. Oklahoma*, 316 U.S. 535, 541 -542 (1942); *contraception*, *Eisenstadt v. Baird*, 405 U.S. at 453 -454; *id.*, at 460, 463-465; *family relationships*, *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944); and *child rearing and education*, *Pierce v. Society of Sisters*, 268 U.S. 510, 535 (1925), *Meyer v. Nebraska* [...].”¹⁷

Of all the rights recognized in this ruling, none can be interpreted as recognizing a positive right to procreate. *Skinner* does focus, *in dicta*, on procreation, but does so in terms of the *capacity* to procreate, not on the procreative act per se. Once again, the Court enlarged the number of rights protected by the substantive component of the due process clause of the Fourteenth Amendment, but these rights do not include a narrowly defined procreative right.

Cleveland Board of Education v. LaFleur (1974)

The Fourteenth Amendment has been repeatedly invoked in the context of reproductive decisions. In *Cleveland Board of Education v. LaFleur*, the Court found that it is unconstitutional for school boards to mandate that pregnant women take a maternity leave at a specific point in time.¹⁸ Nor is it permissible for a statute to require that the baby has reached a minimum age before a teacher can resume her teaching activity. The Court found that “[t]he age limitation serves no legitimate state interest, and unnecessarily penalizes the female teacher for asserting her right to bear children.”¹⁹

The Court did not deny the legitimate interest of the state to ensure continuity of instruction. It also acknowledged that some pregnant women might be unable to properly carry out their duties. But it found that the regulations under scrutiny created an “irrebuttable presumption of physical incompetency,” and that a mandatory, inflexible cut-off date was too rigid a rule. Noting that the Court “has long recognized that freedom of personal choice in matters of marriage and family life is one of the liberties protected by the due process clause” it struck down the school board provisions as not having a “rational relationship to the valid state interest of preserving continuity of instruction.”²⁰

The relevance of this case lies not only in the fact that it once again recognized the constitutional protection of marriage and family-related choices, but also in an implicit recognition of the (positive) right of a woman to bear a child.²¹

¹⁷ See 410 U.S. 113, 152 (1973).

¹⁸ See 414 U.S. 632 (1974).

¹⁹ See 414 U.S. 632, 650 (1974).

²⁰ See 414 U.S. 632, 632 (1974).

²¹ See 414 U.S. 632, 639 (1974).

Carey v. Population Services International (1977)

In *Carey v. Population Services International*, the Court had to determine whether section 6822(8) of the New York Education Law was constitutional.²² This section made it a crime for any person to sell or distribute contraceptives of any kind to a minor under 16. The Court determined, not without considerable ambivalence, that minors “are protected by the Constitution and possess constitutional rights,”²³ but refrained from enumerating these rights. It further decided that the state indeed does not have the power to impose a blanket prohibition on minors’ access to contraceptives. The Court did not deny that the stated purpose of the law, which was to discourage sexual activity among young people, served a legitimate state interest, but it found that section 6822(8) of the New York Education Law did not serve “compelling state interests.”

The majority opinion provides considerable insight into the constitutional reasoning informing this ruling. It makes clear that the “liberty” protected by the due process clause of the Fourteenth Amendment is a “right to personal privacy, or a guarantee of certain areas or zones of privacy.” The Court went on to acknowledge that “the outer limits of this aspect of privacy have not been marked,” but also made clear that over the years it has recognized a number of specific liberties. These are the same liberties enumerated early in *Roe v. Wade*.

²² See 431 U.S. 678 (1977).

²³ See 431 U.S. 678, 692 (1977).

Appendix J – Attitudes toward Science and Medical Research

Q1: “Scientific research is essential for improving the quality of human lives.” Do you strongly agree, somewhat agree, somewhat disagree, or strongly disagree with this statement?

	<i>2004</i>	<i>2003</i>	<i>2002</i>
Strongly agree	56	59	48
Somewhat agree	36	31	42
Somewhat disagree	5	6	6
Strongly disagree	2	3	3
Don't know	1	1	1
No answer	0	1	0

Virginia Commonwealth University Life Sciences Survey, September 7-17, 2004, N=1004.

Q2: On the whole, have developments in science helped make society better or not?

	<i>2004</i>	<i>2003</i>	<i>2002</i>	<i>2001</i>
Better	90	87	86	86
Not better	4	7	7	5
Don't know	4	3	6	7
No Answer	1	2	1	2

Virginia Commonwealth University Life Sciences, September 2003, N=1003.

Q4: “New technology used in medicine allows people to live longer and better.” Do you strongly agree, somewhat agree, somewhat disagree, or strongly disagree with this statement?

	<i>2004</i>	<i>2003</i>	<i>2002</i>
Strongly agree	63	60	57
Somewhat agree	29	31	34
Somewhat disagree	5	5	6
Strongly disagree	2	4	2
Don't know	0	1	0
No answer	0	0	1

Virginia Commonwealth University Life Sciences, September 2003, N=1003.

Q5: Of all the developments made in science over the last 30 years, which one would you say has made the most positive contribution to society? (Open-ended responses recorded verbatim and coded into categories.)

	<i>Percentage</i>
Medical and health (e.g., vaccines, research, devices, medicines)	27
Computers and Internet	24
Mass communication (e.g., cell phones, satellites, TV, radio)	5
Biotechnology (e.g., cloning, embryo research, DNA, genetic research)	2
Other specific issues (e.g., transportation, space exploration)	2
Nothing positive occurred in past 30 years	0
Other	9
Don't know/not sure/no response	30

Virginia Commonwealth University Life Sciences, September 2002, N=1000.

Q6: How much do you agree or disagree with the following: "Scientific research these days doesn't pay enough attention to the moral values of society." Do you strongly agree, somewhat agree, somewhat disagree, or strongly disagree with that statement?

	<i>2004</i>	<i>2003</i>	<i>2002</i>	<i>2001</i>
Strongly agree	25	28	29	28
Somewhat agree	36	35	40	45
Somewhat disagree	22	23	20	15
Strongly disagree	12	9	9	8
Don't know	4	2	2	4
No answer	2	3	0	2

Virginia Commonwealth University Life Sciences, September 7-17, 2004, N=1004.

Q7: "Scientific research has created as many problems for society as it has solutions." Do you strongly agree, somewhat agree, somewhat disagree, or strongly disagree with that statement?

	<i>2004</i>	<i>2003</i>	<i>2002</i>	<i>2001</i>
Strongly agree	17	19	18	18
Somewhat agree	34	36	41	36
Somewhat disagree	30	29	28	26

	2004	2003	2002	2001
Strongly disagree	15	14	11	14
Don't know	4	2	2	4
No answer	0	1	1	2

Virginia Commonwealth University Life Sciences, September 2003, N=1003.

Q8: For each of the following, please tell me if it is very important, somewhat important, not too important, or not at all important to you personally. How about medical researchers finding cures for diseases such as Alzheimer's, diabetes, heart disease, and spinal cord injury?

	Percentage
Very important	82
Somewhat important	16
Not too important	1
Not at all important	1

CNN/ USA Today/ Gallup Poll, July 20, 2001, N=998.

Q34: Even if it brings no immediate benefits, scientific research which advances the frontiers of knowledge is necessary and should be supported by the federal government. Do you strongly agree, agree, disagree, or strongly disagree?

	Percentage
Strongly agree	19
Agree	62
Disagree	15
Strongly disagree	1
Won't say	*
Don't know	3

National Science Foundation, Public Attitudes Towards and Understanding of Science and Technology Trend Survey, February 28-April 30, 2001, N=1574.

Q110: If you were making up the budget for the federal government this year, would you increase spending for ... scientific research ... decrease spending for ... scientific research ... or keep spending the same for this?

	<i>Percentage</i>
Increase spending	41
Decrease spending	10
Spending the same	46
Don't know/refused	3

Pew Research Center, April 18-22, 2001, N=1202.

Q111: We are faced with many problems in this country, none of which can be solved easily or inexpensively. I'm going to name some of these problems, and for each one I'd like you to tell me whether you think we're spending too much money on it, too little money, or about the right amount. Are we spending too much, too little, or about the right amount on ... supporting scientific research?

	<i>Percentage</i>
Too little	34
About right	47
Too much	13
Don't know	6

General Social Survey, February 6-June 26, 2002, N=2765.

Q112: Now for a different type of question. People have frequently noted that scientific research has produced both beneficial and harmful consequences. Would you say that, on balance, the benefits of scientific research have outweighed the harmful results, are about equal, or have the harmful results of scientific research been greater than its benefits? Would you say that the balance has been strongly in favor of beneficial results, or only slightly? Would you say that the balance has been strongly in favor of harmful results, or only slightly?

	<i>Percentage</i>
Balance strongly in favor of beneficial results	47
Balance slightly in favor of beneficial results	25
About equal	19
Balance slightly in favor of harmful results	7
Balance strongly in favor of harmful results	3

National Science Foundation, Public Attitudes Towards and Understanding of Science and Technology Trend Survey, February 28-April 30, 2001, N=1574.

Q95: “The temptation to make money from new technologies puts pressure on scientists to pursue research ideas that violate ethical principles.” Do you strongly agree, somewhat agree, somewhat disagree, or strongly disagree?

	<i>Percentage</i>
Strongly agree	30
Somewhat agree	39
Somewhat disagree	19
Strongly disagree	8
Don't know	3

Virginia Commonwealth University Life Sciences, September 2002, N=1000.

Appendix K – Reproductive Cloning

Q10: Here are a few questions about a different topic, a process called cloning. As you may have read or heard, medical researchers are on the verge of discovering a way to create new embryos, called clones, from a fertile egg. The original embryo and its clones can grow into babies which are identical copies of each other. A cloned embryo can be frozen and put into a mother's womb for development at any time. In general, do you think cloning is a good thing or a bad thing to do?

	<i>Percentage</i>
Good thing	14
Bad thing	75
Not sure	11

Time/CNN, November 3, 1993, N=500

Q12: If you or your spouse were of child-bearing age, do you think you might be interested in cloning an embryo, or don't you think so?

	<i>Percentage</i>
Yes, might be interested	7
No	90
Not sure	3

Time/CNN, November 3, 1993, N=500

Q14: Do you think cloning is morally wrong, or don't you feel this way?

	<i>Percentage</i>
Yes, morally wrong	58
Don't feel this way	31
Not sure	11

Time/CNN, November 3, 1993, N=500

Q15: Do you think cloning is against God's will, or don't you feel this way?

	<i>Percentage</i>
Against God's will	63
Don't feel this way	26
Not sure	11

Time/CNN, November 3, 1993, N=500

Q17: On a scale of 1 to 5, where 1 is unacceptable and 5 is acceptable, how acceptable do you find the use of cloning to make copies of humans?

	<i>Percentage</i>
5 (acceptable)	-
4	-
3	3
2	6
1 (unacceptable)	86

International Food Information Council, March 1997, N=1004

Q18: Would you favor or oppose the cloning of human beings?

	<i>Percentage</i>
Favor	6
Oppose	88
Not sure	6

NBC News/*Wall Street Journal* Poll, March 10, 1997, N=2010

Q19: Recently, a scientist in Scotland successfully cloned, or made an exact genetic copy, of one sheep from another sheep. From what you know, do you think cloning is a good thing or a bad thing?

	<i>Percentage</i>
Good thing	22
Bad thing	62
Depends	10
Not sure	6

Q131: Here are a few questions about a different topic – a process called “cloning,” in which genetic material is taken from an animal and implanted into an unfertilized egg. The egg is allowed to develop into an exact duplicate, or “clone,” of the original animal. Currently, medical researchers have been able to clone sheep and other animals, but have not been able to use the same techniques on humans. Suppose for a moment that it were possible to clone human beings as well as animals. Do you think it is against God’s will to clone human beings, or don’t you feel this way?

	<i>Percentage</i>
Yes, against God’s will	74
No, not against God’s will	19
Not sure	7

Time/CNN, February 26-27, 1997, N=1005.

Q110: Here are a few questions about a different topic – a process called “cloning,” in which genetic material is taken from an animal and implanted into an unfertilized egg. The egg is allowed to develop into an exact duplicate, or “clone,” of the original animal. Currently, medical researchers have been able to clone sheep and other animals, but have not been able to use the same techniques on humans. Suppose for a moment that it were possible to clone human beings as well as animals. Do you think that it is morally acceptable to clone human beings, or don’t you feel this way?

	<i>Percentage</i>
Yes, morally acceptable	7
No, not morally acceptable	89
Not sure	4

Time/CNN, February 26-27, 1997, N=1005

Q111: Here are a few questions about a different topic – a process called “cloning,” in which genetic material is taken from an animal and implanted into an unfertilized egg. The egg is allowed to develop into an exact duplicate, or “clone,” of the original animal. Currently, medical researchers have been able to clone sheep and other animals, but have not been able to use the same techniques on humans. Suppose for a moment that it were possible to clone human beings

as well as animals. In general, do you think it is a good idea or a bad idea to clone human beings?

	<i>Percentage</i>
Good idea	4
Bad idea	93
Not sure	3

Time/CNN, February 26-27, 1997, N=1005.

Q20: Do you favor or oppose using genetic technology – calling cloning – to create a new human being who would be an exact copy of a particular individual?

	<i>Percentage</i>
Favor	8.4
Oppose	83.7
It depends on proper controls, etc.	2.7
Volunteered no opinion	5.2

Southern Focus Poll, Spring 1998, N=1200

Q23: Suppose it does become possible to clone human beings. Would that be good for society, bad for society, or have no impact on society?

	<i>Percentage</i>
Good	10
Bad	73
No impact	9
Not sure	8

Portrait of America, August 23, 2000, N=1000

Q27: If it becomes possible, do you think the cloning of humans should or should not be allowed?

	<i>Percentage</i>
Should	9
Should not	89
No opinion	2

Gallup Poll, June 7, 2001, N=1012

Q26: Do you think scientists should be allowed or should not be allowed to try to clone human beings?

<i>Percentage</i>	<i>overall</i>	<i>men</i>	<i>women</i>
Should be allowed	11	15	8
Should not be allowed	85	80	89
Don't know	4	5	3

CBS News/*New York Times* Poll, May 15, 2002, N=647

Q28: The technology now exists to clone or genetically alter animals. How much do you favor or oppose allowing the same thing to be done in humans – do you strongly favor, somewhat favor, somewhat oppose, or strongly oppose this?

	<i>2003</i>	<i>2002</i>	<i>2001</i>
Strongly favor	4	6	4
Somewhat favor	9	10	10
Somewhat oppose	19	16	18
Strongly oppose	65	65	64
Don't know	1	1	2
No answer	1	2	1

Virginia Commonwealth University Life Sciences, September 2003, N=1003

Q11: Do you approve or disapprove of the use of cloning for each of the following purposes? To make it possible for parents to have a twin child at a later date, if they wanted to.

	<i>Percentage</i>
Approve	17
Disapprove	78
Not sure	5

Time/CNN, November 3, 1993, N=500

Q13: Suppose it were possible for your parents to have cloned you when you were an embryo. Do you think you would like to have been cloned, or not?

	<i>Percentage</i>
Yes, like to be cloned	6
No	86
Not sure	6

Time/CNN, November 3, 1993, N=500

Q9: Do you approve or disapprove of the use of cloning for each of the following purposes?
To provide infertile couples using test-tube fertilization with more embryos to increase their chances of conceiving.

	<i>Percentage</i>
Approve	45
Disapprove	46
Not sure	9

Time/CNN, November 3, 1993, N=500

Q16: If you found out you only had one year to live, would you want to clone yourself?

	<i>total</i>	<i>male</i>	<i>female</i>
Yes	6.5	9.5	3.4
No	91.1	88.1	94.2
Don't know/refused	2.4	2.5	2.4

Global Strategy Group, Inc., June 30, 1997, N=800

Q120: Here are a few questions about a different topic – a process called “cloning,” in which genetic material is taken from an animal and implanted into an unfertilized egg. The egg is allowed to develop into an exact duplicate, or “clone,” of the original animal. Currently, medical researchers have been able to clone sheep and other animals, but have not been able to use the same techniques on humans. Suppose for a moment that it were possible to clone human beings as well as animals. If you had the chance, would you clone yourself, or wouldn't you do that?

	<i>Percentage</i>
Would	7
Would not	91
Not sure	2

Time/CNN, February 26-27, 1997, N=1005

Q22: What about cloning to allow infertile couples to have a child? Would you favor or oppose cloning for that purpose?

	<i>Percentage</i>
Favor in that case	11.4
Oppose in that case	80.3
It depends volunteered	4.7
No opinion	3.6

Southern Focus Poll, Spring 1998, N=1200

Q121: Do you approve or disapprove of the use of cloning for each of the following purposes? To provide infertile couples using test-tube fertilization with more embryos to increase their chances of conceiving.

	<i>Percentage</i>
Approve	33
Disapprove	63
Not sure	4

Time/CNN, December 17-18, 1998, N=1031

Q122: If a very young child were to die of causes that were not genetically related, do you believe that the parents of this child should have the right to use cloning to create another child, one that is a genetic copy of the one who died, or don't you believe so?

	<i>Percentage</i>
Yes, should be able to	10
No, should not be able to	87
Not sure	3

Time/CNN, December 17-18, 1998, N=1031

Q123: Do you approve or disapprove of the use of cloning for each of the following purposes? To produce babies whose vital organs can be used to save the lives of others.

	<i>Percentage</i>
Approve	19
Disapprove	78
Not sure	3

Time/CNN, December 17-18, 1998, N=1031

Q124: Do you approve or disapprove of the use of cloning for each of the following purposes? To make it possible for parents to have a twin child at a later date, if they wanted to.

	<i>Percentage</i>
Approve	13
Disapprove	86
Not sure	2

Time/CNN, December 17-18, 1998, N=1031

Q125: Do you think each of the following justifies creating a human clone or don't you think so? To allow gay couples to have children using only their own genes.

	<i>Percentage</i>
Yes	10
No	86
Not sure	4

Time/CNN, February 7-8, 2001, N=1015

Q126: Do you think each of the following justifies creating a human clone or don't you think so?) To create genetically superior human beings.

	<i>Percentage</i>
Yes	6
No	92
Not sure	2

Time/CNN, February 7-8, 2001, N=1015

Q127: Do you think each of the following justifies creating a human clone or don't you think so? To allow parents to have a twin child at a later date if they wanted to.

	<i>Percentage</i>
Yes	10
No	88
Not sure	2

Time/CNN, February 7-8, 2001, N=1015

Q128: Do you think each of the following justifies creating a human clone or don't you think so? To produce copies of humans whose vital organs can be used to save the lives of others.

	<i>Percentage</i>
Yes	28
No	68
Not sure	4

Time/CNN, February 7-8, 2001, N=1015

Q129: Do you think each of the following justifies creating a human clone or don't you think so? To save the life of the person who is being cloned.

	<i>Percentage</i>
Yes	21
No	74
Not sure	5

Time/CNN, February 7-8, 2001, N=1015

Q130: Do you think each of the following justifies creating a human clone or don't you think so? To help infertile couples to have children without having to adopt.

	<i>Percentage</i>
Yes	20
No	76
Not sure	4

Time/CNN, February 7-8, 2001, N=1015

Q24: We'd like to ask you some questions about cloning. [...] How about cloning of endangered species to keep them from becoming extinct?

	<i>Percentage</i>
Favor	38
Oppose	58
No opinion	4

Gallup Poll, May 16, 2002, N=1012

Q25: If a company announced that a perfect copy of your pet could be made when the pet got old or died, would you order a copy or not?

	<i>Percentages</i>
Yes	6
No	92
Not sure	2

Fox Broadcasting Company, February 15, 2002, N= 900

Q29: Should researchers be allowed to clone animals, such as pigs, sheep, and cows?

	<i>Percentage</i>
Yes	41
No	42
Not sure	17

Portrait of America, August 23, 2000, N=1000

Q41: When the technology is developed, do you think cloning should be completely legal, without restrictions; do you think cloning should be legal but tightly regulated; or do you think cloning should be illegal?

	<i>Percentage</i>
Completely legal	3
Legal but regulated	46
Illegal	46
Not sure	5

Time/CNN, November 3, 1993, N=500

Q21: Do you favor or oppose an outright ban on the cloning of human beings?

	<i>Percentage</i>
Favor	58
Oppose	36
Not sure	6

NBC News/*Wall Street Journal* Poll, January 1998, N=1005

Q138: Do you think that cloning that is designed specifically to result in the birth of a human being should be legal or illegal in the United States?

	<i>Percentage</i>
Legal	11
Illegal	86
No opinion	3

CNN/*USA Today*/Gallup, January 3-5, 2003, N=1000

Appendix L – Research Cloning

Q37: I'm going to mention several issues, and I'd like to get your reaction. For each item I read, please tell me whether this is something you strongly favor, somewhat favor, somewhat oppose, or strongly oppose: Banning medical research on human cloning.

	<i>Percentage</i>
Strongly favor	35
Somewhat favor	12
Somewhat oppose	17
Strongly oppose	31
Not sure	5

NBC News, 1999; N=2011.

Q38: The British government may pass legislation allowing the cloning of human embryos for medical research. Should researchers be allowed to clone human embryos for medical research?

	<i>Percentage</i>
Yes	24
No	64
Not sure	12

Portrait of America, August 23, 2000; N=1000.

Q33: Do favor or oppose each of the following? How about – cloning of human embryos for use in medical research?

	<i>Percentage</i>
Favor	34
Oppose	61
Don't know	4.6
Refused	0.6

Gallup Poll Social Series, May 5, 2002; N=1012.

Q150: Do you approve or disapprove of cloning that is not designed specifically to result in the birth of a human being, but is designed to aid medical research that might find treatments for certain diseases?

	<i>Percentage</i>
Approve	54
Disapprove	41
No opinion	5

CNN/USA Today, November 26-27, 2001; N=1025.

Q45: Do you favor or oppose using human cloning technology if it is used only to help medical research develop new treatments for diseases – do you strongly favor, somewhat favor, somewhat oppose, or strongly oppose this?

	<i>Percentage</i>
Strongly favor	21
Somewhat favor	24
Somewhat oppose	13
Strongly oppose	38
Don't know	2
No answer	1

Virginia Commonwealth University, September 4-16, 2002; N=1000.

Q44: Do you favor or oppose using human cloning technology if it is used only to help medical research develop new treatments for disease? Do you strongly favor, somewhat favor, somewhat oppose, or strongly oppose this?

	<i>Percentage</i>
Strongly favor	21
Somewhat favor	29
Somewhat oppose	16
Strongly oppose	32
Don't know	2
No answer	1

Virginia Commonwealth University, September 3-26, 2003; N=1003.

Q151: Do you favor or oppose using human cloning technology if it is used only to help medical research develop new treatments for disease? Do you strongly favor, somewhat favor, somewhat oppose, or strongly oppose this?

	<i>Percentage</i>
Strongly favor	16
Somewhat favor	26
Somewhat oppose	18
Strongly oppose	38
Don't know	2
No answer	1

Virginia Commonwealth University, September 7-17, 2004; N=1004.

Q152: Thinking for a moment about cloning: Do you approve or disapprove of cloning that is not designed to specifically result in the birth of a human being, but is designed to aid medical research that might find treatments for certain diseases?

	<i>Percentage</i>
Approve	54
Disapprove	41
No opinion	5

CNN/*USA Today*/Gallup Poll, November 26-27, 2001; N=507.

Q35: Do you think it is always, often, seldom, or never a sin to use cloning – that is, copying DNA cells – in medical research that could result in a cure for diseases such as Alzheimer's, Parkinson's, or cancer?

	<i>All</i>	<i>Liberal</i>	<i>Moderate</i>	<i>Conservative</i>
Always	45	23	46	66
Often	18	24	19	13
Seldom	16	26	15	7
Never	8	15	7	4
Refused	13	12	13	10

Los Angeles Times, October 20, 2002; N=1854.

Q36: As with any transplant, some patients may have problems with their bodies rejecting stem cells. To overcome this, a patient's own genetic material can be inserted into an egg to create an embryo that will be used to extract stem cells. The process is called nuclear transfer or therapeutic cloning. Do you approve or disapprove?

	<i>Percentage</i>
Approve	40
Disapprove	41
Undecided	19

Roy Morgan Research, July 24, 2001; N=501.

Q40: Should human embryo cloning be allowed for the treatment of disease?

	<i>Percentage</i>
Yes	33
No	48
Not sure	19

Portrait of America, August 23, 2000; N=1000.

Q153: Do you favor the government allowing scientists to do therapeutic cloning research to produce stem cells for treating life-threatening diseases?

	<i>Percentage</i>
Support	68
Oppose	26
Don't know	6

Coalition for the Advancement of Medical Research, April 18-21, 2002; N=1001.

Q154: Therapeutic cloning is the use of cloning technology to help in the search for possible cures and treatments for diseases and disabilities. Do you think that research into therapeutic cloning should be allowed?

	<i>Percentage</i>
Yes	59
No	35
Don't know	6

Research!America, June 2005; N=1000.

Q30: Now I would like to ask about a few specific types of research on stem cells developed from human embryos that have been created outside a woman's womb. This kind of stem cell research destroys the embryos but may help find treatments for major diseases. Some stem cells may be developed from embryos produced by cloning cells from a living human being rather than by fertilizing a woman's egg. Do you think the federal government should or should not fund research on stem cells from this kind of embryo?

	<i>Percentage</i>
Yes should	28.2
No should not	66.2
Don't know	4.8
Refused	0.8

CNN/USA Today, August 3-5, 2001; N=1017.

Q155: Some scientists want to use human cloning for medical treatments only. They would produce a fertilized egg, or human embryo, that's an exact genetic copy of a person, and then take cells from this embryo to provide medical treatments for that person. Supporters say this could lead to medical breakthroughs. Opponents say it could lead to the creation of a cloned person, because someone could take an embryo that was cloned for medical treatments and use it to produce a child. Do you think human cloning for medical treatments should be legal or illegal in the United States?

	<i>Percentage</i>
Legal	33
Illegal	63
No opinion	4

ABC News/Beliefnet, August 8-12, 2001; N=1024.

Q43: Should scientists be allowed to use human cloning to create a supply of human embryos to be destroyed in medical research?

	<i>Percentage</i>
Yes	13.3
No	79.8
Don't know	6.1
Refused	0.7

Pro-Life Secretariat of the U.S. Conference of Catholic Bishops, August 13-17, 2004; N=1001.

Q156: If you had to choose, which comes closest to your preference? A complete ban on all research into human cloning without exception. A ban on human cloning of full-grown humans, while still allowing research on cloned embryos, to learn more about certain diseases. Oppose any law that restricts research into human cloning.

	<i>12/01</i>	<i>6/01</i>
A complete ban	33	42
Allow research on embryos	39	39
Oppose any restrictions	21	17
Not sure	6	2

Ipsos Reid Express, November 30-December 2, 2001; N=1000.

Q157: As you may know, Congress is considering several proposals to ban human cloning. Which of the following positions do you most agree with – human cloning should not be banned, only human cloning that leads to the birth of a human should be banned, but cloning for purposes of laboratory research should be allowed, or all human cloning should be banned?

	<i>Percentage</i>
Should not be banned	4
Should be allowed for purposes of research	34
Should be banned	59
Other (vol.)	1
No opinion	2

Gallup, January 13-16, 2003; N=1000.

Q39: Which of these statements comes closest to your view on human cloning: I support a complete ban on all research into human cloning without exception; I support a ban on human cloning that would still allow research on cloned embryos to learn more about diseases; or I oppose any law that restricts research into human cloning.

	<i>All</i>	<i>Democrats</i>	<i>Ind.</i>	<i>Republicans</i>
Complete ban	43	31	37	58
Partial ban	41	47	49	34
Oppose law restricting	11	17	12	6
Don't know	5	5	2	2

Los Angeles Times, January 30-February 2, 2003; N=1385.

	<i>Favor</i>	<i>Oppose</i>	<i>Intensity</i>
<i>Neutral formulation:</i>			
NBC News, 1999; N=2011 (37)	48	47	~
Portrait of America, August 23, 2000; N=1000 (38)	24	64	--
<i>Research benefits:</i>			
<i>Los Angeles Times</i> , October 20, 2002; N=1854 (35)	24	63	--
Roy Morgan Research, July 24, 2001 (36)	40	41	~
Portrait of America, August 23, 2000; N=1000 (40)	33	48	--
Virginia Commonwealth Univ., Sep. 2003; N=1003 (44)	49	48	~
Virginia Commonwealth Univ., Sep. 2002; N=1000 (45)	45	51	~
CNN/ <i>USA Today</i> , Nov. 2001; N=1025 (150)	54	41	+
Virginia Commonwealth Univ., Sep. 2004; N=1004 (151)	42	56	-
CNN/ <i>USA Today</i> /Gallup, Nov. 2001; N=507 (152)	54	41	+
Coal. for the Adv. of Med. Res., Apr. 2002; N=1001 (153)	68	26	++
Research!America, June 2005; N=1000 (154)	59	35	++
<i>Research benefits and destruction of embryos:</i>			
Gallup Poll, August 2001; N=1017 (30)	28	66	--

Table 18: Summary data.

Appendix M – Stem Cell Research

Q54: On the whole, do you strongly support, somewhat support, somewhat oppose, or strongly oppose medical research that uses stem cells from human embryos?

	<i>Percentage</i>
Strongly support	34
Somewhat support	26
Somewhat oppose	11
Strongly oppose	16
Don't know	13

Opinion Research Corporation, June 10-13, 2004, N=1017.

Q50: Based on what you know about embryonic stem cell research, would you say you favor or oppose it?

	<i>Percentage</i>
Strongly favor	18
Somewhat favor	21
Somewhat oppose	11
Strongly oppose	22
Unsure/need more info	25
Refused	3

Juvenile Diabetes Foundation, March 2004, N=600 (conservative voters).

Q51: Based on what you know, do you support or oppose each of the following: Allowing medical research using tissue from fertilized human eggs – commonly called stem cell research.

	<i>Percentage</i>
Support	43
Oppose	40
Don't know	17

Fox Broadcasting, July 13, 2001, N=900.

Q52: Percentage of likely voters who support stem cell research

	<i>Percentage</i>
Support	52
Oppose	30

Zogby International, July 30 2001, N=1006.

Q53: On the whole, how much do you favor or oppose medical research that uses stem cells from human embryos – do you strongly favor, somewhat favor, somewhat oppose, or strongly oppose this?

	<i>2003</i>	<i>2002</i>	<i>2001</i>
Strongly favor	17	12	17
Somewhat favor	30	23	31
Somewhat oppose	21	22	21
Strongly oppose	23	29	22
Don't know	6	11	7
No answer	3	4	2

Virginia Commonwealth University Life Sciences, September 2003, N=1003.

Q60: Do you approve or disapprove of stem cell research – that is, medical research using tissue from human embryos?

	<i>All</i>	<i>Pro-choice</i>	<i>Pro-life</i>
Approve	46	67	27
Disapprove	37	21	54
Not sure	17	12	18

Fox Broadcasting, August 1, 2003, N=900.

Q61: I'm going to read you a list of issues. Regardless of whether or not you think it should be legal, for each one, please tell me whether you personally believe that in general it is morally

acceptable or morally wrong. How about medical research using stem cells obtained from human embryos?

	<i>Percentage</i>
Morally acceptable	54
Morally wrong	38
Depends	3
Not a moral issue	0
No opinion	5

Gallup Poll, May 14, 2003, N=1005.

Q62: Please indicate whether you tend to agree or disagree with the following statement: Using cells from human embryos for research comes too close to allowing scientists to play God.

	<i>Percentage</i>
Agree	40
Disagree	53
Not sure/refused	7

Harris Poll, July 25, 2001, N=1011.

Q63: Please indicate whether you tend to agree or disagree with the following statement: Allowing any medical research using stem cells from human embryos should be forbidden because it is unethical and immoral.

	<i>Percentage</i>
Agree	32
Disagree	60
Not sure/refused	8

Harris Poll, July 25, 2001, N=1011.

Q64: Which of the following statements comes closest to your own point of view about stem cell research:

A: Stem cell research is an important step forward in finding a cure or treatment for things like Parkinson's disease and MS. Such research should be funded by the U.S. government because of the possibility of helping millions of people overcome such devastating diseases.

B: Stem cell research will take the lives of innocent unborn children. Taking the life of an innocent person to help another is immoral. We must find another way to help people suffering from things like Parkinson’s disease and MS.

	<i>Percentage</i>
Important (A)	52.3
Immoral (B)	30.0
Neither	6.2
Not sure	11.5

Zogby International, August 9, 2001, N=1006.

Q66: Which comes closest to your view of this kind of stem cell research – it is morally wrong and is unnecessary, it is morally wrong, but may be necessary, it is not morally wrong and may be necessary, or it is not morally wrong but is unnecessary?

	<i>Percentage</i>
Wrong and unnecessary	19.9
Wrong, may be necessary	34.2
Not wrong, may be necessary	34.5
Not wrong, unnecessary	4.1
No opinion	7.3

CNN/USA Today/Gallup Poll, July 20, 2001, N=998.

Q68: I am going to read you a list of issues. Regardless of whether or not you think it should be legal, for each one, please tell me whether you personally believe that in general it is morally acceptable or morally wrong. How about – medical research using stem cells obtained from human embryos.

	<i>Percentage</i>
Morally acceptable	51.8
Morally wrong	39.3
Depends on the situation	2.2
Not a moral issue	0.4
Don’t know	5.8
Refused	0.4

Gallup Poll, May 2002, N=1012.

Q69: As you may know, President Bush gave a speech Thursday night on stem cell research, and he announced that he would allow the government to fund research using stem cells that have been created in the past in a process that destroyed human embryos. The government will not fund stem cell research that would destroy additional embryos in the future. Thinking about embryos that have been created in a laboratory by fertilizing a woman's egg outside the womb and have not been implanted in a woman's womb, which comes closer to your view about this type of embryo:

- The embryo is a human life that should be given the same protection as all other human lives.
- The embryo has the potential for life, but is not the same as life, because it cannot develop on its own.

	<i>Percentage</i>
The embryo is a human life that should be given the same protection as all other human lives	35.9
The embryo has the potential for life, but is not the same as life, because it cannot develop on its own	59.9
Don't know/refused	4.2

Gallup Poll, August 2001, N=1017.

Q47: Do you think the federal government should or should not fund stem cell research?

	<i>Percentage</i>
Should	43
Should not	35
Depends	4
No opinion	18

Pew Research Center for the People and the Press and the Press and Pew Forum on Religion and Public Life, February 25, 2002, N=2002.

Q55: Based on what you have read or heard, do you think that the federal government should or should not fund stem cell research?

	<i>Percentage</i>
Should	43
Should not	27
Depends	3
Not sure	27

Time/CNN, July 19, 2001, N=1015.

Q57: Do you think the federal government should or should not fund this type of research [stem cell research]?

	<i>Percentage</i>
Should	55
Should not	29
Depends	3
No opinion	13

CNN/USA Today/Gallup Poll, August 10, 2001, N=581.

Q46: Do you support federal funding of stem cell research?

<i>Personal View</i>	<i>July 30</i>	<i>June 24</i>
Support	63	58
Oppose	58	30

<i>Government Funding</i>	<i>July 30</i>	<i>June 24</i>
Support	60	36
Oppose	60	31

Washington Post/ABC News, July 26, 2001, N=1352

Q58: Please indicate whether you tend to agree or disagree with the following statement: As long as the parents of the embryo give their permission, and the embryo would otherwise be destroyed, stem cell research should be allowed.

	<i>Percentage</i>
Tend to agree	72
Tend to disagree	13
Not sure/refused	15

Harris Interactive, July 12-18, 2004, N=2242.

Q59: I'm going to read you a brief description of embryonic stem cell research, and then get your reaction. Embryonic stem cells are special cells that can develop into every type of cell in the human body. The stem cells are extracted from frozen embryos in fertility clinics, donated by couples who no longer want or need the embryo. This process destroys the embryo. These stem cells can then reproduce on their own, creating what is called a "line" of stem cells that many researchers can work with. Scientists believe that there is a good chance that stem cells can be developed into cures or treatments for diseases such as cancer, Parkinson's, Alzheimer's, juvenile diabetes, and spinal cord injuries. Having heard this description, do you strongly support, somewhat support, somewhat oppose, or strongly oppose medical research that uses stem cells from human embryos?

	<i>Percentage</i>
Strongly support	41
Somewhat support	32
Somewhat oppose	10
Strongly oppose	14
Don't know	4

Results for America, June 10-13, 2004, N=1017.

Q92: I'm going to read you a brief description of embryonic stem cell research, and then get your reaction. Embryonic stem cells are special cells that can develop into every type of cell in the human body. The stem cells are extracted from frozen embryos in fertility clinics, donated by couples who no longer want or need the embryo. This process destroys the embryo. These stem cells can then reproduce on their own, creating what is called a "line" of stem cells that many researchers can work with. Scientists believe that there is a good chance that stem cells can be developed into cures or treatments for diseases such as cancer, Parkinson's, Alzheimer's, juvenile diabetes, and spinal cord injuries. Having heard this description, do you strongly support, somewhat support, somewhat oppose, or strongly oppose medical research that uses stem cells from human embryos?

	<i>Percentage</i>
Strongly support	43
Somewhat support	29
Somewhat oppose	11
Strongly oppose	14
Don't know	2

Results for America, February 3-6, 2005, N=1022.

Q96: Stem cells come from embryos left over from in vitro fertilization, which are not used and normally destroyed. Many medical researchers want to use them to develop treatments, or to prevent diseases, such as diabetes, Alzheimer's or Parkinson's disease. On balance, do you think this research should or should not be allowed?

	<i>2001</i>	<i>2004</i>
Should be allowed	61	73
Should not be allowed	21	11
Not sure/refused	18	16

Harris Interactive, July 12-18, 2004, N=2242.

Q90: Two years have passed since President Bush's decision on this issue. Only 11 stem cell groups have become available for research so far and many scientists say that the research value of such a limited pool of cell groups is hindering progress in the search for cures. I'm going to read you what some people are saying, and please tell me whom you agree with most:

	<i>Percentage</i>
Group A says there should be a ban on all embryonic stem cell research and no federal funding. They say research based on destroyed embryos is wrong.	23
Group B says that we should continue to research only those stem cell groups developed from embryos destroyed in the past. They say that destroying human embryos in order to create new stem cell groups is wrong and that the currently available stem cell groups are enough for scientists.	23
Group C says that President Bush's decision should be broadened to include federal funding for research on stem cells developed from excess embryos frozen in fertility clinics. They say these excess embryos are almost certain to be discarded at the direction of couples that have successfully had children. But with a couple's consent, these frozen embryos could be used in research and bring us closer to important cures for diabetes, Parkinson's, Alzheimer's, cancer, heart disease, severe burns, and spinal cord injuries.	44

Juvenile Diabetes Foundation, March 2004, N=600.

Q81: Stem cells come from embryos left over from in vitro fertilization, which are not used and are normally destroyed. Many medical researchers want to use them to develop treatments, or to prevent diseases, such as diabetes, Alzheimer's, or Parkinson's disease. On balance, do you think this research should or should not be allowed?

	<i>All</i>	<i>Republican</i>	<i>Democrat</i>	<i>Ind.</i>
Should be allowed	61	49	68	68
Should not be allowed	21	33	16	15
Not sure/refused	18	18	16	17

Harris Poll, July 25, 2001, N=1011.

Q82: Please indicate whether you tend to agree or disagree with the following statement. As long as the parents of the embryo give their permission, and the embryo would otherwise be destroyed, stem cell research should be allowed.

	<i>Percentage</i>
Agree	72
Disagree	21
Not sure/refused	7

Harris Poll, July 25, 2001, N=1011.

Q83: I would like to ask about a few specific types of research on stem cells developed from human embryos that have been created outside a woman's womb. This kind of stem cell research destroys the embryos but may help find treatments for major diseases. As you may know, fertility clinics increase a woman's chance to have a child by fertilizing several embryos, but only a few are implanted in her womb to enable her to have a baby. Some stem cells are developed from the remaining embryos that the fertility clinics usually discard. Do you think the federal government should or should not fund research on stem cells from this kind of embryo?

	<i>Percentage</i>
Should	55
Should not	40
Depends	2
No opinion	3

CNN/USA Today/Gallup Poll, August 10, 2001, N=581.

Q84: As you may know, this kind of so-called stem cell research is being used by scientists trying to find cures for diseases such as Alzheimer’s disease, Parkinson’s disease, or diabetes. It involves using destroyed embryos discarded from fertility clinics that no longer need them. Do you favor or oppose using discarded embryos to conduct stem cell research to try to find cures for diseases such as those I mentioned?

	<i>Percentage</i>
Favor	75.0
Oppose for moral reasons	16.2
Oppose for other reasons	3.5
Don’t know	5.7

Ipsos Reid, August 13, 2001, N=1000.

Q86: The kind of stem-cell research the government is considering involves human embryos that have been created in medical clinics by fertilizing a woman’s egg outside the womb. An embryo may be implanted into a woman’s womb to develop into a baby. If an embryo is not implanted into a woman’s womb to develop into a baby, it may be destroyed, either by being discarded or by being used for medical research. Some scientists believe this type of medical research could lead to treatments for such diseases as Alzheimer’s, diabetes, heart disease, and spinal cord injuries. Given this information, do you think the federal government should or should not fund this type of research?

	<i>Percentage</i>
Should	54.6
Should not	38.6
No opinion	7.8

CNN/USA Today/Gallup Poll, July 20, 2001, N=998.

Q87: Sometimes fertility clinics produce extra fertilized eggs, also called embryos, that are not implanted in a woman’s womb. These extra embryos either are discarded, or couples can donate them for use in medical research called stem cell research. Some people support stem cell research, saying it’s an important way to find treatments for many diseases. Other people oppose stem cell research, saying it’s wrong to use any human embryos for research purposes. What about you – do you support or oppose stem cell research?

	<i>Percentage</i>
Support	63
Oppose	33
No opinion	4

Washington Post/ABC News, August 2, 2001, N=1352.

Q88: Now I would like to ask about a specific type of research on stem cells developed from human embryos that have been created outside a woman’s womb. This kind of stem cell research destroys the embryos but may help find treatments for major diseases. As you may know, fertility clinics increase a woman’s chance to have a child by fertilizing several embryos, but only a few are implanted in her womb to enable her to have a baby. Some stem cells are developed from the remaining embryos that the fertility clinics usually discard. Which comes closest to your view of this kind of stem cell research:

- It is morally wrong and unnecessary.
- It is morally wrong, but may be necessary.
- It is not morally wrong and may be necessary; or it is not morally wrong but is unnecessary.

	<i>Percentage</i>
It is morally wrong and is unnecessary	18.1
It is morally wrong, but may be necessary	31
It is not morally wrong and may be necessary	42
It is not morally wrong but is necessary	4.4
Don’t know/refused	4.2

Gallup poll, August 2001, N=1017.

Q108: Sometimes fertility clinics produce extra fertilized eggs, also called embryos, that are not implanted in a woman’s womb. These extra embryos either are discarded, or couples can donate them for use in medical research, called stem cell research. Some people support stem cell research, saying it’s an important way to find treatments for many diseases. Other people oppose stem cell research, saying it’s wrong to use any human embryos for research purposes. What about you – do you support or oppose stem cell research?

	<i>Support</i>	<i>Oppose</i>
Total	58	30
<i>Gender:</i>		
Women	58	30
Men	57	30
<i>Race:</i>		
Blacks	48	44
Whites	60	29
<i>Abortion:</i>		
Legal	76	15
Illegal	39	50

ABC News/Beliefnet, June 2001, N=1022.

Q70: One of the issues involved in this type of (stem cell) research is whether or not the embryos used were developed specifically for stem cell research. Do you think the federal government should or should not allow scientists to fertilize human eggs specifically for the purpose of creating new stem cells?

	<i>Percentage</i>
Yes	38.2
No	53.5
No opinion	8.3

CNN/USA Today/Gallup Poll, July 20, 2001, N=998.

Q71: Now I would like to ask about a few specific types of research on stem cells developed from human embryos that have been created outside a woman's womb. This kind of stem cell research destroys the embryos but may help find treatments for major diseases. Some stem cells are developed from embryos that are created in laboratories specifically for the purpose of conducting this research and not to help women have a child. Do you think the federal government should or should not fund research on stem cells from this kind of embryo?

	<i>Percentage</i>
Yes, should	46.5
No, should not	48.9
Depends	1
Don't know	3.2
Refused	0.3

Gallup, August 2001, N=1017.

Appendix N – Genetic Engineering

Q101: Do you approve or disapprove of the use of cloning for each of the following purposes? To establish embryos banks from which prospective parents could select a child with genetic characteristics they desire.

	<i>Percentage</i>
Approve	16
Disapprove	80
Not sure	4

Time/CNN, November 1993, N=500.

Q102: Do you approve or disapprove of the use of cloning for each of the following purposes? To make it possible for societies to clone and reproduce large numbers of individuals with genetically desirable traits.

	<i>Percentage</i>
Approve	6
Disapprove	89
Not sure	5

Time/CNN, November 1993, N=500.

Q107: Do you approve or disapprove of the use of cloning for each of the following purposes? To make it easier for scientists to screen embryos for inherited abnormalities.

	<i>Percentage</i>
Approve	40
Disapprove	52
Not sure	8

Time/CNN, November 1993, N=500

Q160: It is now possible for scientists to make a test tube baby that is guaranteed to be free of certain genetic diseases. Do you think this is a good use of genetic engineering, or do you think this is going too far?

	<i>Percentage</i>
Good thing	26
Going too far	67
Don't know/no answer	7

CBS News, February 15-17, 1994, N=1193.

Q162: If you were planning to have a child and could choose various traits your baby would have, do you think you would or would not choose to... rule out a genetically transmitted fatal or crippling disease?

	<i>Percentage</i>
Would choose	60
Would not choose	35
Not sure	5

Time/CNN, December 17-18, 1998, N=1031.

Q163: If you were planning to have a child and could choose various traits your baby would have, do you think you would or would not choose to... determine the child's sex?

	<i>Percentage</i>
Would choose	11
Would not choose	88
Not sure	1

Time/CNN, December 17-18, 1998, N=1031.

Q164: If you were planning to have a child and could choose various traits your baby would have, do you think you would or would not choose to... ensure greater intelligence for the child?

	<i>Percentage</i>
Would choose	33
Would not choose	65
Not sure	2

Time/CNN, December 17-18, 1998, N=1031.

Q165: If you were planning to have a child and could choose various traits your baby would have, do you think you would or would not choose to... influence the child's height or weight?

	<i>Percentage</i>
Would choose	13
Would not choose	86
Not sure	2

Time/CNN, December 17-18, 1998, N=1031.

Q166: If you were planning to have a child and could choose various traits your baby would have, do you think you would or would not choose to... influence other physical characteristics of the child such as hair or eye color?

	<i>Percentage</i>
Would choose	10
Would not choose	89
Not sure	1

Time/CNN, December 17-18, 1998, N=1031.

Q103: New technology in science and medicine may allow couples who want to have a baby to pick and choose the baby's genetic characteristics such as hair color or the risk for certain diseases. Do you strongly favor, somewhat favor, somewhat oppose, or strongly oppose picking and choosing an unborn baby's characteristics using these new technologies?

	<i>Percentage</i>
Strongly favor	5
Somewhat favor	13
Somewhat oppose	21
Strongly oppose	58
Don't know	2
No answer	2

Virginia Commonwealth University Life Sciences, September 2002, N=1000

Q167: Would you approve or disapprove if parents were offered a way to use PGD to:

	<i>Approve</i>	<i>Disapprove</i>	<i>Don't know</i>	<i>Refused</i>
a. Choose the sex of their child	28	68	4	*
b. Make sure their baby does NOT have a serious genetic disease	74	22	4	*
c. Make sure their baby has desirable characteristics such as high intelligence and strength	22	72	5	*
d. Make sure their baby does NOT have a tendency to develop a disease like cancer when he or she is an adult	60	33	6	*
e. Make sure their baby would be a good match to donate his or her blood or tissue to a brother or sister who is sick and needs a transplant	69	25	5	1

Genetics and Public Policy Center, October 15-29, 2002, N=1211.

Q168: When you think about these topics (genetic testing, in vitro fertilization, genetic engineering, and cloning), which of the following, if any, do you think is the greatest benefit? That parents can improve the chances their baby will be healthy, that parents can improve the chances their baby will have the features they want, that the overall cost of health care in America will be less, that certain genetic diseases can be wiped out forever, or don't you think any of these are benefits?

	<i>Percentage</i>
That parents can improve the chances their baby will be healthy	27
That parents can improve the chances their baby will have the features they want	2
That the overall cost of health care in America will be less	8
That certain genetic diseases can be wiped out forever	41
Don't think any of these are benefits	12
It depends/mixed (vol.)	5
Don't know	4
Refused	1

The Genetics and Public Policy Center, October 15-29, 2002, N=1211.

Q104: Would you say that changing a baby's genetic characteristics for cosmetic purposes such as eye or hair color is making appropriate use of medical advances or is it taking medical advances too far?

	<i>Percentage</i>
Appropriate use	4
Taking medical advances too far	94
Don't know	2
No answer	0

Virginia Commonwealth University Life Sciences, September 2003, N=1003.

Q105: Would you say that changing a baby's genetic characteristics to reduce the risk of serious diseases is making appropriate use of medical advances or is it taking medical advances too far?

	<i>Percentage</i>
Appropriate use	41
Taking medical advances too far	54
Don't know	4
No answer	2

Virginia Commonwealth University Life Sciences, September 2003, N=1003.

Q106: New genetic techniques may prove able to slow down the aging process in human beings. How likely would you be to use genetic therapies if it meant you could live longer – very likely, somewhat likely, not too likely, or not at all likely?

	<i>Percentage</i>
Very likely	14
Somewhat likely	23
Not too likely	25
Not at all likely	36
Don't know	1
No answer	0

Virginia Commonwealth University Life Sciences, September 2003, N=1003.

Q169: Suppose scientific discoveries make it possible for parents to select genetic traits such as intelligence, height, or artistic talent when planning to have a child. Which comes closer to your view – parents should be allowed to select the traits they wish their child to have or parents

should not be allowed to select the traits for their child and the child should be born with whatever traits it would naturally have?

	<i>Percentage</i>
Should be allowed to select traits	8
Should not be allowed to select traits	88
No opinion	4

CNN/*USA Today*, January 23-25, 2003; N= 1000.

Q170: Scientific discoveries may some day make it possible for parents to select genetic traits such as intelligence, height, or artistic talent when planning to have a child. If you were having a child, and this were possible, would you select the traits you wanted your child to have, or let the child be born with whatever traits he or she would naturally have?

	<i>Percentage</i>
Select traits	7
Be born with whatever traits naturally have	91
No opinion	2

CNN/*USA Today*, January 23-25, 2003; N= 1000.

Appendix O – Awareness and Knowledgeability

Q135: How much are you personally interested in new medical discoveries – a lot, some, not much, or not at all?

	<i>2004</i>	<i>2003</i>	<i>2002</i>	<i>2001</i>
A lot	46	47	40	49
Some	44	42	47	41
Not much	7	6	10	9
Not at all	2	3	3	1
Don't know	0	0	0	0
No answer	0	0	0	0

Virginia Commonwealth University, September 7-17, 2004, N=1004.

Q76: Have you seen, read, or heard anything recently about embryonic stem cell research?

	<i>Percentage</i>
Yes	61
No	34
Unsure	5
Refused	1

Juvenile Diabetes Foundation, March 2004, N=600.

Q78: Have you seen, heard, or read anything about the debate on whether to allow the use of stem cells from human embryos to be used in medical research?

	<i>2004</i>	<i>2001</i>
Yes, seen, heard, read	83	68
No, have not/not sure	17	32

Harris Interactive, July 12-18, 2004, N=2242.

Q134: How often do you pay attention to news reports about developments in science – regularly, seldom, hardly ever, or never?

	<i>Percentage</i>
Regularly	57
Seldom	32
Hardly ever	7
Never	2
Don't know	0
No answer	0

Virginia Commonwealth University, September 7-17, 2004, N=1004.

Q75: As you may know, the federal government has debated whether to fund certain kinds of medical research known as “stem cell research.” How much have you heard about this?

	<i>Percentage</i>
A lot	27
A little	52
Nothing at all	20
Don't know/Refused	1

Pew Research Center for the People and the Press and Pew Forum on Religion and Public Life, 2002, N=2002.

Q132: How much have you seen, read, or heard about medical research involving embryonic stem cells – a lot, a little, not much, or nothing at all?

	<i>Percentage</i>
A lot	13
A little	40
Not much	26
Nothing at all	20
Don't know	1
No answer	1

Virginia Commonwealth University Life Sciences, September 4-16, 2002, N=1000.

Q74: How much have you seen, read, or heard about medical research involving embryonic stem cells – a lot, a little, not much, or nothing at all?

	<i>Percentage</i>
A lot	25
A little	44
Not much	19
Nothing at all	10
Don't know	1
No answer	0

Virginia Commonwealth University Life Sciences, August 2001, N=1122

Q73: Have you seen, heard, or read anything about the debate on whether to allow the use of stem cells from human embryos to be used in medical research?

	<i>Total</i>
Yes, seen, heard or read	68
No, have not/not sure	32

Harris Poll, July 25, 2001, N=1011

Q77: Thinking some more about embryonic stem cell research, how well do you think you could explain this topic to a family member or friend – very well, somewhat well, not very well, or not at all well?

	<i>Percentage</i>
Very well	9
Somewhat well	37
Not very well	30
Not at all well	20
Unsure	4
Refused	*

Juvenile Diabetes Foundation, March 2004, N=600

Q139: There are several different terms used when it comes to human cloning technology. How clear are you, personally, on the difference between human reproductive cloning and human therapeutic cloning – very clear, somewhat clear, not very clear, or not at all clear?

	<i>Percentage</i>
Very clear	8
Somewhat clear	26
Not very clear	34
Not at all clear	30
Don't know	1
No answer	1

Virginia Commonwealth University, September 7-17, 2004, N=1004.

Q99: There are several different terms used when it comes to human cloning technology. How clear are you, personally, on the difference between human reproductive cloning and human therapeutic cloning – very clear, somewhat clear, not very clear, or not at all clear?

	<i>Percentage</i>
Very clear	8
Somewhat clear	26
Not very clear	32
Not at all clear	33

Virginia Commonwealth University, September 2003, N=1003

Q100: There are several different terms used when it comes to human cloning technology. How clear are you, personally, on the difference between human reproductive cloning and human therapeutic cloning – very clear, somewhat clear, not very clear, or not at all clear?

	<i>Percentage</i>
Very clear	11
Somewhat clear	31
Not very clear	29
Not at all clear	28
Don't know	1
No answer	1

Virginia Commonwealth University, September 30, 2002, N=1000

Q133: How well informed are you about medical discoveries – are you very informed, somewhat informed, not very informed, or not at all informed?

	2004	2003	2002	2001
Very informed	9	10	7	11
Somewhat informed	67	65	60	64
Not very informed	19	20	28	22
Not at all informed	4	4	5	3
Don't know	0	0	0	0
No answer	0	0	0	0

Virginia Commonwealth University, September 7-17, 2004, N=1004.

Q136: Next, I have a few questions about genetic engineering. As far as you know, is it scientifically possible today to use genetic engineering to change a baby's genetic make-up before it is born to prevent it from having a genetic disease?

	<i>Percentage</i>
Yes	23
No	35
Don't know	43
Refused	*

Genetics and Public Policy Institute, October 15-29, 2002, N=1211.

Q137: As far as you know, is it scientifically possible today to change a baby's genetic make-up before it is born so it is smarter, stronger, or better-looking?

	<i>Percentage</i>
Yes	16
No	52
Don't know	32
Refused	*

Genetics and Public Policy Institute, October 15-29, 2002, N=1211.

Appendix P – Attitudes toward Stem Cell Research by Individuals of Religious and other Orientations

Q56: The federal government provides funding to support a variety of medical research. Do you think federal funding for medical research should or should not include funding for stem cell research?

	<i>Support</i>	<i>Oppose</i>	<i>Don't Know/ Refused</i>
Total	60	36	3
<i>Denomination:</i>			
Catholics	65	33	2
Protestant, Non-Evangelical	77	19	
Evangelicals	51	40	9
Evangelical White Protestants	47	47	6
<i>Ideology:</i>			
Conservatives	53	42	5
Moderates	64	32	4
Liberals	75	23	2
<i>Party:</i>			
Republicans	60	36	4
Independents	67	29	4
Democrats	60	36	4
<i>Race:</i>			
Whites	65	31	4
Blacks	50	47	3

Washington Post/ABC News, August 2, 2001, N=1352.

Q98: The federal government provides funding to support a variety of medical research. Do you think federal funding for medical research should or should not include funding for stem cell research?

	<i>Support</i>	<i>Oppose</i>	<i>Don't Know</i>
Total	60	31	9
<i>Denomination:</i>			
Catholics	54	35	11
Protestant, Non-Evangelical	68	19	13
Evangelicals	51	40	9
White Evangelicals	50	40	10
No Religion	63	24	14
<i>Ideology:</i>			
Conservatives	44	44	12
Moderates	63	26	11
Liberals	76	14	10
<i>Party:</i>			
Republicans	49	37	14
Independents	62	26	12
Democrats	65	27	8
<i>Race:</i>			
Whites	60	29	11
Blacks	48	44	8

ABC News/Beliefnet, June 2001, N=1022.

Q49: All in all, which is more important – conducting stem cell research that might result in new medical cures [or] not destroying the potential life of human embryos involved in this research?

	<i>Conduct Research</i>	<i>Not Destroy Embryos</i>	<i>Don't Know/ Refused</i>
Total	43	38	19
<i>Religious Affiliation:</i>			
White Evangelical Protestants	26	55	19
White Non-Evangelical Protestants	51	29	20
White Catholics	43	39	18
Secular	66	17	17
<i>Party affiliation:</i>			
Republicans	38	47	15
Democrats	45	37	18
Independent	49	33	18
<i>Party and Ideology:</i>			
Conservative Republicans	32	54	14
Moderate/Liberal Republicans	48	38	14
Conservative/Moderate Democrats	43	39	18
Liberal Democrats	55	31	14

Pew Research Center for the People and the Press and the Press and Pew Forum on Religion and Public Life, March 2002, N=2002.

Q109: All in all, which is more important – conducting stem cell research that might result in new medical cures [or] not destroying the potential life of human embryos involved in this research?

	<i>Conduct Research</i>	<i>Not Destroy Embryo</i>	<i>Don't Know/Refused</i>
Total	52	34	
<i>Religious Affiliation:</i>			
White Evangelical Protestants	33	52	15
White Non-Evangelical Protestants	66	22	12
White Catholic	55	31	14
Secular	68	19	13
<i>Party Affiliation:</i>			
Republican	41	45	14
Democrat	60	26	14
Independent	57	31	12
<i>Party and Ideology:</i>			
Conservative Republicans	35	53	12
Moderate/Liberal Republicans	54	32	14
Conservative/Moderate Democrats	58	29	13
Liberal Democrat	72	19	9

Pew Research Center for the People and the Press and the Press and Pew Forum on Religion and Public Life, August 2004, N=1512.

Q89: A stem cell is the basic cell in the body from which all other cells develop. Medical researchers have been able to take stem cells from adults, but they believe stem cells taken from embryos have far greater research potential. Excess human embryos are developed through the process of in vitro fertilization, a process that typically fertilizes more eggs than are needed. These excess embryos are usually frozen at fertility clinics after maturing for five days. There are approximately 400,000 of these frozen embryos at fertility clinics across the United States. Almost all of these excess frozen embryos are discarded after couples have had children and wish to have no more. The process of extracting the stem cells destroys the embryo. Medical researchers believe that embryonic stem cells can be developed into replacement cells to cure diseases such as diabetes, Parkinson's, Alzheimer's, cancer, severe burns, and spinal cord injuries. I'm going to read you some scenarios for stem cell research, and please tell me if you support or oppose each of the following.

<i>Percentage</i>	<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>E</i>	<i>F</i>	<i>G</i>
Medical research using stem cells obtained from adults with their permission:	78	48	30	6	10	16	6
Medical research using stem cells obtained from human embryos that have been destroyed in the past:	52	28	24	13	26	39	9
Medical research using stem cells obtained from excess human embryos:	49	26	22	13	27	41	11
Medical research using stem cells obtained from human embryos that are frozen in fertility clinics five days after an egg has been fertilized, have been donated by the parents, and will be discarded if they are not donated:	56	34	22	9	28	36	8

A: Total support

D: Somewhat oppose

G: Unsure

B: Strongly support

E: Strongly oppose

C: Somewhat support

F: Totally oppose

Juvenile Diabetes Research Foundation, March 2004, N=600 self-identified conservative voters.

Appendix Q – Acronyms

Organizations

AAAS	American Association for the Advancement of Science
AATB	American Association of Tissue Banks
ABA	American Bar Association
AFA	American Fertility Association
AHEC	Australian Health Ethics Committee (Australia)
AHRAC	Assisted Human Reproduction Agency of Canada
ASHG	American Society of Human Genetics
ASRM	American Society for Reproductive Medicine
ASTM	American Society for Testing and Materials
BIO	Biotechnology Industry Organization
CAMR	Coalition for the Advancement of Medical Research
CAP	College of American Pathologists
CDC	Centers for Disease Control
CDER	Center for Drug Evaluation and Research
CEQ	Council on Environmental Quality
CIRM	California Institute for Regenerative Medicine
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMS	Center for Medicare and Medicaid Services
CSSP	Council of Scientific Society Presidents
DOE	Department of Energy
EPA	Environmental Protection Agency
ERLC	Embryo Research Licensing Committee (Australia)
ESCRO	Embryonic Stem Cell Research Oversight committee
FAA	Federal Aviation Administration
FASEB	Federation of American Societies for Experimental Biology
FCSRCA	Fertility Clinic Success Rate and Certification Act of 1992
FDA	Food and Drug Administration
FTC	Federal Trade Commission
HFEA	Human Fertilisation and Embryology Authority (UK)
HHS	U.S. Department of Health and Human Services
HREC	Human Research Ethics Committee (Australia)
ICC	Interstate Commerce Commission
JCAHO	Joint Commission on Accreditation of Healthcare Organizations

NABER	National Advisory Board on Ethics in Reproduction
NAIC	National Adoption Information Clearinghouse
NAS	National Academy of Sciences
NCOART	National Coalition for Oversight of Assisted Reproductive Technologies
NFPA	National Fire Protection Association
NHMRC	National Health and Medical Research Council (Australia)
NHS	National Health Service (UK)
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NOF	National Osteoporosis Foundation
OCC	Office of the Comptroller of the Currency
OECD	Organisation for Economic Co-operation and Development
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
OTA	U.S. Office of Technology Assessment
RAC	Recombinant DNA Advisory Committee
RESOLVE	National Infertility Association
RLAP	Reproductive Laboratory Accreditation Program
ROSNI	Round Spermatid Nucleus Injection
SART	Society for Assisted Reproductive Technology
SMRU	Society of Male Reproduction and Urology
SREI	Society for Reproductive Endocrinology and Infertility
SRS	Society of Reproductive Surgeons
UL	Underwriters Laboratories
USP	U.S. Pharmacopeia

Legislation

AAHRA	Assisted Human Reproduction Act (Canada)
APA	Administrative Procedure Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
FACA	Federal Advisory Committee Act of 1972
FDAMA	FDA Modernization Act
NEPA	National Environmental Policy Act
PHCA	Prohibition of Human Cloning Act of 2002 (Australia)
RCRA	Resources Conservation and Recovery Act
RIHEA	Research Involving Human Embryos Act of 2002 (Australia)
SARA	Superfund Amendments Reauthorization Act

Terms

ART	assisted reproductive technology
CAG	community advisory group
DBA	Diamond Blackfan Anemia
EIS	environmental impact statement
ESC	embryonic stem cell
GIFT	gamete intrafallopian transfer
GMO	genetically modified organism
HGGM	human germ-line genetic modification
hGH	human growth hormone
ICSI	intracytoplasmic sperm injection
IND	investigational new drug
IND	investigational new drug
IRB	institutional review board
ISS	idiopathic short stature
IUGR	intrauterine growth restriction
IUI	intrauterine insemination
IVF	in vitro fertilization
PGD	pre-implantation genetic diagnosis
rDNA	Recombinant DNA
ROD	record of decision
SCNT	somatic cell nuclear transfer
TAG	technical assistance grant
ZIFT	zygote intrafallopian transfer

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