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978-0-521-74813-1 — The 'Healthy' Embryo: Social, Biomedical, Legal and Philosophical Perspectives

Edited by J. Nisker , F. Baylis , I. Karpin , C. McLeod , R. Mykitiuk

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The 'Healthy' Embryo

Social, Biomedical, Legal and Philosophical Perspectives

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Preface

Characterizations of both 'health' and of the human embryo, and how both should be created, vary considerably among and within investigative, clinical and social communities. Thus, when characterizations of 'health' and of the human embryo are taken together, the complex and controversial entity of a 'healthy' (or 'unhealthy') human embryo emerges. The increasing capabilities in genetic science and reproductive technology, and their potential clinical usages, have at the same time inspired hope for the new era of regenerative medicine and raised concern as to the strategies that are increasingly being developed to promote the perceived 'health' of a child not yet born or gestated (or even conceived). Exploring the concept of a 'healthy' embryo serves as a focal point from which disparate views emerge and are aired. Understanding what a 'healthy' embryo means to people with different perspectives opens discussion among researchers, scholars, clinicians and members of the general public. The results of these discussions may assist the regulators hurrying to catch up with the scientists by providing a framework that supports the benefits to the individual of genetic and reproductive science, while promoting the collective good.

To open this discussion, *The 'Healthy' Embryo: Social, Biomedical, Legal and Philosophical Perspectives*, brings together researchers and scholars from five countries and twelve disciplines to focus their methodologies, scholarship, and insights on the concept of a 'healthy' embryo, including how such a concept may shape and be shaped by conceptions of the health of children and adults. The authors bring their own perspectives on the 'healthy' embryo from the fields of philosophy, ethics, law, genetic and reproductive science, sociology, critical disabilities studies, women's studies, cultural studies, medicine, history, art history and health policy.

Section I focuses on the question of what is a human embryo, drawing on historical, social, and legal perspectives, and in light of twenty-first-century assisted reproduction and embryo research. Section II examines the recently developed entities that are 'humanesque embryos' and explores whether these entities should be considered human embryos. Section III investigates the reasons for and impacts of using 'healthy' as a characterizing term applied to human embryos. Section IV examines research using human (and 'humanesque') embryos, particularly the considerations that should precede but currently result from using 'healthy' human embryos for research purposes. Section V shifts the focus to reproductive purposes and explores the concept of 'healthy' (or 'unhealthy') embryos in regard to having a 'healthy' child. Authors in each section of the book enlist and contribute to insights in other sections.

This Preface presents the scope of the book, which is long in temporal consideration and broad in both subject area explored and perspectives of the investigators. It also describes how the book came into being, which in itself reflects how genetic and reproductive science and their clinical uses may precede ethics, social and legal research on the science being explored, as well as why genetic and reproductive scientists should participate step by step in research teams with investigators and scholars of several other disciplines. The Preface concludes with brief summaries of each chapter.

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In this book, the term 'embryo' is generally used to represent the continuum from 'pre-embryo' to 'embryo' to 'term fetus', as distinctions between these terms are often artificial and determined by specific technical possibilities, clinical considerations, research purposes, social reasons, and vested interests; while also examining reasons to consider distinctions between these terms. The investigation of the concept of a 'healthy' human embryo considers both the in vivo (inside a woman) and the in vitro (inside a petri dish) embryo. It examines how characterizations of the 'health' of either affects characterizations of the 'health' of the other, and how both may differently or similarly influence and be influenced by characterizations of the health of children and adults.

The book's temporal landscape includes discussions of the hypothetical existence of an embryo in Ancient Greece; examination of drawings and photographs of 'healthy' and 'unhealthy' embryos from the sixteenth to the twenty-first centuries; consideration of microscopic criteria of embryo 'health' through in vitro fertilization (IVF) in the 1970s; and the current creation of 'humanesque' embryos through cloning and the use of non-human animal eggs. In medical practice, the 'health' of an embryo began to be tested in the 1950s with the development of amniocentesis and chromosomal analysis. Initially this testing was limited to use in pregnancies in which a family history or the woman's age suggested that her embryo would have a higher than average chance of association with a genetic-based anomaly.¹ The routine use of ultrasonographic imaging in the late 1970s promoted visualization of anomalies in addition to those that could be predicted by genetic testing, or indeed suggested by family history or the woman's age. In the 1980s, while physicians had an increasing ability to offer pregnant women assessment of the potential ill 'health' of their embryos, feminist writers, such as Barbara Katz Rothman in her book *The Tentative Pregnancy*, were increasingly cautioning about potential or actual harms to women of routine ultrasounds for all pregnant woman and routine amniocentesis for older pregnant women, as well as the social impacts of such assessments.² The 1980s ended with Abby Lippman coining the term 'geneticization' as a warning that the increasing focus on genetic characteristics will distort not only how 'health' is perceived but how it is promoted, and how ill health will be researched.³ In the 1990s, preimplantation genetic diagnosis (PGD) was developed to perform genetic assessments of the 'health' of IVF embryos, and, through implanting only 'healthy' embryos, to avoid children with genetic anomalies or genetic-based abortion.⁴ Today, many IVF units routinely use PGD technology to screen all embryos for 'health', including those of many women who do

¹ Summers, A. M., Langlois, S., Wyatt, P., et al. (2007). Prenatal screening for fetal aneuploidy. *Journal of Obstetrics and Gynaecology Canada*, 29, 146–79; Pioro, M., Mykitiuk, R., Niskier, J. (2008). Wrongful birth litigation and prenatal screening. *Canadian Medical Association Journal*, 179(10), 1027–30.

² Katz Rothman, B. (1986). *The Tentative Pregnancy: Prenatal Diagnosis and the Future of Motherhood*. New York: Viking.

³ The term 'geneticization' and Abby Lippman's other early arguments are summarized in Lippmann, A. (1993). Worrying – and worrying about – the geneticization of reproduction and health, in *Misconceptions: The Social Construction of Choice and the New Reproductive and Genetic Technologies*, G. Basen, M. Eichler, and A. Lippmann (eds.) Hull (QC), Voyageur Publishing, pp. 39–65.

⁴ Handyside, A. H., Kontogianni, E. H., Hardy, K., and Winston, R. M. (1990). Pregnancies from biopsied human preimplantation embryos sexed by Y-specific DNA amplification. *Nature*, 344, 768–70; Niskier, J. A., Gore-Langton, R. E. (1995). Pre-implantation genetic diagnosis: a model of progress and concern. *Journal of Obstetrics and Gynaecology of Canada* 17(3), 247–62.

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not require IVF to become pregnant.⁵ Several chapters of this book consider how PGD and its regulation shape conceptions of both embryo 'health' and the 'health' of children and adults.

The broad scope of subject areas investigated in *The 'Healthy' Embryo: Social, Biomedical, Legal and Philosophical Perspectives* includes an analysis of what a human embryo is and means; the ethical, social and legal implications of applying the term 'healthy' or 'unhealthy' to an embryo; the regulatory frameworks that in attempting to license laboratories and approve tests related to selection of embryos for 'healthy' characteristics may in themselves promote the concept that a 'healthy' embryo can be determined; and considerations of informed choice for the donation of 'healthy' or 'unhealthy' embryos (fresh or frozen) in both clinical and research settings.

This book also explores how the 'health' of an embryo may be based on the perceptions of clinicians, potential parents and policy-makers. For example, an embryo assessed as carrying a Y chromosome would be considered 'unhealthy' if the reason for the assessment is to prevent having a child that would develop an X-linked recessive condition, such as Duchenne's muscular dystrophy or haemophilia, whereas the same embryo would be considered 'healthy' if the reason for its genetic evaluation was to ensure having a male child. Similarly, an embryo carrying the gene for deafness would be considered 'unhealthy' if the reason for testing the embryo was to avoid a deaf child, whereas an embryo with the same gene would be considered 'healthy' if a deaf couple requested testing for the same gene to ensure having a child who is deaf.

The international team of authors also draws attention to the wide international variation in both state regulation and the guidelines of professional bodies, such as regarding what constitutes a 'healthy' embryo. These regulations and guidelines have implications for how the 'health' of an embryo is perceived in the relevant jurisdiction (and indeed beyond). For example, genetic conditions that are deemed legally appropriate for the use of PGD may result in these conditions being characterized as 'serious diseases' in those jurisdictions. Further, professional practice guidelines produced by medical associations differ across countries. In some countries, for example, the professional obligation to offer all pregnant women screening for chromosomal anomalies could suggest that all pregnant women must not only be aware that it is possible to control particular characteristics of the 'health' of their embryo but also that undergoing prenatal screening is a responsible practice. In other jurisdictions where it is not routine medical practice to make these tests available, the idea of a 'healthy' embryo may differ considerably from jurisdictions where it is routine.

Several chapters of this book explore the interdependencies of purpose, perspective, and regulation when characterizing 'healthy' embryos, as well as conceptions of 'health' in embryos and children. This book also examines how and why general public voices, as well as those of pregnant women, their partners, and clinicians must be included in future policy development related to the 'health' of embryos and provides a resource for all of these publics and policy-makers in this regard.

The roots of this book date back to 2001, when the Canadian Institutes of Health Research, responding to both the dramatic increase in triplets and other high-order multiple pregnancies in Canada and the lack of research in this regard, requested Canadian investigators apply for a special funding opportunity in this area. Four of the editors of this

⁵ Verlinsky, Y., Rechitsky, S., Sharapova, T., Morris, R., Taranissi, M., and Kuliev, A. (2004). Preimplantation HLA testing. *Journal of the American Medical Association*, 291, 2079–85.

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book participated in one of the successful grant applications (2003–2008), the purpose of which was to determine the biological characteristics of embryos that would enable clinicians to place only one embryo in a woman without decreasing her overall chance of pregnancy. We worked alongside researchers in molecular biology, physiology, zoology and clinical medicine, who shortened the lengthy title of the grant to 'The Healthy Embryo'. This working title spawned our reflection on the concept of a 'healthy' embryo and its implications. We soon felt both that the insights of other researchers and scholars were required to fully explore this area and that a book was required to share the resulting collaboration with other researchers and scholars, clinicians, and policy makers, and also perhaps potential patients and the general public. To this end, in 2006, researchers, scholars, and clinicians from five countries and many disciplines were invited to participate in *The 'Healthy' Embryo: Social, Biomedical, Legal and Philosophical Perspectives*. In order to cross-pollinate ideas, the chapter writers came together in November 2007 to present working drafts of their chapters and receive insight from other authors before moving towards their completed work and the integrated book. In January 2009 the book was completed.

Section I, 'Human Embryos', investigates the characterizations of the human embryo and the new social and legal relationships that have developed alongside new assisted reproductive technologies. In the first chapter, 'What is an embryo and how do we know?', Jane Maienschein and Jason Scott Robert explore how the human embryo has captured the imagination of scholars, researchers, clinicians and the general public. They examine hypothetical discussions of an embryo in Ancient Greece, the formal study of embryology, the first microscope observation of a human embryo, chromosomal and molecular-genetic characterizations, Dolly the cloned sheep, and embryonic stem cell research. Maienschein and Robert see today's human embryo as no longer a fixed natural object, but rather one in which we can rearrange or even replace cells, recombine genes, discover natural and produce experimental chimeras, and manipulate the internal and external environments to influence development. They describe today's human embryo as a highly malleable, literally and socially constructed, and contested object. Jackie Leach Scully, Christoph Rehmann-Sutter and Rouven Porz, in their chapter, 'Human embryos: donors' and non-donors' perspectives on embryo moral status', consider social, ethical and legal constructions of 'spare' embryos (those in excess of clinical need). Based on their current research in Basel, Switzerland, the authors examine the views of potential donors who are making or have made decisions about what should happen to their IVF embryos, as well as the views of clinicians, scientists, legal scholars and policy-makers involved in the development of Swiss regulation. The authors discuss perceptions of the moral status of 'spare' and other embryos of potential donors and members of these other groups. Radhika Rao, in 'Property, privacy and other legal constructions of human embryos', investigates legal constructions of the human embryo and examines factors that shape its legal status, including the physical location of the embryo, its stage of development, and the method of its creation. Rao argues that the legal status of the embryo rests not only on these criteria but on the context and the consequences of that legal status for others. Charis Thompson in 'Informed consent for the age of pluripotency and embryo triage: from alienation, anonymity, and altruism to connection, contact, and care', suggests ways in which the definition of a human embryo is increasingly under-determined and argues that the proliferation of contenders to human embryo-hood and the rise of embryo screening puts pressure on existing, already outdated, informed consent regimes. She argues that the old

'three As' model, characteristic of consented tissue donation, including embryo donation – 'alienation' of donated cells, 'anonymity' of the donor, and 'altruism' as the motive – is now untenable due to the proliferation and screening of embryos, and the rise of pluripotentiality. Thompson offers three Ps in place of the three As: 'property' in relation to in vitro cells and their products, the creation of a 'profile' from the uniquely identifying characteristics of embryos that would provide medical information and a biologically matched tissue source, and a 'profit' incentive that is both informational and has economic potential.

In Section II, 'Creating "human" embryos', the authors consider current and future methods of creating 'humanesque' embryos and the use of human DNA other than from a human oocyte and sperm. In the first chapter, 'Interspecies somatic cell nuclear transfer: not yet healthy human embryos', molecular biologists José Cibelli and Kai Wang begin by describing cloning from the work of Nobel Laureate Hans Spemann in newts a century ago to the cloning of Dolly in 1997 through somatic cell nuclear transfer (SCNT) from an adult sheep cell, to the current focus on using SCNT technology to create human embryonic stem cells (hESCs). Cibelli and Wang discuss the advantages of using enucleated non-human animal oocytes to receive human DNA to create embryos for hESC research. The Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom has recently ruled that embryos created in this way should be considered human embryos and therefore subject to their regulations. Cibelli and Wang include their recent data. Molecular biologist Paul De Sousa in 'Parthenogenesis and other strategies to create human embryos for stem cell research and regenerative medicine' explores several innovative strategies that would allow 'almost human embryos' to largely replace IVF embryos in stem cell research. De Sousa provides the scientific evidence for the use of clinically failed human oocytes, whose developmental competence is recovered by interventions not suitable for use in assisted conception. He also explores the use of immature eggs donated by women undergoing elective sterilization or other surgery, the use of eggs generated in vitro from pluripotent stem cells, and parthenogenesis, which involves the activation of development from an egg in the absence of sperm. De Sousa proposes that parthenogenesis could lead to genetically less diverse stem cells as an important source of histocompatible cells for transplantation in degenerative disease or damaged tissues. In 'Creating humanesque embryos', Françoise Baylis examines the ethics of creating such embryos for stem cell research. She draws attention to the enthusiasm of stem cell scientists regarding SCNT and their practical problem of accessing the large numbers of human eggs required for cloning research to overcome the shortage of human eggs and the ethical issues inherent in women being 'invited' to 'donate' their oocytes to research. Baylis then reviews ethical and regulatory considerations of using enucleated non-human animal oocytes to create cytoplasmic hybrid embryos from which 'humanesque' stem cell lines could be derived. She contends that, taken together, ethical concerns about the moral status of the human embryo, crossing species boundaries and potential harms to women who donate oocytes and embryos through IVF provide good reason to eschew humanesque cytoplasmic hybrid embryo research in favour of less ethically controversial means to the laudable end of successful regenerative medicine.

In Section III, 'Healthy human embryos', the authors explore how conceptualizations of the term 'health' in general and when applied to an embryo, vary according to and even within communities that consider the term and influence the perception of 'health' in children and adults. Art historian Lianne McTavish in 'A visual dialogue on "healthy" human embryos from the sixteenth to the twenty-first centuries', suggests new ways of approaching longstanding debates about 'healthy' and 'unhealthy' embryos through comparing sixteenth-century engravings with modern photographic renderings. These

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images speak to each other and reveal the complex ways in which modern images of embryos communicate meaning. McTavish offers alternative, open-ended ways of thinking, not only about human embryo 'health', but about biotechnology in general, and in ways which can engage a broader public. In 'Social determinants of "health" of embryos', Roxanne Mykitiuk and I use the World Health Organization's social determinants of health, including poverty, poor nutrition and toxic environments, as well as other social determinants, such as laws, professional practice guidelines and institutions, to explore this aspect of embryo 'health'. We examine the effect that biomedical and social determinants of the health of the embryo may have on constructing new ways of characterizing the social health of children and adults, and vice versa. Isabel Karpin, in 'Taking care of the 'health' of preconceived human embryos or constructing legal harms', interrogates the willingness to attribute qualities of 'health' to what she calls the 'preconceived embryo'. She analyses and compares the promotion of preconception healthcare for women with the legal attribution of preconception harm in the context of preconception tort claims. Karpin uses the term 'preconceived embryo' to reflect the importance being placed on an entity which only exists as a potential eventuality and argues that the concern with 'preconception health' can be problematic if it is directed to all women of reproductive age rather than those who are actively contemplating pregnancy. She questions whether women are now being asked to live their lives in constant preparedness for pregnancy so as to ensure 'healthy' babies rather than their own health and happy lives. In 'Public understandings of a "healthy" embryo: a citizen deliberation on preimplantation genetic diagnosis', Susan Cox and I bring to this book voices of the general public in describing the results of a Canadian Institutes of Health Research and Health Canada-funded citizen deliberation on PGD. Canadians were concerned with the implications of drawing lines between acceptable and unacceptable uses of PGD, who would draw such lines, and the responsibilities all citizens bear in shaping future societies by making individual choices with collective effects and collective choices with individual effects.

In Section IV, '"Healthy" human embryos and research', the authors explore the ethical and legal considerations essential to the designation of embryos as 'healthy' in clinical or research settings. Carolyn McLeod and Françoise Baylis, in 'Donating fresh versus frozen embryos to stem cell research: in whose interests?', explore why donating 'fresh' embryos to research is not in the self-interests specifically of female IVF patients. They consider the other-regarding interests of these patients and believe that although 'fresh' embryo donation may serve those interests, it does so at unnecessary cost to patients' self-interests. The authors also discuss some of the potential barriers to the autonomous donation of fresh embryos to research and highlight the risk that female IVF patients invited to donate these embryos will misunderstand key aspects of the donation decision, be coerced to donate or be exploited in the consent process. Angela White and Robyn Bluhm, in 'Embryo health and embryo research', further discuss informed consent to donate IVF embryos, focusing on its potential health risks. The authors examine the implications of 'embryo quality' and a 'healthy embryo' in regards to donating embryos for hESC research. They argue that, unless handled very carefully, presenting women with the opportunity to donate their embryos for research may threaten their reproductive autonomy.

In Section V, '"Healthy" human embryos and reproduction', the authors explore the impact of selecting, for reproductive purposes, embryos with or without certain characteristics. Adrienne Asch and David Wasserman, in 'Making embryos healthy or making healthy embryos: how much of a difference between prenatal treatment and

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selection?', contend that the professional endorsement and parental acceptance of prenatal selection for or against particular characteristics of 'health' display and perpetuate attitudes inconsistent with the ideals of familial welcome and societal inclusion, and that to reject a parental relationship with a future child based on knowledge of a single characteristic is morally problematic. The authors also argue that prenatal surgery and replacement of genes or modification of chromosome number reflect harmful attitudes towards people with disabilities. Wasserman and Asch also explore the duties prospective parents may have towards the children they intend to raise, and whether the strength of that duty depends on the severity of the impairment to be prevented and the impositions and risks of in utero surgery for the mother and whether the recognition of any such duty conflicts with a woman's 'right to choose.' Daniel M. Weinstock, in 'Facing up to the disability critique of the use of genetic testing and selection to combat disease', critically addresses four of the criticisms of disability theorists regarding PGD: the social construction critique which claims the badness of almost all diseases is due to a lack of accommodation; the expressivist critique which claims screening technologies discriminate against persons who possess the trait that is screened for; the 'synecdoche' critique which claims screening 'reduces' a view of a person to a single trait; and the 'non-identity' argument which claims because traits can only be screened out by preventing their bearers from being born, no identifiable person is benefited by the use of these technologies. Weinstock argues that the plausibility of the first three arguments tacitly rests on the plausibility of the fourth and that the fourth argument is vulnerable to the objection that a moral attitude – namely concern for future children, as opposed to concern for any particular child – blunts the force of the non-identity argument. Elisabeth Gedge further explores the expressivist argument in '"Healthy" human embryos and symbolic harm'. Following Jean Harvey and Christine Koggel, she argues that *de facto* moral status is relationally bestowed, through mechanisms such as the construction of identities in the moral imaginary. A message of inferior *de facto* moral status may be conveyed by well-intentioned practices, if the illocutionary conditions governing the symbolic practice are present. She reviews several accounts of the symbolism of acts, demonstrating the reliance of meaning both on established conventions and the structure of practices within which particular acts fall. She concludes by situating expressivism in the complex of ethical considerations surrounding reproductive policy and choice, noting that even if the expressivist argument is sound, expressivism alone does not determine the ethical acceptability of the practice of PGD. In 'Saviour siblings, other siblings and whole organ donation', Sally Sheldon and Stephen Wilkinson investigate the ethics and legality of embryo selection for the creation of a 'saviour sibling', an embryo determined to be suitable on the basis of its tissue compatibility with, and thus the health needs of, a third party. They analyse permissible parameters of the United Kingdom's Human Fertilisation and Embryology Act, focusing specifically on the prohibition against selecting a 'saviour sibling' to act as a whole organ donor, and challenge the intuition that donation from a selected saviour sibling is more morally problematic than donation from a naturally occurring saviour sibling.

The 'Healthy' Embryo: Social, Biomedical, Legal and Philosophical Perspectives aims to provide insight and reflection regarding the concept of a 'healthy' embryo, to stimulate readers to develop their own concepts, and to encourage further research in this and related areas.

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