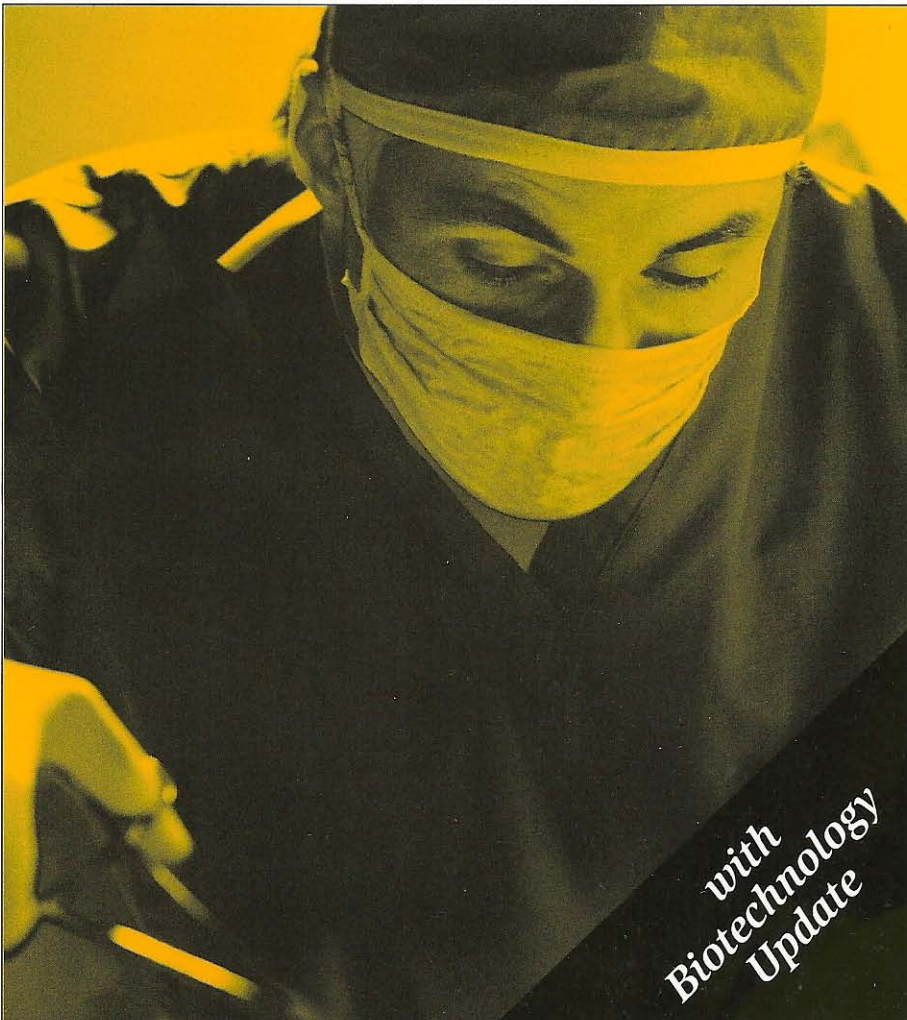


# Ethics & Medicine

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*Trinity International University, Deerfield, Illinois, USA*  
bmitchell@tiu.edu

**FOUNDING EDITOR: NIGEL M DE S CAMERON**  
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C Ben Mitchell, Associate Professor of Bioethics,  
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**PROF DR G A LINDEBOOM INSTITUUT,**

Postbus 224, NL6710 BE, Ede, The Netherlands

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lindinst@che.nl

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michelle@excelprintmedia.com

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## CONTRIBUTORS

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**Carlo Bellieni, M.D.**, is a member of the European Society of Pediatric Research and of the Bioethics Centre of the University of Siena, and Professor of Neonatal Therapy in the Pediatrics School of the University of Siena, ITALY.

---

**Robert Carlson** is Clinical Senior Lecturer in Medical Ethics based in the Clinical Pharmacology Unit at the Western General Hospital in Edinburgh, having initially worked as Locum Consultant in Public Health Medicine (Communicable Disease and Environmental Health) as well as teaching in the Edinburgh University's MSc programme in Public Health. Mr. Carlson has also worked in both public health medicine and general practice, having completed his postgraduate training in public health medicine in Dunedin, and has Masters Degree in theology from Regent College in Vancouver. He is currently completing his PhD on the ethical dimensions and impact on biomedical research of the most recent amendment (Edinburgh, 2000) to the Declaration of Helsinki.

---

**J. Daryl Charles, Ph.D.**, is associate professor of religion and ethics at Union University in Jackson, Tennessee, USA. A 2003/4 Visiting Fellow of the Institute for Faith and Learning at Baylor University, Charles is author of *Between Pacifism and Jihad: Just War and the Christian Tradition* (InterVarsity Press, forthcoming), *The Unformed Conscience of Evangelicalism: Recovering the Church's Moral Vision* (InterVarsity Press), and *Virtue amidst Vice* (Sheffield Academic Press). He writes frequently on New Testament ethics, criminal justice, issues surrounding war and peace, and religion and culture.

---

**William P. Cheshire, Jr., M.D.**, is Associate Professor of Neurology at Mayo Clinic in Jacksonville, Florida, USA and Director of Biotechnology Ethics for The Center for Bioethics and Human Dignity. The views expressed herein are his own and do not necessarily reflect the positions of Mayo Clinic or Mayo Foundation.

---

**Nancy L. Jones, Ph.D.**, a cell biologist and bioethicist, is Associate Professor of Pathology at Wake Forest University School of Medicine, Winston-Salem, North Carolina, USA and serves on the U.S. Secretary of Health and Human Services Secretary's Advisory Committee on Human Research Protection. The views expressed herein are her own and do not necessarily reflect the positions of Wake Forest University or the U.S. department of Health and Human Services.

---

**Fr. Juan R. Vélez G., M.D., Ph.D.**, is a Roman Catholic priest of the Prelature of Opus Dei who works as chaplain with college students in Princeton, New Jersey, USA. He holds a doctorate in dogmatic theology from the University of Navarre, and is a board certified internist.

EDITORIAL

## THE WISDOM OF COSTA RICA

C. BEN MITCHELL, PH.D.

The United Nations' legal committee has been debating two conflicting proposals on cloning. The so-called Costa Rican resolution, which is co-sponsored by the United States and about 60 other countries, would prohibit cloning for purposes of both reproduction and research. A measure sponsored by Belgium and about 20 other countries would ban only reproductive cloning, thereby permitting the production of clones who would be destroyed when stem cells are extracted for research.

By the time this issue of E&M reaches readers, we may know if the Costa Rican resolution has passed at the UN. But whether or not it passes, it is worth exploring the wisdom of such a ban.

Embryo cloning has been an extraordinarily controversial and divisive issue internationally. Groups like Britain's Human Fertilisation and Embryology Authority (HFEA) have given permission to two labs in the UK to clone human embryos for research purposes. Interestingly, the HFEA's first license was awarded to a clinician, not a scientist, at Newcastle University. This underscores the HFEA's commitment to see the research target therapeutic goals rather than pure research goals.

When queried by the *Guardian* about the ethics of human embryo cloning for research purposes, Suzi Leather, the HFEA's chief executive, said they proceeded only "after careful consideration of all the scientific, ethical, legal and medical aspects of the project. This is an important area of research and a responsible use of technology."<sup>1</sup> No one doubts that stem cell research is a worthy pursuit. Everyone believes the promise of stem cells warrants increased funding. The questions are whether (1) human embryos should be destroyed to obtain stem cells and (2) whether human embryos should be generated through cloning for the express purpose of embryo-destructive experiments.

Two profound issues are at stake. The first issue is whether we regard members of our species, *Homo sapiens*, as deserving of respect and having at least a right not to be unnecessarily harmed. Thousands of years of moral and legal evolution have led civilized societies to reject human chattel slavery on the grounds that all members of our species are deserving of respect. "Respect" in this case has meant at least that humans should not be commodified, owned for the benefits of others. Human beings, we have learned through painful social experiments, are not to be instrumentalized. Yet, use of living members of our species for research purposes, especially in research that results in their destruction, threatens to undue the lessons learned from the past.

Moreover, the other issue at stake in this debate is how, in a global culture, we will resolve moral, legal, and ethical issues, especially when human life is at risk. Critics of the Costa Rican resolution charge that the nations opposed to

human cloning are being obstructionist by maintaining their stance. But, why, in light of the western tradition, should those who oppose the commodification and instrumentalization of human beings be characterized as obstructionists? In a past generation, William Wilberforce and other defenders of human dignity were regarded as heroes for their indefatigable efforts to end the slave trade in England. Doubtless, those who advocated for slavery viewed Wilberforce and company as obstructionists as well; but history has proven that they were courageous moral visionaries who understood that human beings could not be used as mere tools for the economic, social, and even health benefits of the British culture.

Thus, one of the lessons of history is that when it comes to protecting human beings—members of our species—special care must be taken and extraordinary caution must be exercised. Otherwise, the risk to some members of the moral community becomes a risk to all members of the human community.

In a global environment, where moral, social, and legal traditions are very diverse, it seems reasonable to argue that the most conservative position should be maintained; namely, that no human being—no matter how young, how old, how marginalized socially, or how infirm—should be instrumentalized. Commodification of any class of human beings threatens the freedom of every class of human beings.

In sum, it is wrong to characterize the Costa Ricans and their supporters as obstructionists with respect to human embryo-destructive cloning. If anyone is guilty of creating an impasse, it is those who continue to lobby for the right to destroy members of our species in order to exploit their body parts, even for the laudable goal of healing.

## **Notes**

- 1 [http://www.guardian.co.uk/uk\\_news/story/0,3604,1338727,00.html](http://www.guardian.co.uk/uk_news/story/0,3604,1338727,00.html)

# PAIN DEFINITIONS REVISED: NEWBORNS NOT ONLY FEEL PAIN, THEY ALSO SUFFER

CARLO BELLINI, M.D.

## Abstract

*Premature babies are relatively unreactive, often being completely isolated in an incubator and considered incapable of social behavior. To the attentive observer, however, they reveal an unsuspected emotional world: not only do they feel pain (the clash arising from an attack to their physical integrity), but they are also capable of suffering (the clash arising from an attack to their person's integrity) as they are persons. In this paper the author argues in favour of newborns' personhood. This needs to be considered in neonatal analgesic treatment, even for extremely small babies, as recognition and adequate treatment of neonatal pain is still resisted: full acknowledgement of neonatal dignity and personhood is a prerequisite for an effective treatment of neonatal pain.*

\* \* \*

Newborns are immature preverbal beings: what is the correct definition of pain in their case? Neonatal pain is a controversial question. Until the 1980s it was uncommon to anaesthetise newborns undergoing surgery. Anand's studies<sup>1</sup>, published in 1985, were a milestone in the recognition of the importance of analgesic treatment even in small prematures. Anand showed that newborns feel pain as much or even more than adults: the relative immaturity of their cerebral cortex, their not-yet-myelinated nerve fibres, and the absence of previous painful experience does not prevent them from feeling pain. He showed that newborns who undergo very painful procedures without analgesia have a high risk of brain damage: pain causes oxygen desaturation while increasing intracerebral pressure and blood pressure, which could lead to brain hemorrhage. However, recognition and adequate treatment of neonatal pain is still resisted, as a recent study showed: the use of analgesia was investigated in five clinical situations associated with pain (e.g., intubation, catheter insertion) in 143 French neonatal intensive care units<sup>2</sup>; the rate of pharmacotherapy use varied widely across the five clinical situations studied (from 16 to 77%) and a strong heterogeneity for pain treatment was observed.

A first resistance is connected with the interpretation of the word "pain". In 1991 the International Association for the Study of Pain (IASP) proposed the following definition: "A sensory and emotional experience based on actual or potential tissue damage or described in terms of such damage"<sup>3</sup>. This definition has two problems as far as newborn infants are concerned. First, emotional experiences require subjective expression. This is impossible in the usual sense in preverbal neonates because even individual behavioural cues are non-specific (e.g., cry of hunger, discomfort, pain). Second, if this experience is based on

previous “actual or potential” tissue damage, where did the newborn acquire the experience and for how long does the baby have to gather experience before it is subjectively “pain”? Derbyshire says:

If this “multidimensionality” is the basis of conscious pain experience, it seems unlikely that we can attribute this experience to the neonate or unborn fetus, which is naive as to all the cognitive, affective and evaluative experiences necessary for pain awareness. This is accepted in the current definition of pain that is further extended to state: “pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life.” Pain does not, so to speak, spring forth “from the depths of the person’s mind” prior to any experience, but is gradually formed as a consequence of general conscious development<sup>4</sup>.

Anand and Craig<sup>5</sup> highlighted the limits of the IASP definition, complaining that it means that pain is a learned phenomenon; they maintained that it is an inherent quality of life itself, expressed by all viable living organisms and while influenced by life’s events, it does not require prior experience in the first instance. This is more in line with the observations of neonatologists and mothers who report no difference between infants’ reactions to first and subsequent painful stimuli.

Another difficulty is the proposition that pain cannot be felt before emergence of the “self”. Derbyshire wrote: “The lack of self-awareness and conceptual and symbolic abilities means we can be certain that...early neonatal ‘experiences’ will be of a lesser significance” and concludes: “Pain is suggested to arise with development of the necessary neurological, cognitive and emotional structures. Pain experience is placed at approximately 12 months of age”<sup>6</sup>. In short, he denies pain in the absence of “personhood”, in line with Doyal who wrote: “All these capabilities must be present over sustained periods of time, enough for individual human identity—“personhood”—to be both formed and expressed. Of course, the fact is that even healthy infants do not possess these attributes and therefore are not persons in these terms”<sup>7</sup>. The biomedical ethicist Tristram Engelhardt approved the practice of subjecting newborn infants to painful procedures (for example, circumcision) on the grounds that they cannot integrate the experience of pain sufficiently to be said to actually suffer<sup>8</sup>.

It seems we need to clarify the terms we are using, because there is much confusion between the terms *pain* and *suffering*. This confusion leads to negation of evidence (neonatal pain) on the basis of a feature (personhood) that is unnecessary for the perception of pain, but is necessary to *suffer* (as we shall see). The definition of pain of Anand and Craig was aimed at overcoming this difficulty, but is indeterminate, as it attributes the capacity to feel pain to all living beings, including perhaps plants. This vagueness devalues the neonatal pain that all neonatologists know and treat.

What is pain? Paraphrasing Augustine of Hippo, we can say: “If nobody asks me, I know; if I try to explain it, I don’t know” (Conf. 11,14,17). Pain is the only sensation of which we have no memory. Humans can remember the stimulus that provoked pain, or its organic consequences, but we cannot recall pain to mind as we recall flavours, noises, scenes, and similar sensations. It is difficult



to describe and explain pain, but we can describe its manifestations, which are of three types:

1. *The stimulus*: we recognize a stimulus as potentially painful even though we cannot see the victim's reaction, because we appreciate its intensity and kind (e.g., a scalpel on the skin, a needle prick, or even excessive pressure on some part of the body).
2. *Bodily consequences*: lesions, hormone production (cortisol, endorphins, epinephrine), changes in physiological parameters (heart rate, blood pressure, sweating).
3. *Behavioural changes*: emotion (fear, anxiety, flight) manifested through mime and posture.

These three manifestations are evident in newborns, even emotion: studies on neonatal developmental care by Als demonstrated that it is correct to talk about anxiety and fear in newborns, who are "psychobiologically social beings"<sup>9</sup>. Thus newborns feel pain in a way that depends neither on self-awareness nor on previous painful experience.

The word "suffering" is often confused with the word "pain." Cassell wrote: "A search in the medical and social-science literature did not help me in understanding what suffering is: the word 'suffering' was often coupled with the word 'pain', as in 'pain and suffering'"<sup>10</sup>. Although pain and suffering are closely identified in the medical literature, they are phenomenologically distinct. "Pain has a felt quality, a felt intensity. Suffering on the other hand, is not located in the body"<sup>11</sup> or "Pain refers to extreme physical distress and comes in many varieties: throbbing, piercing, burning. Suffering, by contrast, refers to a state of psychological burden or oppression, typically marked by fear, dread or anxiety"<sup>12</sup>. What is suffering? Cassell writes: "Suffering can be defined as the state of severe distress associated with events that threaten the intactness of the person"<sup>10</sup>. Schopenhauer usefully defined suffering as "the gap between what we demand or expect from life and what actually comes to us"<sup>13</sup> [and is recently echoed by van Hoof: "Suffering is to be understood as frustration of the tendency towards fulfilment of the various aspects of our being"<sup>14</sup>]. Schopenhauer's definition is in my opinion more adequate for human experience, though even the former obviates the dichotomy between physical and psychological experience. Cassell's definition regards suffering as a withdrawal of what is, while Schopenhauer's links suffering to what will be, to desire. Desire is what more fully identifies humans: frustration of the desire for fullness, in whatever form, is a source of suffering. In humans this desire manifests as a desire for beauty, power, freedom, love, and physical integrity. Is it possible to speak of desire in newborns? Some deny it, as they do not strictly consider newborns to be "persons". Various philosophical definitions of "person" exist, some based on the criterion of relationship or on self-awareness<sup>15</sup>, others on sensation<sup>16</sup>. Engelhardt writes: "What distinguishes persons is their capacity for self-awareness, rationality and reliability"<sup>17</sup>, excluding newborns from the realm of personhood, as other authors do<sup>6,7</sup>. Boetius, whose definition is accepted by

many authors, defined person as “an individual substance of rational nature” (*naturae rationalis individua substantia*)<sup>18</sup>. This definition contains three elements: *substance*, *individuality*, and *rationality*. We cannot understand the term “person” without explaining the term “substance”. What does “substance” mean? Aristotle said that “it is what is not predicated of a subject, but of which all else is predicated”<sup>19</sup>. Although we cannot separate accidents from substance, neither can we identify substance with accidents. For instance defining a person as an entity because he/she is self-aware, means identifying an accident with the substance, because self-awareness is an accident. Do those who are not self-aware (for instance during sleep or coma) cease to be persons?

Second: newborns are individuals.

Third: have newborns a rational nature? As they have a human genome, newborns are human beings. The fact that they do not yet exercise rationality is due not to a lack of rational nature and capability, but to the fact that this capability is temporarily not exercised because the neurological development necessary to exercise it is not completed.

Thus it is reasonable to consider that newborns are persons and that they may have desires.

But also clinical observation of newborns suggests a nature marked by deep desires. Growing, feeding, seeking milk and crying to obtain it are signs of a desire for health. Our observations on neonatal pain reinforce this. If newborns are given a series of stimuli (massage, perfume, sweet taste, voice) during blood sampling, the pain is felt less<sup>20,21</sup>. If the same stimuli are given by a hasty, inattentive caregiver the effect is different: an attentive caregiver administering the same stimuli allows the infant to obtain much better analgesia. Thus we showed that non-pharmacological analgesia is useful for newborns, but to work, it must be administered in a certain way. In other words, newborns can recognize and distinguish an “attentive” caregiver from a “hasty” one. They express a form of preference and desire. Since our definition of suffering is based on frustration of desires, it is legitimate to speak of “neonatal suffering”.

Thus, although pain and suffering are closely identified in the medical literature, they are phenomenologically distinct: pain is a fundamentally “physical” phenomenon—the clash arising from an attack to our physical integrity—whereas suffering is something broader, where pain is one of its sources and desire is its condition: we can define it as *the clash arising from an attack to our person’s integrity*. Both definitions highlight the non-passivity (clash) of the “victim”.

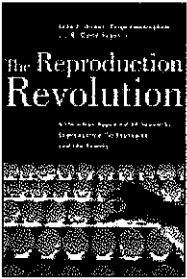
In conclusion, we can say that *newborns feel pain* and that *newborns suffer*. These two statements are important because they justify the use of analgesics in newborns, which is still rarely considered<sup>2</sup>. They are also important because they accord dignity to newborns, often treated as persons *in fieri*, incomplete and unworthy of respect. Much is still to be done towards full recognition of their dignity: premature newborns, unlike adults<sup>22,23</sup>, are still subjected to stressful and painful procedures without adequate analgesia; they are isolated from the family environment; they live in an incubator deprived of the sensory input necessary for their neurological development. Full acknowledgement of their dignity may be a prerequisite for better treatment of premature babies.

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# IMMEDIATE ANIMATION: THOMISTIC PRINCIPLES APPLIED TO NORMAN FORD'S OBJECTIONS

FR. JUAN R. VÉLEZ G., M.D., PH.D.

## Abstract

*Norman Ford and other scholars argue that the human embryo cannot have a human soul until after week two of fertilization. They claim that the individuality proper to ensoulment requires the development of the primitive streak and excludes the possibility of twinning. Their arguments are refuted by principles of philosophical realism inspired by Aristotle and Aquinas. According to these principles, the new substance formed by the union of the paternal and maternal DNA has a rational soul. The zygote, to be human, requires a human soul that determines its human development. The primitive streak is part of this development, not a condition of it. Twinning does not disprove the existence of a previous embryo with a human soul. Instead it indicates the existence of a new embryo derived from some totipotent cells that separate from the first embryo.*

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Contemporary biology confirms the intuition that a human individual begins to exist at the moment of fertilization yet the perennial philosophical controversy concerning the time of animation or ensoulment persists.<sup>1</sup> Although Christians have always taught respect for the human fetus and condemned abortion as a grave sin, none of the ecumenical councils issued a magisterial declaration regarding the time of ensoulment. In the 13<sup>th</sup> century Thomas Aquinas maintained Aristotle's theory of delayed animation. In subsequent centuries however the theory of immediate animation gained prevalence over that of delayed animation.<sup>2</sup> During the second half of the 20<sup>th</sup> century, this widely held view of immediate animation was contested by various authors.<sup>3</sup> Norman M. Ford, one of the authors who argue against immediate animation has restated his position in support for a mediate theory of hominization in his recent book titled *The Prenatal Person*.<sup>4</sup>

The first part of this article examines the positions held by Thomas Aquinas based on the foundations of Aristotle's embryology and metaphysics. Employing the same philosophical principles, but starting from correct embryological facts, it argues in support of the proposition that the human embryo has a rational or intellectual soul from the moment of the union of the male and female gametes.<sup>5</sup> On the basis of Aristotelian-Thomistic principles the second part of the article examines and refutes the objections to the theory of immediate animation posited by Norman Ford, S.D.B., John Mahoney, S.J., and Richard McCormick, S.J.

In the 4<sup>th</sup> century B.C. Aristotle formulated a theory on the soul or intellectual principle of life that organizes the human body. He defined the soul as “the cause and first principle of the living body”;<sup>6</sup> it is the animating principle of living things. According to his hyleomorphic theory of the composition of things the form or soul “is a kind of actuality and principle of that which has potentiality to be such.” The soul “is the first grade of actuality of a natural body having life potentially in it.”<sup>7</sup> Living organisms are a composite of actuality and body, where the actuality is understood as form or soul. The soul organizes the parts into a whole that is more than the sum of parts. The soul of this organized whole possesses powers or faculties that actuate the “life potentially in it.”

The Greek philosopher described a gradation of souls from plants to humans based on the powers of each type of soul. The lowest type of soul is the vegetative soul which is found in plants. It only has the powers of nutrition and reproduction. Animals possess a sensitive soul, which is a higher type of soul that directs sensation and local movement. Humans have the highest type of soul, the rational soul, that contains in itself all the lower forms in addition to the power for reasoning. According to Aristotle, human generation begins with a vegetative soul which is later replaced by a sensitive soul and finally by a rational or intellectual soul.

Following Aristotle’s primitive theory of generation and embryology, Thomas Aquinas worked out a theory of delayed animation. Aquinas thought that the soul, the substantial form of man, can only exist in matter capable of receiving it. In other words the soul and body must be proportionate to each other.<sup>8</sup> According to him the intellectual soul needs “diversity in parts” for it to be “disposed for the different operations of the soul”<sup>9</sup> so only after certain development could the body receive an intellectual soul.<sup>10</sup>

Aquinas considered that the union of the “fetal matter” provided by the female and the semen lacked those “diverse parts” and therefore an intellectual soul could not be present in the *conceptus*. In the words of Donceel, what Aquinas had in mind at the start of pregnancy is “potentially, virtually, a human body.”<sup>11</sup> For Aquinas ensoulment did not occur until an animal body was generated that was capable of receiving a rational soul. He did not know that a fertilized egg (zygote) has the complete genetic information which directs the development of a new and unique human being and therefore constitutes adequate matter to discern the simultaneous existence of a human soul.

Aquinas theorized that the male semen acts as a “formative power” or *virtus formativa* that organizes the fetal matter provided by the female to generate first a vegetative substance with a vegetative soul. The father’s soul is the principal cause for the generation of the vegetative soul and later the sensitive soul. He thought that it is “through the transmission of semen that the nutritive and sensitive souls begin to be; but this is not true of the intellectual soul.”<sup>12</sup> He argued that the semen cannot transmit the intellectual soul because this would mean that the soul would be dependant on matter for its being<sup>13</sup> and that there would be loose substantial forms preceding the generation of bodies.<sup>14</sup>

The vegetative soul that is present at the moment of fertilization ceases to be when an animal body is formed<sup>15</sup> and a sensitive soul makes its appearance.<sup>16</sup> The new animal body develops until the ordering of its parts makes it capable

of receiving a rational soul. Then in turn the sensitive soul ceases to be and it is succeeded by an intellectual soul created directly by God.<sup>17</sup> It is more perfect than the other souls since it is nutritive, sensitive, and intellectual.<sup>18</sup> The succession of souls is a philosophical explanation to account for the existence of vegetative and sensitive souls prior to animation with a rational human soul. In sum, Aquinas held that the human body is generated by the parents and when it is sufficiently disposed it is animated by a rational soul that is created by God.<sup>19</sup>

Today our present knowledge of embryology allows us to criticize Aquinas' conclusion while maintaining his philosophical principles. In the first place it is known that the sperm disappears after copulation and as such cannot have an organizing power or *virtus formativa* that functions after fertilization of the ovum. Following fertilization neither the sperm nor the ovum exist, but rather a distinct organism that begins to develop to become a mature human adult. If one were to hold as Aquinas that the embryo develops gradually in order to become apt for a sensitive soul and later continues to develop until it is ready for infusion of a rational soul, then one is faced with the lack of an apparent intrinsic cause.<sup>20</sup> As Stephen J. Heaney points out, the development of the embryo is an activity internal to the embryo based on its genetic material rather than one performed by an extrinsic power.<sup>21</sup> The embryo is the cause of this development and therefore the human soul is necessary at the time that the formation of a specifically human body begins.<sup>22</sup>

When Aquinas argued that organs or diverse parts must be present before human ensoulment he did not actually believe that at day 40 or 90, male and female embryos respectively, actually engage in rational thought. John Haldane and Patrick Lee think that Aquinas did not consider that actual organs to support the operations of the rational power were required for the embryo to receive a rational soul. Aquinas only reasoned that the *primordia* of the organs for rational activity should be present in the embryo.<sup>23</sup> Haldane and Lee rightly affirm that Aquinas was unaware that the embryo satisfies the conditions of sufficient material organization for the development of the organs necessary for its species.<sup>24</sup>

Aquinas adopted other mistaken premises from ancient embryology such as the passivity of the female, and his notion of menstrual blood, and he ignored the highly organized female gamete as well as the genetic structure of the chromosomes that makes the embryo ready for rapid development. However, his philosophical principles regarding the immaterial nature of the rational soul, formal causality, and the relationship between act and potency are key to a correct understanding of human ensoulment. Various scholars such as Stephen J. Heaney, Benedict Ashley, Albert Moraczewski, John Haldane, and Patrick Lee convincingly argued that, if Aquinas' reasoning were rightly interpreted in light of current embryology, one would conclude that the zygote is matter well disposed for animation by a spiritual soul.<sup>25</sup>

Beginning in the 17<sup>th</sup> century, Thomas Aquinas' theory was contested by some physicians and theologians who advanced the theory of early and even immediate animation. Thomas Fiennus (1567-1631) and Paolo Zacchia (1584-1659) were the first to advance this theory.<sup>26</sup> Fiennus was a Belgian physician and professor at the University of Louvain. He wrote a book entitled

*De formatrice fetus liber* that challenged the idea of delayed animation. Fiennus held that the fetus was infused with a rational soul about the third day after conception and that the soul was responsible for the formation of the fetus. He argued that if higher mental faculties were required for the ensoulment then one would have to wait until the age of two or three.<sup>27</sup> After him, Zacchia, physician general of the Vatican State, also argued in *Quaestiones medico-legalis* in favor of immediate animation. He thought that the soul, which organizes the *conceptus*, is internal to it rather than remote, namely the father acting through the instrumental power of the semen.<sup>28</sup> Both refuted the Aristotelian-Thomistic notion of a succession of souls.

One of the arguments that can be made against the notion of a succession of souls with a successive creation of body and soul is its dualistic conception of the human being.<sup>29</sup> This notion reverts to the Platonic vision of the human being as a “body-soul” aggregate and describes it in terms of “a soul within a body” or “a body that has a soul.” One of the problems it poses is the relationship of the mind, understood as the soul, and the world, whereby an irreconcilable gap is established between both. Also according to this notion, physical actions are in some way independent from the soul or do not reach it. The Cartesian “*cogito ergo sum*” (“I think therefore I am”) undermines the common sense perception of ourselves as “thinking bodies” rather than “pure intellects” trapped in a body.<sup>30</sup>

The actual term “ensoulment” and the synonymous expression “infusion of the soul” are to an extent misleading.<sup>31</sup> To infuse a soul into something implies that the soul is an extrinsic principle that can be added to a substance to make it a human being.<sup>32</sup> If this were the case, one would have substance A to which a soul is added changing it into substance B. This not only does not account for the nature of substance A, but endorses the notion that the soul and body are two substances (A and B) that are united to form a human being. This dualism disregards the intrinsic or substantial unity of the human being, verified in his thoughts and actions, which is only severed by death.

Despite Aquinas’ conclusion, Aristotelian-Thomistic philosophy of being in fact argues against this dualism and favors the notion of immediate animation of the embryo by an intellectual soul. For Aquinas, in the human person there is an intrinsic and all-embracing union of body and soul.<sup>33</sup> The extent of this union, which reaches the most basic and internal level of the person, is underlined by expressions such as “an embodied soul” and “a body animated by a soul.” The intellectual soul makes the body to be and to operate, and although it is subsistent, in human life it does not exist in a separate state, but wholly united to the body.

Moderate realist philosophy lays the following foundations for a correct understanding of the immediate animation of the embryo by a subsistent rational soul. It holds that a living thing or substance exists as such until it changes into another substance by a type of change referred to as substantial. This change is a radical change in the nature of something; for example, when an oak tree is cut down, and its wood is used to make a desk, it ceases to be an oak tree and becomes a piece of furniture. In an analogous manner when the human sperm and egg are joined, there is a substantial change in which the



sperm and the egg cease to be what they were in order to become a new human substance or being called a zygote.

Each person is a concrete and unified subsistent being with potential for many different rational activities or operations. According to the scholastic adage *operatio sequitur esse* the operations of a being proceed from the nature of a thing. The operations proper to a being of a given nature cannot exist without having a “being” in the first place. The nature or essence of the human person is precisely its potential for rational activity, which distinguishes it from other animals. The person perfects its nature through rational activity, but, in itself, it is a composite whole that is independent of the actual exercise of its rational nature. Someone who does not develop the capacity to reason, or who loses that capacity through illness, may be deficient or sick, but he is no less a person.

Although there are continuous changes in the material constitution of the developing human being, none of these anatomical or biochemical developmental changes constitute a substantial change. These numerous changes are called accidental changes because they do not change the substance from one to another. They are the progressive development and growth brought about by a specific substance already constituted by its genetic make-up.<sup>34</sup> These changes point to an ultimate design, namely the mature development of a child. Rather than isolated changes, they are part of a complex and orderly design. This plan and the potential for its realization are present in the human being that is conceived at the moment of fertilization.

According to these metaphysical principles a soul makes something “what it is” from the start, namely a plant, an animal or a human being. The matter of the sperm and the ovum are the proximate matter of the zygote. The union of this proximate matter as a zygote constitutes adequate or “proportionate matter” for a rational soul that exerts an intrinsic causality on the new substance. From the start of fertilization a rational soul created by God is the cause for the change of the proximate matter into the new substance of the zygote. This human soul by means of the DNA<sup>35</sup> directs the subsequent gradual development of the new human being immediately present, normally in the maternal womb. This process is already evident within hours through a myriad of specifically oriented cell divisions and human protein synthesis.

The origins of an organism, rather than its external appearance, provide a better indication of its nature. The human gametes that contribute the original matter for the embryo point to the need for a rational soul as an organizing principle. The physical appearance of the embryo is deceiving because of its likeness to other species, but it is, in fact, the likeness of a human being in its early stages of development. Unless the embryo suffers some major defect it will exhibit as gestation advances, the external appearance of a human fetus.

Nutrition, sensation, and local movement denote a living organism which possesses at least a sensitive soul. By virtue of its human origin and its final end, a human being, regardless of its size, not only has a sensitive, but also a rational soul with the potential powers for all the operations proper to a human person. Among these powers reason and self-will are unique to humans. Although the embryo does not apparently display the operations of these powers, it must have an actual rational soul because it has the potentialities for these activities.

The actualization of these higher powers requires the brain and sense organs that are necessary for a normal human life. The embryo's early development prepares the parts of the body that will allow the future actualization of its potentialities. From the start of its existence, however, the embryo displays inferior powers—namely, nutrition, development, and growth. The new and distinct living organism derived from the union of two human reproductive cells gives immediate signs of intrinsic activity or operations proper to its species: chromosomal rearrangement, cell division, protein synthesis, and spatial configuration.

These actions indicate a unity stronger than the mere aggregation of cells. There is a coordinated activity with an end-specific direction that is brought about by the soul. The cell nuclei provide the initial integrating function in the organism. They act as the instruments of the same internal organizing principle or rational soul in a manner analogous to the brain before the actual development of this organ.<sup>36</sup> The human embryo is considered a living being belonging to the species *homo sapiens* because of the presence and activity of specifically human cells with the intrinsic potential for reasoning.

The philosophical focus of the last few centuries on the person as a “thinking subject” has led to define persons based on the capacity to perform acts such as reasoning or self-consciousness. Certainly, these are important faculties that are proper to human nature. Persons, however, actualize or develop their existing potential capacities over time unless a serious, incapacitating illness intervenes. Regardless of functional capacities, a human being is a person because he has a human nature with an inherent potential for rational activity. Under normal circumstances, the future child will develop these potentialities as his sense organs and brain grow and he receives education.

Robert E. Joyce has described well what potentiality is in the following words: “[E]very potentiality is an actuality. A person's potential to walk across the street is an actuality that the tree beside him does not have. A woman's potential to give birth to a baby is an actuality that a man does not have.”<sup>37</sup> The embryo is a person in act, not in potency; only its functional capacity is potential.<sup>38</sup> Whether it achieves certain potential functions does not determine what it already is, namely a human person at its early stage of development.

Ethicist Renée Mirkes, O.S.F., points out that some of the objections raised against the embryo's personal condition are based, in part, on a functional model of the human person. If the person is defined primarily as a human being able to perform certain functions, then the absence of some of these will disqualify him from the status of human. The functional model is adumbrated by ethicist Joseph Fletcher who presented the following list of person-defining behavior in a 1972 *Hastings Center Report*: minimum intelligence, self-awareness, self-control, a sense of time, a sense of futurity, a sense of the past, the capability to relate to others, concern for others, communication, control of existence, curiosity, change and changeability, balance of rationality and feeling, idiosyncrasy, and neocortical function.<sup>39</sup>

For practical purposes, these criteria can be summarized by three qualities, self-consciousness, the capacity to reason, and the capacity for communication. According to those who hold these criteria, personhood depends on the

possession of these characteristics. If these criteria were valid, hardly any five-year-old would qualify as a person. More importantly, the simple application of these criteria disregards the philosophical doctrine of potency and act,<sup>40</sup> a basic element in the understanding of beings and their development under normal conditions.

Mirkes criticizes this restrictive “functional” criterion for personhood: “Ultimately, it excludes all but adult human beings from personhood status or awards moral status to non-human creatures that otherwise fail to meet even a generally-accepted, common sense notion of human personhood. On its face, the theory is counterintuitive. You and I spend a great deal of our lives eating, sleeping, relaxing, all the while engaging only minimally or not at all in the person-defining activities of thinking, planning, and self-reflective interaction with the world.”<sup>41</sup> For this author, the degree of consciousness, or lack thereof, cannot be the criterion for giving or withholding respect, just as it is unethical to disrespect an adult in a state of coma.

The moral status of the embryo is founded on its human nature and corresponding inalienable rights rather than on its functional capacity. The constitutions and laws of many countries defend the person from unjust aggression based on the notion of the inalienable rights of each human being.<sup>42</sup> However in many of these countries the embryo is not considered a person and is excluded from rightful protection under the law. The laws that permit abortion and *in vitro* fertilization contradict the inherent respect due to each member of the human species. In these nations the right to human life seems to hinge on functional and utilitarian criteria established by legislatures and courts. These arbitrary criteria often reached by consensus contradict the conclusions that stem from a metaphysical analysis of the human embryo.

## **Objections of Norman Ford and Other Contemporary Authors**

A number of authors sustain the theory that a fetus can only be animated with a human soul after the second week of life. Nonetheless among these some hold that from its beginning the human embryo must be treated with the respect due to human life because it has the potential or promise of becoming a human person. Norman Ford, S.D.B. reasons that, since there is a reasonable doubt about whether it is a person, the embryo should be treated as a person.<sup>43</sup> Mahoney concludes similarly but makes exceptions for cases such as genetic abnormality of the embryo or rape of the mother.<sup>44</sup> Their reluctance to posit the personhood of the human embryo *ab initio* is based on their assessment of an initial lack of individuality in the embryo.<sup>45</sup> Both consider biological stability as a necessary pre-requisite of personhood and, therefore, hold that the possibility of twinning precludes personhood before the end of the second week of life.<sup>46</sup>

According to these scholars the principal objection to the personhood of the embryo at moment of fertilization is its purported lack of ontological individuality. A theory of “delayed personhood” of the embryo was presented in the 1980’s by Norman Ford<sup>47</sup> and John Mahoney, and more recently by Richard McCormick, S.J. Mahoney argues that self-differentiation, rather

than cell multiplication, indicates the presence of an “irrevocably individual biological subject,” which he sets forth as the condition for ensoulment and the consideration of the embryo as a human person.<sup>48</sup> Oddly, he does not go on to try to establish when that stability occurs. He only affirms that to ask for a rudimentary brain would amount to requiring too much and would disregard the findings of genetics. Ford and later McCormick sustain that the development of the primitive streak<sup>49</sup> at the start of the third week is necessary for the formation of an “ontological individual.”<sup>50</sup>

Ford explains that notwithstanding the continuity in the biological identity of the zygote, embryo, fetus, and child, a genetic individual should not be assumed to be the same ontological individual. He points out that, although some twins are genetically identical, they are different ontological individuals. For him, the genetic constitution is not enough to distinguish the existence of an individual human being. Ford repeats the idea that “There can be no person before the actual formation of a human individual, beginning as an on-going individual embryonic human body”<sup>51</sup> where the latter is understood to be a “truly multicellular individual living body.”<sup>52</sup>

In principle, one would agree with Ford that a person exists when the presence of a human individual can be established. The problem is then formulated in terms of what constitutes a human individual. Must it be a multicellular organism? What degree of unity does it need for it to be an organism rather than a conglomerate of cells loosely held together? Although Ford presents well-documented scientific facts, his interpretation of these is debatable. He argues that the eight-cell zygote does not have the necessary unity to be considered an ontological human being because it lacks tight junctions between its cells and the cells are simply in contact with the protective *zona pellucida*. He also points out that the human zygote does not grow rapidly until implantation in the uterus.<sup>53</sup>

It can be countered that the unity of eight cells, which comprise the zygote, appears to be rudimentary, but it is not negligible. The covering around these cells separates them as one unit called a zygote. After all, these cells are not considered eight zygotes, and neither do they develop into eight embryos. On the other hand, the slow growth of the zygote until it reaches the uterus does not indicate lack of unity. It may be due to the slow initial cell divisions, the small space available for growth in the Fallopian tubes and the need for a rich uterine supply of nutrients. Until then, it is efficient for the blastomeres to take up their own nutrients through absorption of fluids in the oviduct.

The zygote has a purposeful, self-directed activity that is independent from the two originating gametes. It is an embryo with genetic individuality that follows a continuous process of development and growth. Regardless of its possibility of twinning, it constitutes a new, living, human organism that can be considered a person. Furthermore, the possibility of having identical twins on day 2 is an indication of early determination of the embryo rather than of indetermination.<sup>54</sup>

Ford admits that the Aristotelian-Thomistic philosophical principles of actuality and potentiality, matter and form, could, in theory, explain the existence of the human person at fertilization.<sup>55</sup> Next he rightly cautions that

correct scientific facts and interpretation must be used in order to apply these principles properly. Ford however thinks that those who profess these principles may unwittingly be influenced by philosophical dualism in the interpretation of the body-mind relationship.<sup>56</sup> According to this way of thinking, the spiritual soul would be an autonomous, ontological entity that would dualistically unite to a zygote to form a person. The same criticism can, in fact, be applied to his own implicit notion of ensoulment. For him, the embryo is infused with a spiritual soul once it has developed the primitive streak. Isn't this the same dualistic interpretation of the body-soul relationship to which he objects, only delayed by two weeks?<sup>57</sup>

Others might even unknowingly adopt Aristotle's notion of supervening souls whereby a vegetative soul is replaced by a sensitive one and later by a rational one. Both options seem flawed with the same dualistic approach. The rational soul does not unite to a zygote or to a two-week embryo in order to form a person. Instead, at the start of the process of fertilization two gametes of the opposite sex are simultaneously united by a soul. Precisely, the soul causes this biological process, but in an intrinsic manner rather than acting as an external agent. If the latter were to occur, a rational soul would have to inhere into a substance with an already given substantial form and unity.

Richard A. McCormick also holds that genetic individuality is not sufficient to consider an embryo a person.<sup>58</sup> Like Ford he contends that only after the appearance of the primitive streak, after which twinning does not occur, does an embryo obtain the "developmental individuality" necessary to be considered a human individual.<sup>59</sup> However, both authors conclude that in light of its intrinsic potential, the "pre-embryo" should be treated as a person.<sup>60</sup>

The key issue for Ford and McCormick remains the identification of an ontological individual defined as a multicellular organism with a complete human nature signaled by the development of the primitive streak. According to them, the process of twinning precludes the identification of an ontological individual. Ford considers that, prior to twinning (when it occurs), it would be better to speak of a potential person or persons.<sup>61</sup> He posits as the necessary condition for the existence of a human soul the presence of a living body actuated by a human form.<sup>62</sup> But isn't the human form precisely that which the soul provides? How can one expect to have a body informed by a human form without already having the soul that informs matter in a way that such a body exists as a determinate matter?

Ford insists that the primitive streak is the *sine qua non* for determining the presence of a human body because this structure serves as a body axis and provides bilateral symmetry for the process of gastrulation (formation of the three germ layers) during the third week. It could be argued, however, that the appearance of the primitive streak is a part of the intrinsic development of the embryo rather than a defining or rate-limiting step in its formation. Furthermore, why not consider the formation of the bilaminar disc during the first week as the indispensable step for the appearance of the primitive streak? In fact, the blastocyst, with its inner cell mass producing the bilaminar disc, provides an earlier axis for the development of the embryo.

Furthermore, one cannot ignore the unitary nature of the zygote and its

purposeful activity such as the development of the blastocyst, the formation of the bilaminar embryonic disc and the embryo's implantation.<sup>63</sup> Ford is obliged to admit the differentiation that takes place in the blastocyst and gives rise to the placenta and extraembryonic membranes.<sup>64</sup> He thus recognizes a cohesion that indicates a unity in the zygote, and even more in the blastocyst, yet he denies that these express the ontological unity of a human being.<sup>65</sup>

Rather than contradict his own position, Ford admits a degree of differentiation in the developing human individual. This differentiation is the development of a type of being which is individuated by certain matter. Despite the changes in matter, the process of differentiation is not a successive transformation into different kinds of intermediary beings. From the start the embryo is a determinate type of matter that possesses an individual human nature. This human form of being, already individuated by matter, reaches different degrees of development, but, from the beginning, its nature is human.

The high degree of undifferentiation of the embryonic cells makes the process of twinning possible, but these cells do not exist by themselves. They are part of a zygote that functions as a whole and will be recognized as such by the female body during the uterine implantation on the second week and even earlier. During the first weeks, the embryonic cells are considered totipotent in virtue of their capacity to commit to different cell types and, in some cases, to separate and constitute a new embryo. In the case of monozygotic, or identical twins that derive from one ovum, a blastomere which is a totipotent cell separates and originates a new embryo. This can occur at the two-cell stage, but more often, twins are the result of the separation of some cells from the inner cell mass during the early blastocyst stage.

Another principal objection to the existence of an ensouled human embryo before the end of the second week is, that in the case of twinning, the embryo would have to split into two human beings or cease to exist as an ontological individual. Ford states that it is more plausible to argue that an ontological human individual had not yet begun to exist. But this leads to a question that he does not answer: why would the original embryo have to lose its ontological individuality? In the analogous cases of cloning or asexual reproduction of animals, the original animal does not cease to exist.

A comparison with the division of a flatworm can illustrate this point. When a flatworm is cut, a new one arises, but the original one does not lose its being.<sup>66</sup> Ford does not show how the occurrence of twinning necessarily refutes the assertion that the zygote is a human individual from the beginning of fertilization. On the other hand, considering that the human soul as a non-material principle of life cannot divide into two, one should postulate that during twinning a second human soul is created by God. The development of two embryos suggests that two distinct souls have actually begun to exist in successive moments.<sup>67</sup> In twinning there is, in the first place, an individual A with a human soul. Then one or more totipotent cells from this individual separate and form individual B that is animated by another human soul.

The concept of "biological stability" that authors such as Ford defend in light of the possibility of twinning is in part untenable. The very possibility

of the cloning of adult cells serves as a rebuttal to this pre-condition for ensoulment. It seems reasonable to assume that, if humans are cloned in the future, the resulting embryo transferred to a woman's uterus will develop as a human being, body and soul. This would not make the adult from whom the clone was taken any less of a person. The same can be said for embryonic cells. In fact an identical twin can be considered a clone of an earlier embryo whose individual existence it does not negate.

A conceptual difficulty regards the manner of causality that the soul exerts over matter. However, the problem is not whether a non-material principle divides or whether God can create more than one soul during a gestation. Neither is the claim that the soul arises from matter a real difficulty. Analysis of human knowledge refutes such possibility; only a non-material principle can give rise to non-material operations, such as the apprehension of universals. Aquinas' theory of the causality of being by the First Being provides an adequate explanation for the existence of the rational soul.<sup>68</sup>

The divine causality of being has matter as a principle of individuation. Wherever there is appropriate matter, God causes a new rational soul to exist. Appropriate matter should not be considered the end product, namely an embryo with human appearance, but the matter with the necessary elements from which it is created, that is, the human sperm and egg that when adequately united produce a human zygote.

The appropriate matter for a human soul, therefore, is human gametes of different sex whereas non-human gametes (or a combination of human and non-human gametes) would not fulfill the conditions for the procreation of a human being.<sup>69</sup> For example, a human sperm mixed with a sheep egg would not constitute adequate matter for a human soul. Matter is proportionate to a human being when it meets the requirement for the formation of an individual of the human species. The need for proportionate matter for human life is underscored by the requirement in human procreation of human gametes of opposite sex, an adequate environment for fertilization, and a precise window of time. Only human gametes (as opposed to gametes of a different species) are appropriate for animation of human beings.

This does not mean that individual gametes constitute persons, but that they are the matter which the soul created by God unites and converts into a human being. The rational soul determines or informs the matter to be what it is, a human body (matter determined and quantified) organized by a soul.<sup>70</sup> At the beginning of fertilization, when the soul determines the gametes, they cease to exist as such; from the gametes, the soul has formed a new substance, or human being. Otherwise to hold that the zygote is the apt matter for ensoulment implies that the zygote already has a substantial form that *a posteriori* receives a rational and immortal soul. This would bring us back to Aristotle's notion of a succession of souls from a vegetative one to a sentient one and finally to rational one.<sup>71</sup>

As explained earlier authors such as Ashley and Moraczewski hold that the zygote constitutes the proportionate matter for ensoulment and human personhood.<sup>72</sup> However, in keeping with the reasoning developed in this article, namely that the soul is the substantial form of the human body, it would seem logical to argue that the gametes instead are the proportionate matter. When

they are informed by a soul they become a zygote.

In the end, the debate centers on the subject of potentiality and actuality that was briefly discussed above. What is considered by some “a potential human being” is an actual human being with potential for development and growth. The Aristotelian notion of act and potency supports an understanding of the embryo as the beginning of a human person in constant development and growth towards a final end. This individual human being is a person that if uninterrupted continuously develops its potential as a fetus, child, and finally a mature adult.

In *The Pre-natal Person*, Norman Ford has also raised another objection to the individuality of an embryo before the second week of gestation.<sup>73</sup> Based on extrapolation from the studies of chimeras in certain mammals he denies the ontological individuality of human embryos before the end of the second week. Although human chimeras have not been created we will briefly consider this hypothetical objection. A chimera is an individual that has more than one genetically distinct population of cells because it originated in more than one embryo. Chimeras are non-monozygotic twins that have similar genetic and physiological characteristics as if they were monozygotic twins.

Naturally occurring chimerism is common in cows because of the propensity that cows have to form vascular anastomoses early in gestation.<sup>74</sup> It occurs less commonly in other species. In the case of naturally occurring chimeras, two embryos eventually give rise to two offspring so that there is no argument against the individuality of each embryo. The possible objection to individuality is only raised with the production of artificial chimeras.

In recent years scientists have experimentally produced chimeric embryos that have resulted in the birth of chimeric mice as well as sheep. In these experiments two or more early embryos are fused into one, producing a chimeric embryo. Unlike the naturally occurring chimerism in cattle, the result is one offspring. This biological phenomenon that is a current subject of research can be attributed to the plasticity of the early embryo. As is widely known, embryonic cells have an extraordinary degree of developmental flexibility. It is therefore not surprising that embryos can incorporate other genetic material into their own genetic code. This incorporation can be likened to a sophisticated graft at a cell nuclear level. In this case, instead of receiving a heart or kidney transplant, the embryo receives a “genetic transplant.”

Ford implies that when the results of these experiments are applied to the human species, they argue against the individuation of human embryos at the four-cell stage on day 2 of the embryo’s development. Yet all that can be said according to this logic is that individuation would occur at the earliest after day 2. In other words it would not necessarily be delayed until day 14.

Ford’s objection against immediate animation is better supported by actual twinning; when it occurs in the first week it would suggest a delay in the differentiation or individuation of the embryo. However, applying the same logic of individuation, how can it be asserted that identical twins, in fact, become human individuals after day 14 when the process of twinning by which they are clearly distinguished as individuals often takes place during the first week? Therefore, the differentiation of twin embryos a few days after fertilization



actually refutes the claim of indetermination until day 14.

The question concerning the ontological individuality of the embryos that exist prior to the production of a chimera should nonetheless be addressed. The empirical observation in the lab production of chimeras indicates that a chimera is produced from a given number of embryos. When a chimera is produced one or more of the contributing embryos cease to exist, but the end of their existence does not pose a logical refutation to the fact of their previous existence as individual organisms. As everything in nature, things are and later cease to exist.

Further consideration suggests two explanations for the causality of a chimeric embryo. If for example we take two embryos to form a chimera, either one embryo received a "genetic graft" from an embryo that ceased to exist, or both embryos contributed with their matter to the production of a sole chimeric embryo. In the latter case both embryos ceased to exist and a new embryo appeared.

If in the future human chimeras are produced it will not be difficult to explain the cessation of the existence of embryos and much less to counter the contradictory notion of the fusion of souls. The philosophical question to be answered will be why this occurs. If embryos cease to exist philosophy will need to reflect on the purpose for this type of generation.

In the case in which the earlier embryos cease to exist, these embryos do not give their substantial form to the new embryo since they cannot transmit or create a new immaterial form. Instead they contribute some or all of their matter to the formation of a new organism. The rational soul of a chimera would require a higher cause, namely God. Based on this same philosophical principle Aquinas argued that the succession of souls was not a transformation of a vegetative soul to a sensitive soul and finally to a rational soul. For Aquinas the vegetative soul was succeeded by a sensitive soul and this one was succeeded by the rational soul created directly by God.

In other words, if human chimeras were to be produced *in vitro* one could imagine the following sequence of events: First one has embryos "A" and "B"; when these are joined they cease to exist and an embryo "C" is produced. Embryos "A" and "B" contribute to the generation of the body of embryo "C," but its rational soul is created by God at the moment when "A" and "B" are fused. Put in other words, the souls of "A" and "B" are not fused to produce the soul of embryo "C"; only part or all of their matter is fused. The soul, as an immaterial principle that does not have parts, can neither be fused nor divided. Just as twinning does not represent the division of souls, chimerism does not represent their fusion.

## Conclusion

Norman Ford, Richard McCormick, and other contemporary scholars claim respect for the human embryo from the moment of conception, but they assert that a rational soul cannot be present in an embryo until after the appearance of the primitive streak at the end of week two. Their arguments in favor of the delayed animation of the human embryo lend support to those who justify the

unethical treatment of human embryos that they themselves reject.<sup>75</sup>

Instead classical philosophy of being provides good arguments for the existence of a rational soul in the embryo from the first moment of fertilization. Its metaphysical foundations support the understanding of the embryo as a new and unique being that undergoes successive, non-substantial changes to develop its potential as a human being.

The ontological nature of a human being refutes the purported necessity for "biological stability" as a pre-requisite for animation of the fetus. Rather than a rate-limiting step for the animation of an embryo the primitive streak is the actualization of the potential inherent in the embryo's human nature. For that potential to be actualized there first needs to be an individual being with a human nature. Thus instead of speaking like Ford of a "pro-embryo"<sup>76</sup> with developmental potential to become an ontological human individual we should speak of the embryo as an actual human being with potentialities that will be actualized over time.

Twinning during the first week actually refutes the common objection against immediate personhood. If twinning during the first week gives rise to two or more individual beings how is it possible to argue for the delay of personhood until after the appearance of the primitive streak? In itself the process of twinning does not disprove the previous existence of an embryo informed by a soul. In a similar line of reasoning neither would the hypothetical phenomena of chimeras in humans refute the previous existence of embryos with a rational soul.

In addition, the human embryo displays physiological characteristics proper of the human person. The nuclei of the cells serve the intellectual soul or organizing principle, until the brain begins to develop. The embryo carries out functions in an organized and end-oriented manner, such as the synthesis of specific human proteins and the formation of human organs. This new and complete human substance, with a rational soul, has the potential for reasoning and, in time, will develop into a mature adult person.

For contemporary society, the assertion that the embryo deserves respect because it represents the beginning of a human life affords the embryo a weak and insufficient defense. It is obvious that the embryo constitutes human life, but is it a person? If it is a new individual human substance or being, then it must have a rational soul as its organizing principle. As such, it is properly considered a human person and is entitled to the rights of a person. In short, "how could a human individual not be a human person?"<sup>77</sup>

## Notes

- 1 In this article by the term "substance" we mean a being that subsists. For practical purposes, we use it as a synonym of the term "being" and "individual." See James F. Anderson, *An Introduction to the Metaphysics of St. Thomas Aquinas*, Regnery Publishing Inc., Washington D.C., 1997, pp. 24-25. By "nature" is understood the essence or "make up" of a thing. It also responds to the questions "What is it for?"
- 2 See E. C. Messenger, "A Short History of Embryology," in *Theology and Evolution*, ed. E. C. Messenger, Sands & Co. Ltd., London, 1949, pp. 233-242. In this chapter, Messenger recounts the theories of many theologians as well as scientists.
- 3 See Joseph Donceel, S.J., "Immediate Animation and Delayed Hominization," *Theological Studies*

- 31 (1970):76-105, Canon Henri Dorlodot, "A Vindication of the Mediate Animation Theory," in E. C. Messenger, ed., *Theology and Evolution*, London, Sands & Co., 1949, p. 260.
- 4 *The Prenatal Person: Ethics from Conception to Birth*, Norman M. Ford, SDB, Blackwell Publishing, 2002. In a thorough and balanced article, Stephen J. Heaney responded to these objections and presented philosophical arguments in favor of immediate animation. See "Aquinas and the Presence of the Human Rational Soul in the Early Embryo," Stephen J. Heaney, *The Thomist*, Vol. 56, No. 1, 1992, pp. 19-48.
- 5 In this article we espouse the general principles of philosophical moderate realism or philosophy of being based on the Aristotelian-Thomistic tradition.
- 6 Aristotle, *De Anima*, Bk 2, Ch 4.
- 7 Aristotle, *De Anima*, Bk 2, Ch 1.
- 8 In other words, matter needs to be disposed or arranged in such a way that it could be a human body. A tadpole embryo, for example, does not have matter proportionately arranged for the intellectual soul of a human. The latter must be united to a body with the sensory organs that are indispensable for the soul.
- 9 Thomas Aquinas, Commentary on *De Anima* X, ad 2.
- 10 Aquinas follows Aristotle's notion that the rational soul is infused in males at 40 days, and in females at 90 days. See *Commentary on the Book of Sentences*, Bk. III, dist. 3, q. 5, a. 2.
- 11 Joseph Donceel, S.J., "Immediate Animation and Delayed Hominization," in *Theological Studies* 31, 1970, p. 80.
- 12 *Summa Contra Gentiles* II, 86, 2.
- 13 *Summa Contra Gentiles* II, 86, 5. In another place Aquinas writes "[S]ince the human soul does not have matter as part of itself, it cannot be made from something as matter. It therefore remains that the soul is made from nothing," *Summa Contra Gentiles* II, 87, 3.
- 14 *Summa Contra Gentiles* II, 89, 4.
- 15 "This matter therefore is transmuted by the power which is in the semen of the male, until it is actually informed by the sensitive soul; not as though the force which was in the semen becomes the sensitive soul; for thus, indeed, the generator and generated would be identical." Thomas Aquinas, *Summa Theologiae* I, q. 118, a. 1, ad. 4.
- 16 According to Aquinas the vegetative soul is not transformed or does not transform itself into a sensitive soul. A thing can only generate something similar to its species.
- 17 *Summa Theologiae* I, q. 118, a. 2, ad 2.
- 18 See *Summa Theologiae* I, q. 76, a. 3, corpus; I, q. 118, a. 2, ad 2.
- 19 E. C. Messenger, "A Short History of Embryology" in *Theology and Evolution*, p. 254.
- 20 Haldane and Lee write that "If there is no extrinsic agent responsible for the regular, complex development, then the obvious conclusion is that the cause of the process is within, that is in the embryo itself", John Haldane and Patrick Lee, "Aquinas on Human Ensoulment, Abortion and the Value of Life," *Philosophy*, Vol. 78, 2003, p. 271.
- 21 "Aquinas and the Presence of the Human Rational Soul in the Early Embryo," Stephen J. Heaney, *The Thomist*, Vol. 56, No. 1, 1992, p. 30.
- 22 See John Haldane and Patrick Lee, "Aquinas on Human Ensoulment, Abortion and the Value of Life," *Philosophy*, Vol. 78, 2003, p. 269.
- 23 *Ibid.*, p. 267.
- 24 *Ibid.*, p. 268.
- 25 See "Aquinas and the Presence of the Human Rational Soul in the Early Embryo," Stephen J. Heaney, *The Thomist*, Vol. 56, No. 1, 1992, p. 31; Benedict Ashley and Albert Moraczewski, "Cloning, Aquinas, and the Embryonic Person," in *National Catholic Bioethics Quarterly*, Vol. 1, No. 2, Summer 2001, pp. 189-201.
- 26 John Connery, *Abortion: The Development of the Roman Catholic Perspective*, pp. 168-170.
- 27 See John Haldane and Patrick Lee, "Aquinas on Human Ensoulment, Abortion and the Value of Life," *Philosophy*, Vol. 78, 2003, p. 263.
- 28 *Ibid.*
- 29 Aquinas' line of reasoning is followed by some contemporary authors who argue for delayed animation, but unlike them Aquinas did not have accurate knowledge of embryology.
- 30 According to this view the human being is not one substance, but two, mind and body. The mind exists in a body or machine.

- 31 The traditionally held term “infusion of the soul or ensoulment” is not necessary to sustain the thesis of an uncaused mover put forth by natural theology and the creation of the human soul taught by Catholic Theology.
- 32 In the 5th century, Gennadius of Marseilles employed the metaphor of God “pouring” the soul into the body already formed in the womb. See John Mahoney, *Bioethics and Belief*, p. 72. Mahoney tries to distance himself from this position. He writes that “Such reflections and speculations as these are evidence of dissatisfaction with the traditional idea of the soul as a closed, extra-terrestrial reality which is somehow and miraculously ‘added’ by God to each and every human conceptus...”, *Ibid.*, p. 78. However, his reasoning demands the acceptance of an intermediate being that is a human yet not ensouled. It is a being that he compares with primates in an evolutionary stage towards *homo sapiens* (p. 82). Ensoulment turns out to be a gradual process of “hominization” in the womb whereby he precisely posits the dualism that he wishes to avoid. Parents prepare a body and over time give it a soul, albeit acting as secondary agents.
- 33 Joseph Torchia provides a good summary of Aquinas’ notion of human nature in “Postmodernism and the Persistent Vegetative State” in *The National Catholic Bioethics Quarterly*, Summer 2002, Vol. 2, No. 2, pp. 268-270.
- 34 This constitution or determination is not an absolute one. Environmental factors such as nutrition and later education will also play an important.
- 35 The DNA of the embryo could be likened to the instrumental cause employed by the efficient cause, in this case, the soul. The soul is not equivalent to the DNA, just as the mind is not equivalent to the brain but rather it makes use of the brain.
- 36 The article cannot consider here the materialist position that equates the soul or mind with the brain. The existence of this current of thinking makes even more necessary the recognition of the embryo as a human being from the start of the process of fertilization.
- 37 Robert E. Joyce, “The Human Zygote is a Person” in *Abortion: a New Generation of Catholic Responses*, Stephen J. Heaney, ed., Pope John XXIII Medical-Moral Research and Education Center, Braintree, Massachusetts, 1992, p. 32.
- 38 The moral theologian Martin Rhonheimer argues that potential persons do not exist; rather persons who have potential exist. The fetus is not a person in potency, but a person whose potency has not yet been actualized. See Martin Rhonheimer, *Etica della Procreazione*, Pontificia Università Lateranense, Roma 2000, p. 232.
- 39 See Renée Mirkes, “NBAC and Embryo Ethics” in *The National Catholic Bioethics Quarterly*, Vol 1, No. 2, Summer 2001, p. 169. Dennis M. Sullivan criticizes the same functional definition of man in “The Conception View of Personhood: A Review” in *Ethics & Medicine* 19:1, 2003, pp. 17-18.
- 40 Aquinas’ notion of human nature is based on his understanding of God as the First and Perfect Being and other things as caused beings. God is the act of being that subsists by itself. As uncaused cause God is pure act while every created substance is a composition of act and potentiality. The caused substances participate in the act of existing of God. See James F. Anderson, *An Introduction to the Metaphysics of St. Thomas Aquinas*, pp. 28-35.
- 41 Renée Mirkes, “NBAC and Embryo Ethics” in *The National Catholic Bioethics Quarterly*, p.171.
- 42 The following are some declarations and constitutions that safeguard the inalienable rights of the human person: United States Declaration of Independence 1777, preamble; United States Constitution 1787, Constitutional Amendment n. 14; Constitution of Colombia 1991, Title 1, articles 2 and 5. Number 5 speaks of “inalienable rights”; Ch. 1, article 11 (on “right to life”), 12, 23, 14, 16 and 17; Ch 2, article 44 (on the rights of children); Constitution of Germany 1949, Ch 1, article 1 reads “Human dignity is inalienable”; Constitution of Ireland 1937, Ch 12, article 44,3,3 explicitly protects the right to life of the “unborn”; Constitution of France 1946, preamble; Constitution of Italy 1947, articles 2, 13, 31; article 32 affirms person’s right to immunity from harmful medical treatment.
- 43 “Wherever there are reasonable doubts about the personal status of the early embryo, moral principles, without prejudice to the search for truth, require that the human embryo from conception be treated as a person”. Norman Ford, “Ethics, science and embryos: weighing the evidence,” in *The Tablet*, Jan. 13, 1990, p. 46; *The Prenatal Person*, pp. 64-68.
- 44 See John Mahoney, *Bioethics and Belief*, Sheed and Ward, London 1984, p. 85.
- 45 See Norman Ford, *When Did I Begin?*, Cambridge University Press, Cambridge 1988, pp. 84-86.
- 46 See John Mahoney, *Bioethics and Belief*, pp. 64, 66-67.
- 47 Norman Ford, “The Human Embryo as Person in Catholic Teaching” in *The National Catholic Bioethics Quarterly*, Summer 2001, Vol. 1, No. 2, p. 155-161. Ford advocates ethical respect for human embryos, but he holds that “While there are good reasons to believe the early human embryo is an individual and person from conception, it is difficult to establish this with the certitude required for the Church to formally teach this,” p. 159. He argues that only about fourteen

- days after fertilization are there specialized cells and membranes that enclose an organized human individual, p. 160.
- 48 John Mahoney, *Bioethics and Belief*, pp. 64-67.
- 49 The primitive streak is a fold along the central axis of the embryo that develops into the first rudimentary structure for the future brain. For some authors, until the formation of the primitive streak the embryo is only entitled to limited respect and protection. See Michael R. Panicola, "Three Views on the Preimplantation Embryo" in *The National Catholic Bioethics Quarterly*, Spring 2002, Vol. 2, No. 1, p. 74.
- 50 John Ford, *When Did I Begin?*, pp. 170-173; *The Prenatal Person*, pp. 66-67.
- 51 *Ibid.*, preface, xvii.
- 52 *Ibid.*, p. 130.
- 53 *Ibid.*, pp. 137-139.
- 54 The study of mouse embryos by Surani and Barton at the morula stage have shown that some blastomeres become inner cells and other outer cells with the inner cells regulating the process. From these facts, namely the indeterminate potential of cells, Ford surprisingly infers that the morula lacks the necessary unity for an ontological individual, *ibid.*, pp. 148-149.
- 55 *Ibid.*, p. 129.
- 56 *Ibid.*, p. 130.
- 57 Alberto Caturelli argues instead that as first Efficient cause God causes the whole embryo simultaneously rather than in a succession of parts that are united. He gives the human embryo a participation in his own act of being, "Identity and Status of the Human Embryo from the Perspective of Metaphysics," in *The Identity and Status of the Human Embryo*, Juan de Dios Vial Correa, Elio Sgreccia, eds., Libreria editrice Vaticana, Vatican 1997, p. 335.
- 58 See Richard A. McCormick, "Who or What is the Pre-embryo?" in *Kennedy Institute of Ethics Journal*, Vol. 1, No. 1, March 1991, p. 13.
- 59 See Richard A. McCormick, "Who or What is the Pre-embryo?" pp. 6-9.
- 60 "However, because the preembryo does have intrinsic potential—in a sense is *personne en devenir*—and because of the many uncertainties mentioned above, I would argue that the preembryo should be treated as a person but that this is a *prima facie* obligation only, albeit a strong one," *ibid.*, p. 13. McCormick also thought that due to the importance and controversial nature of this matter decisions on the subject should be based on nationally established criteria and therefore dissented from the ethics committee of the American Fertility Society's call for approval of experimentation on pre-embryos. See also Norman Ford, "The Human Embryo as a Person in Catholic Teaching," in *The National Catholic Bioethics Quarterly*, Vol. 1, No. 2, Summer 2001, p. 160.
- 61 See Norman Ford, *When Did I Begin?* p. 136.
- 62 *Ibid.*, p. 172.
- 63 Ford himself mentions these activities as well as the multiple interactions between cells during the blastocyst stage, yet he does not recognize these as an expression of a unified organism, pp. 151-156.
- 64 "It is very difficult to sustain that the human embryo could be a human individual prior to the blastocyst stage when it differentiates into that which it will develop into the embryo, fetus and adult human and that which will not strictly constitute the embryo proper but will sustain such development—the placenta and extraembryonic membranes," *ibid.*, p. 156.
- 65 *Ibid.*, p. 158.
- 66 In a statement by Robert P. George of the President's Council of Bioethics, Prof. George argues that when there is twinning, the totipotent character of early embryonic cells does not prove that before detachment the cells within the human embryo were a simple mass of cells. He makes the following comparison: "Parts of a flatworm have the potential to become a whole flatworm when isolated from the present whole of which they are part. Yet no one would suggest that prior to the division of a flatworm to produce two whole flatworms the original flatworm was not a unitary individual," July 2002, [www.bioethics.gov](http://www.bioethics.gov), p. 4.
- 67 In theological terms, we can simply state that God, the creator of all living beings, creates one human being first and afterwards creates a second human being with its own soul.
- 68 Aquinas adds the notion of participation to Aristotle's theory of the first cause. He argues that all beings other than God are "not their own being, but are beings by participation." They are caused by one First Being, who possesses being perfectly, and they are more or less perfect according to their degree of participation in being. See *Summa Theologiae*, I, Q. 44, A. 1, c.

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- 69 Although cloning of animals has been achieved, the cloning of humans has not, and the hypothetical consideration of the nature of the soul of a cloned individual goes beyond the subject of this paper.
- 70 Alberto Caturelli explains that the soul is united to matter simultaneously to the union of the gametes. He writes: "Simultaneously, the actual determination, in that instant, of the zygote as such, could not be made without the determining principle which makes him be this embryo and not another," "Identity and Status of the Human Embryo from the Perspective of Metaphysics," in *The Identity and Status of the Human Embryo*, p. 333.
- 71 In addition this way of reasoning would not allow for the possibility that a human clone can have a rational soul. A clone derives from an egg that receives the genetic material from an adult cell rather than from a zygote.
- 72 See Benedict Ashley and Albert Moraczewski, "Cloning, Aquinas and Embryonic Person" in *National Catholic Bioethics Quarterly*, Vol. 1, No. 2, Summer 2001, p. 194.
- 73 *The Prenatal Person*, p. 66.
- 74 There is a naturally occurring chimerism that is found in the twins of some cows. Chimerism takes place when there are vascular anastomoses or communication between the fetal circulation of both fetuses early in gestation. The hematopoietic stem cells of one fetus "seed" the twin with stem cells and vice-versa. As a result both animals are hematopoietic chimeras. Some of cells derived from the hematopoietic stem cells (red blood cells, white blood cells, Kupffer cells in the liver) of one twin are found in its chimera. When chimeras occur in cattle with a male and a female fetus, the female fetus is exposed to male hormones and does not develop properly its female system. The female offspring is called a freemartin and is sterile.
- 75 *The Prenatal Person*, pp. 70-74.
- 76 *The Prenatal Person*, pp. 67.
- 77 *Instruction on Respect for Human Life in Its Origin and Dignity of Procreation: Replies to Certain Questions (Donum Vitae)*, Part I, No. 1. The text reads "[T]he conclusions of science regarding the human embryo provide a valuable indication for discerning by the use of reason a personal presence at the moment of the first appearance of a human life: how could a human individual not be a human person?"

# CAN ARTIFICIAL TECHNIQUES SUPPLY MORALLY NEUTRAL HUMAN EMBRYOS FOR RESEARCH?

## Part I. Creating Novel Categories of Human Embryos

*(Part II, "The Meaning of Artificial Life," to be published in the next issue of Ethics & Medicine [21:2].)*

NANCY L. JONES, PH.D.

WILLIAM P. CHESHIRE, JR., M.D.

### Abstract

*Manipulations of the molecular composition and formation of human embryos are posing vital new challenges to traditional concepts of human identity and procreation. Current trends in embryology in particular are reshaping the ethical question of how scientific research should treat experimentally derived embryos. Some investigators have argued that embryos created through artificial means are technologically novel entities that should be exempt from ethical restraints placed on research involving human embryos that come into being through natural processes. These include uniparental embryos derived through cloning or parthenogenesis, as well as multiparental, hybrid-parental, and xenohybrid-parental embryos. If confined to natural means many of these genetic unions could not occur, but through the intervention of technology, it is becoming possible to design and grow strange and unusual forms of embryos, in some cases using human gametes. Regardless of the genetic contributors or the processes used to fertilize and stimulate egg activation, in each case the new embryo represents an individual organism that begins a process of development. We conclude that the prospect of creating or redesigning new human life should be held to a stringent ethical standard of precaution, even higher than that of deciding to destroy existing embryonic life. Accordingly, we urge cautious ethical reflection and broad public discussion prior to deciding whether to permit embryologic research into novel forms of procreative means in nonhuman animals, to be further extended to humans.*

### Introduction

The isolation of human embryonic stem cells in 1999, with its far-reaching implications for medical research, propelled to the forefront of public debate the question of what moral status should be assigned to the human embryo.<sup>1</sup>

Several years and much rhetoric later, public discussion seems no closer to a consensus. Regardless of what view scientists may take of early human life, it is clear that public controversy over research on human embryos has slowed human embryonic stem cell research.

Response to the public conscience has prompted a shift in research aims toward finding a noncontroversial alternative by engineering what could be widely regarded as a nonhuman embryo fashioned out of human genetic and cellular material. These further scientific developments have sought a technological fix that has, in effect, rephrased the question. The new question is whether human embryos created through technologically novel means qualify for the same level of moral status that should be afforded to natural human embryos. The development of a living model of human embryogenesis that lacks a claim to human moral status would presumably enable scientists to pursue further questions about early human development and harvest potentially useful cellular byproducts unhindered by calls for ethical restraint. Some embryologists have articulated a “duty to provide mankind with the best understanding of early human development.”<sup>2</sup>

For those who oppose research that destroys embryos created through fertilization and which are composed of genetic material from one egg and one sperm, it is not immediately obvious whether similar research should be permitted on some other types of embryos, such as those derived from asexual combination of gametes, cloning, or parthenogenesis. Some of those entities may lack one or more biologic markers by which we have traditionally understood and identified embryos as human. It is essential to examine which biologic attributes should define embryonic humanity, because these entities lay now before us in the petri dish.

This paper will examine the biological nature of the types of novel embryos that have already been constructed in nonhuman animal models and explore the ethical implications of the categories into which these entities may be classified. A second accompanying paper will examine more closely the meaning of artificiality as imposed on these novel embryos and reflect on how notions of artificiality challenge the evaluation of human dignity.

## **Types of Artificial and Asexually Created Human Embryos**

Somatic cell nuclear transfer (cloning) and parthenogenesis (Greek for “virgin birth”) represent only two of the many potential experimental methodologies that in principle could be utilized to generate novel types of human embryos. Several additional categories can be postulated based on current research in animal models. For the sake of discussion, the following classification scheme is proposed: embryos may be considered to be traditional parental, uniparental, unisex, multiparental, or hybrid-parental. The traditional parental is where a unique genetic offspring is created through syngamy of a single male (sperm) and single female (oocyte) gamete. An embryo will be classified as uniparental if the nuclear genetic information comes from only one person, i.e. a single parental genetic contributor. The unisex embryo will be defined as the combination of two gametes from the same sex, for example, two oocytes



or two sperm, into a single embryo. The multiparental embryo will be defined as that which derives from two or more genetic contributors other than those classified by the traditional or unisex categories. Finally, the hybrid-parental category will refer to embryos with genetic material coming from multiparental sources in which there is a partial, but not a complete, haploid contribution of the chromosomes. A subcategory within the multiparental category is the xenohybrid-parental category, whose embryos are defined as donation of either a gene or chromosome from a nonhuman contributor.

## Defining Asexual and Artificial

Precise and consistent definitions of the terms *sexual*, *asexual*, and *artificial* are needed to facilitate discussion. *Sexual* reproduction refers to propagation by mating and genetic recombination. The traditional or conventional concept of syngamy refers to an offspring having a unique genetic combination created through the union of a single male and single female gamete. Difficulty of terminology would arise should it become possible to produce offspring by recombining genetic material from two or more human individuals of the same sex. Considering that some novel reproductive technologies in nonhuman animals have involved combination of gametes from parents of a single sex, for the purpose of this discussion *sexual* reproduction will be defined as the recombination of genetic material from more than one parent, including but not limited to recombination between homologous chromosomes, even in hypothetical cases where both human parents might be of the same sex. Such cases will be defined as *unisexual* but not *asexual*.

*Asexual* is defined as reproduction by propagating offspring to have the exact same genetic material or without the recombination of genetic material. Here also the possibility of introducing genetic contributions of mitochondrial DNA from additional donors presents a quandary. Although the mechanisms of mitochondrial DNA recombination have not been solved, the source is always maternal, with no recombination from a paternal source.<sup>3</sup> For the purpose of this discussion, the distinction of *sexual* versus *asexual* reproduction will be defined on the basis of whether recombination of nuclear chromosomal DNA occurs.

The term *artificial* could be invoked to refer to several non-natural processes used to create a diploid embryo. First, *artificial* could be used in reference to mechanical or chemical processes utilized to join gametes, for example, mechanical insertion of either sperm or genetic material into the oocyte. Mimicking the initiation of fertilization by either electric shock or a calcium ionophore could also be considered *artificial* interventions. Even further removed from natural processes are genetic engineering techniques applied to the human embryo, including insertion or deletion of single genes or *artificial* chromosomes, which could all be considered *artificial* or non-natural contributions to inherited genetic information. Novel categories of human embryos undoubtedly will conceptually stretch beyond the traditional boundaries of both these terms, *artificial* and *asexual*, rendering them insufficient for a complete classification.

## **Uniparental: Somatic Cell Nuclear Transfer, Parthenogenesis, and Androgenesis**

Three types of embryos have been categorized as uniparental: embryos created by cloning or somatic cell nuclear transfer (SCNT) (single, male or female nuclear genetic contributor), by parthenogenesis (single female nuclear genetic contributor), and androgenesis (single male nuclear genetic contributor). Creating an embryo through SCNT is currently the best-known method. First, a donor oocyte is enucleated in order that all the nuclear genetic material derives from a donor somatic (diploid—46 chromosomes) cell.

For the embryo created through *classical* parthenogenesis, a single female contributes all the genetic material.<sup>4</sup> Since oocytes normally halve their genetic complement (going from 46 to 23 chromosomes) relatively late in their maturation cycle, if activation (any stimulating process that mimics the initiation of fertilization) occurs at an earlier stage of oocyte maturation, a full set of chromosomes is retained. This form of parthenogenesis thus resembles cloning, in that the resultant embryo is an exact genetic match of the parent. Alternatively, methods exist to stimulate a haploid egg (containing 23 chromosomes) to reduplicate its genetic material, making a double set of one half of the genetic material to create a haplodiploid embryo.

Embryos created through parthenogenesis are often referred to as unfertilized eggs. Fertilization, the process whereby gametes join together to begin development of a new individual, however is induced when either the diploid or haplodiploid genetic material directs embryonic development.

In androgenesis a single male sperm contributes all the nuclear genetic material, a rare occurrence in nature. Here, a sperm naturally fertilizes an egg, but the female genetic material is expelled, and the male material replicates to provide the full set of genetic material from one half of the father's genetic material. It is worthwhile to note that androgenesis could be potentially successful only with sperm containing the X chromosome. Doubling of the Y chromosome would have deleterious effects.

These three types of uniparental embryos at first glance could be categorized as asexual, because they do not involve the combination of gametes from two parents. However, in the cases where the diploid genome is replicated to form a haplodiploid embryo, exchange of genetic material occurs *intragenomically*, involving a recombination of genetic material from within the genome of a single female parent, and resulting in offspring that are not an exact genetic replica of the parental genetic source. The prospect of parthenogenesis challenges the traditional understanding of mammalian sexual reproduction, which has been understood to mean the fusion and genetic recombination of male and female gametes. Successful parthenogenesis would satisfy the recombinant sense of the definition of sexual reproduction, minus male participation.

The products of both parthenogenesis and androgenesis could be considered artificial, in that external technological intervention stimulates the haploid genetic material to become diploid. Furthermore, all three types could be considered artificial due to the mechanically invasive procedures that either insert genetic material (SCNT) or artificially stimulate the initial steps of development by exposure to calcium or electric shock.

All of these types of embryonic creation by current methods have severely compromised viability, which in some cases is limited to no more than a few cell divisions. One key block prohibiting normal development is believed to be the lack of inheritance of both paternal and maternal imprinted genes.<sup>4,5</sup> For each gene, an individual inherits two copies or alleles, normally one from the mother, the other from the father. During egg and sperm maturation, certain genes are programmed on the basis of paternal or maternal origin to be either read or relatively silenced. During the developmentally critical time of early embryo growth, this subset of *imprinted* genes is expressed correctly only if inherited from the appropriate parental germ line. Approximately 40 genes (1-2% of all genes) are imprinted differently between the sperm and egg. Some paternally imprinted genes have been found to be essential to direct normal placental growth, and some maternally imprinted genes to embryonic and fetal development.<sup>6</sup>

As more is learned, it may eventually become possible to overcome these limitations of parental genetic imprinting. A number of human genetic diseases, in fact, are the result of imprinting defects,<sup>6</sup> and knowledge about the ways in which imprinting affects the expression of genes encoding specific enzymes continues to accumulate.<sup>4,6</sup> Exceptional cases in nature of cloned embryos possessing only maternally imprinted genes have in some instances prevailed despite deficiencies of paternal imprinting.<sup>7,8</sup>

A further biological factor diminishing the likelihood of full gestational development may be termed the *naked genetic load*.<sup>9</sup> Genetic load refers to the estimated six or more potentially lethal recessive genes that most humans carry and which remain phenotypically silent as single copies alongside a normal functioning homologous gene. In the parthenote or andronote that doubles half its genetic complement, it is as if that haplodiploid embryo had inherited two copies of all recessive genes. The genetic load thus fully exposed and expressed is incompatible with continued life. The absence of a paternal centrosome would further impair the viability of SCNT or parthenogenetically derived embryos. The maternal centrosome can compensate for early embryo cell divisions, but the paternal centrosome is necessary for continued faithful development.<sup>10</sup>

Parthenogenesis in mammals and even humans has been described as occurring spontaneously in nature, but viable offspring as such have never been identified.<sup>11,12</sup> Rather, the usual outcome of human parthenogenesis is an ovarian tumor known as a teratoma or dermoid cyst. Human parthenogenetic embryos (*parthenotes* or *parthenogenones*) are invariably gestationally incompetent. Infrequently they may reach the stage of implantation only to fail during early gestation.<sup>13-17</sup> Interestingly, a parthenogenetic human embryo can very rarely fuse with a normal embryo to result in a genetically chimeric individual.<sup>5,18</sup> Since parthenogenesis is a naturally procreative process in few species of lower animals, such as aphids and wasps, and in some worms, spiders, lizards, and snakes, it is conceivable that future advances in reproductive genetic technology might possibly remove the biologic obstacles to viable human parthenogenesis.

### **Unisex: Combining of Same Sex Gametes**

A female unisex embryo would require genetic material from two oocytes. The first oocyte would be injected with the nucleus from a second oocyte, and development would be *artificially* initiated in a similar manner as intracytoplasmic injection of sperm or SCNT. A male combined embryo would require a donor enucleated oocyte and two sperm. One of the sperm must contain an X chromosome. It may become possible to reconstitute the oocyte with one sperm's genetic material and allow the second sperm to initiate fertilization by otherwise natural means.

Recently, mice were created through a unisex procedure in Japan. A normal mouse egg was combined with a second manipulated mouse egg to form a "parthenogenic" embryo, which was then implanted into a surrogate female mouse and subsequently born.<sup>19</sup> The maternal imprinting on the second egg was reduced by collecting eggs from newborn mice and altering expression of two genes. Although these mice were termed parthenogenic, the methodology stretches the classical definition in that the offspring fused two gametes from two maternal sources to make unique diploid mice. Successful *unisexual* androgenesis, hypothetically, also would not be a purely asexual event in that two male gametes would be fused to form a unique diploid individual and the mitochondrial DNA would presumably be from a maternal oocyte.

There is, thus, a sense in which unisex procreation involving recombination of genetic material between two parents of the same sex might be thought of as an alternative form not of asexual, but of sexual, reproduction. The choice of classification would depend on whether sexual reproduction was viewed primarily as a procreative event involving recombination of genetic material from two parents, or a procreative event involving two parents of opposite gender. Those defending a traditional view of sexual reproduction might then be asked to define what makes the X and Y "sex" chromosomes in sexual reproduction so special, if most of the recombination occurs between the other chromosomes? In other words—what has gender to do with sex?

These two types of unisex embryos could be categorized as sexual, because they involve combining of gametes. They would also be categorized as artificial, not only because of the mechanical procedure that inserts genetic material (SCNT) or prepares the enucleated oocyte, or the activation by calcium or electric shock, but more importantly because such procedures engender a type of genetic union that could not occur within the constraints of nature apart from the intervention of human technology. The survival rates of parthenogenic unisex embryos are similar to that of an embryo created through SCNT.<sup>19</sup>

### **Multiparental: Artificial Gametes and Mitochondrial DNA Donors**

The concept of an artificial gamete has recently been proposed.<sup>20,21</sup> In this scenario, a somatic cell would be injected into an enucleated donor oocyte, similar to SCNT. Instead of initiating development of an embryo, however, the oocyte would first be stimulated to lose one complement of chromosomes,

as occurs in the last stages of natural oocyte maturation. This would result in a new haploid oocyte or artificial gamete containing half the genetic material of the somatic cell donor cell. If successful, a sperm could then fertilize this oocyte.

Some in vitro fertilization (IVF) clinics have already begun using oocyte cytoplasmic donors. In this setting oocytes that have been in storage past the point of viability or that are otherwise incompetent have been reconstituted by intracytoplasmic injection of a donor oocyte's cytoplasm. A sperm then fertilizes the fused oocyte. Since the donor cytoplasm carries with it mitochondria containing their own DNA, the resultant embryo has three genetic contributors: the primary maternal nuclear and mitochondrial DNA, the paternal nuclear DNA, and the secondary maternal mitochondrial DNA.<sup>22</sup>

These types of multiparental embryos would be categorized as sexual, because they involve combining of gametes. They would also be artificial, due to the mechanical insertion of nuclear or mitochondrial genetic material or the use of artificial interventions that initiate fertilization. Whereas the cytoplasmic injection procedure has resulted in viable offspring<sup>22</sup> the gestational competence of other forms of multiparental embryos remains to be determined.

## Hybrid-parental Embryos

Hybrid-parental embryos are a diverse category that may have nearly limitless permutations. Two major subclassifications are conceivable. The first would construct embryos from human multiparental sources with only partial chromosomal contributions rather than a complete haploid complement. For example, it may become possible to replace a single chromosome or genes within a single chromosome, but all the genetic material would be from the human genome.

The second subclass, xenohybrid-parental embryos, would incorporate contributions from other species. Enucleated cow eggs, for example, which retain cow mitochondrial DNA and have already been used in some human SCNT experiments, have been proposed as a means to overcome the limited resource of human oocytes donated for cloning.<sup>23</sup> Embryos containing hybrid nuclear DNA have also been proposed. Some have entertained the possibility of inserting owl genes encoding night vision or genes from ferocious animals into human embryos.<sup>24</sup> Techniques to insert single genes into the mammalian germline have existed since the 1980s. The efficiency of transgenic production to introduce single genes can be as great as 30% for mice and less than 1% for pigs or sheep.<sup>25</sup> More recently artificial chromosomes containing many genes have been used to create transgenic mice, rabbits, and pigs.<sup>26,27</sup> The proof in principle that transgenic primates can be created was ANDi, a transgenic rhesus monkey that now carries the green fluorescent protein from jellyfish.<sup>28</sup> That experiment, starting from 244 oocytes, yielded three live births and only one transgenic monkey.

These types of hybrid-parental embryos would be categorized as sexual because of the recombination of genetic material. They would also be instances of artificially created entities greatly exceeding the degree of artificiality of the

preceding categories. The application of biotechnology to manipulate specific, chosen subsets of genetic material and to cross species boundaries would be to engineer categories of procreation previously unknown to occur in nature.

The gestational competence of such hybrid-parental embryos would be compromised by numerous nontrivial biologic obstacles, such as the compatibility of cross-species mitochondrial enzymes, limited ability of the recipient cell to retain faithful copies of the full length of donated DNA, and interference with expression of the recipient's genome. Nevertheless, it is conceivable that a number of these technical obstacles could in time be overcome and that additional hybrid-parental entities could be made viable, as has been demonstrated in animal (including primate) models.<sup>29</sup>

Chimeras, a special case of hybrids, are aggregates of two or more genetically different groups of cells combined into a single organism, analogous to a plant graft. The Korean Maria BioTech Company, for example, announced the creation of "hu-mice" in June of 2003.<sup>30</sup> These xenochimeras were created by inserting human embryonic stem cells into mouse blastocysts. The human embryonic stem cells contributed to cells in various tissues, including the heart, liver, kidney and cartilage.

Another all-human chimera, albeit extremely novel because of aggregation of male and female cells, was created through a process termed *blastomere transplantation*. Blastomeres (the cells of an embryo at the two- to eight-cell stage) from male embryos were injected into three-day-old female embryos. The amount of integration of these injected cells was determined for the next few days, before subsequent destruction of the she-he chimera embryos.<sup>31</sup>

Because chimeras are aggregates of cells—any one of which retains genetic fidelity to its parental source—then depending on which cells form the gonads, the offspring of a chimera would be genetically the same as one of its parents (e.g., mouse or human, or female or male), such that genetic blending would not be passed to subsequent generations. Chimeras do occur in nature and can be viable, such as the example of the parthenote-normal chimera.<sup>18</sup>

## **Discussion**

Federally funded research on human embryos in the United States historically has permitted only research addressing human infertility. More recently, the promise of embryonic stem cell research, along with advancements in embryo research in nonhuman animals, has introduced a cornucopia of nonprocreative goods potentially obtainable from human embryos. These goods include understanding basic scientific questions about early human development such as nuclear programming and functional studies of inheritance, as well as the prospect of eventual cellular cures for medical diseases. It falls to society to weigh these speculative and occasionally exaggerated instrumental goods against the increasingly uncertain moral value of novel versions of embryonic life, and to decide whether the two can legitimately be compared on the same scale. It also falls to the scientific profession to examine its own ethical mandates and limits. For the sake of scientific freedom and medical benefit, society now seeks a source of human embryonic tissue for unrestricted experimental purposes.

Emerging research that combines human and nonhuman animal genetic or cellular material to generate novel xenohybrids generates a further dilemma.<sup>32</sup> Some combinations might turn out to be new types of beings that should be considered partly or fully human, whereas other combinations in which the human genetic contribution is solely informational might not yield true human beings. As long as moral certainty is beyond reach, it seems unwise to embark upon the creation of xenohybrid human embryos. As with other types of novel human embryos, once the technology to create them were developed, and since IVF techniques are readily available, this would also facilitate the risk that a zealous researcher somewhere might implant them in a mother's womb.<sup>33</sup>

At the heart of human embryo research, weighty scientific interests are colliding head-on with the duty to respect human life, and for many that duty embraces life at its earliest stages.<sup>34</sup> The deliberate creation of human embryos solely for research purposes is a disturbing prospect, even if such embryos were not granted the status of full personhood. The concern about creating human life for instrumental use is not diminished by claims that the entities would be the products of artificial techniques. Furthermore, many of these techniques thrust on society innovative and nonnatural means of propagating the human genome that should not be tested without the benefit of thoughtful ethical reflection. Ethical reflection must precede the experimentation.

The relationship between genetic composition and moral value has important implications for deciding the ethical restrictions that govern research entailing their creation, use, and destruction. How this new question is answered also has broader implications for how science and society may come to regard mature human life that in other respects is impaired or different due to technological intervention.

Recognizing the inestimable value of human life, and respecting the mystery of its origin, we believe that the decision whether to create novel variations on human life should be held to a higher precautionary standard than the decision to destroy existing life.

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## Glossary of Biological Terms

**Activation.** The process whereby an egg becomes metabolically active, triggered by a transient increase in calcium propagated by sperm penetration or artificially by mechanical or chemical means.

**Androgenesis.** The process whereby a sperm stimulates activation of an egg but the male genome(s) is the only nuclear genetic material that takes part in subsequent embryo development. *Unisexual* androgenesis is the recombination of two (or more) male gametes in the absence of any nuclear genetic contribution from a female gamete. Andronote is the term for an embryo or adult animal derived through the process of androgenesis.

**Asexual Reproduction.** Propagation of offspring without genetic recombination. Parthenogenesis, androgenesis, and cloning are examples.

**Blastomere.** Cells from an embryo at the two- to eight-cell stage. A single blastomere can sustain full organism development. Blastomeres are the cells that are biopsied for pre-implantation genetic diagnosis, and the resulting embryo, less one or two cells, is viable.

**Chimera.** A single organism in which are combined aggregates derived from two or more genetically different groups of cells, analogous to a plant graft. No genetic recombination between the aggregates occurs and only the progenitor cells of the gonads pass on their genetic material to subsequent offspring. In the xenochimera cells of the aggregate come from differing species.

**Clone.** (1) To produce an exact replica (2) Somatic Cell Nuclear Recombination (SCNR), where an egg's haploid genetic material is removed and replaced with a somatic (diploid cell—any cell other than a germ cell) cell's genetic material. The egg is then activated by mechanical or chemical means to initiate embryo development. The subsequent offspring is genetically identical to the somatic cell.

**Diploid.** A cell that is a full genetic complement. For humans that is two copies of each of the 23 chromosomes for a total of 46 chromosomes. All cells of the body are diploid with the exception of sperm and egg, which are haploid.

**Embryo.** In humans, the prefetal product of fertilization representing the earliest stages of development, until 8 weeks gestation at which time all major structures are represented. Sometimes classified separately are the initial stages of embryonic development prior to the appearance of the long axis, starting with the cleavage of the fertilized ovum to form the solid mass of blastomeres termed the morula, then forming a fluid-filled sphere termed the blastocyst.

**Fertilization.** The processes whereby gametes join together to begin the development of a new individual.

**Gamete.** A mature male (sperm) or female (oocyte or egg) germ cell, both of which are haploid and capable of initiating a new diploid individual if combined together.

**Genomic Imprinting.** The expression or repression of genes based solely on parental inheritance. During maturation of sperm (spermatogenesis) and

egg (oocytogenesis), previous developmental signals are first erased from imprinted genes before the genes undergo modifications. These epigenetic modifications silence or activate specific genes necessary for embryo and placental development.

**Haploid.** A cell that is half the full complement of genetic material. For humans, haploid is 23 chromosomes. Sperm and eggs are haploid.

**Hybrid.** Offspring that have combined genetic inheritance from more than the standard two parental sources. The genetic inheritance is a partial, but not a complete, haploid contribution, and can be single genes, multiple genes, or chromosomes.

**Parthenogenesis.** The production of an embryo from a female gamete in the absence of any contribution from a male gamete. *Unisexual* parthenogenesis is the production of an embryo from two (or more) female gametes in the absence of any contribution from a male gamete. *Parthenote* and *parthenogenone* are terms for an embryo or adult animal derived through the process of parthenogenesis.

**Sexual Reproduction.** Propagation through mating and genetic recombination. Until recently, anatomical and physiological barriers prevented genetic recombination and syngamy of any combination other than one male and one female gamete of the same species.

**Syngamy.** The fusion of gametes to form a new and distinct genome.

**Xeno-hybrid.** An organism in which some of the genetic contribution, in the form of a gene or a chromosome for example, comes from a nonhuman contributor.

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**Nancy L. Jones, Ph.D.**, a cell biologist and bioethicist, is Associate Professor of Pathology at Wake Forest University School of Medicine, Winston-Salem, North Carolina, USA and serves on the U.S. Secretary of Health and Human Services Secretary's Advisory Committee on Human Research Protection. The views expressed herein are her own and do not necessarily reflect the positions of Wake Forest University or the U.S. department of Health and Human Services.

**William P. Cheshire, Jr., M.D.**, is Associate Professor of Neurology at Mayo Clinic in Jacksonville, Florida, USA and Director of Biotechnology Ethics for The Center for Bioethics and Human Dignity. The views expressed herein are his own and do not necessarily reflect the positions of Mayo Clinic or Mayo Foundation.

# LEBENSUNWERTES LEBEN: THE DEVOLUTION OF PERSONHOOD IN THE WEIMAR AND PRE-WEIMAR ERA<sup>1</sup>

J. DARYL CHARLES, PH.D.

## Abstract

*Radical social change in most societies does not typically occur “overnight.” It requires preparation—preparation in the way people think. The rise of euthanasia in western culture is a case in point. In order for assisted death to be increasingly accepted, the social-moral consensus must be altered. Typically, that consensus will be influenced by trends in biology, the behavioral sciences, ethics, law, even economics. Examining the manner in which assisted death was “prepared” in the decades before the ascendancy of National Socialism is highly instructive as we witness the rise of euthanatic thinking in our own day several generations removed.*

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A recurring theme in the encyclicals of John Paul II has been the necessity of freedom’s harnessing to truth. Speaking from the vantage-point of one who has had intimate acquaintance with political tyranny, John Paul addresses those of us who live in a “free” society by reminding us that the wedding of democratic pluralism and moral relativism constitutes a thinly-veiled totalitarianism.<sup>2</sup> Indeed, the historical record would seem to vindicate the pontiff: the century immediately behind us constitutes a sobering reminder that freedom is capable of annihilating itself; this occurs when human freedom is no longer tethered to a universal moral law.

Only a half-century removed, we in the West—and we Americans, in particular—seem to have forgotten a most disturbing fact of recent history: *moral atrocity, couched in medical and scientific justification, is the end result of the encroachment on ethics that implants itself in the realm of medical science.* Consequently, we are increasingly comfortable with speaking of “death with dignity,” “compassionate release” and “merciful exit preference” for those we deem “no longer worthy of life itself.” This utilitarian strain of thinking, perhaps dormant for several brief decades, would appear to have emerged once more in full force.

Consider the attempts to redefine personhood by influential ethicists of our day. One such attempt is that of John Harris, the Sir David Alliance Professor of Bioethics and Director of the Institute of Medicine Law and Bioethics at the University of Manchester. Harris wrote in the pages of the *Kennedy Institute of Ethics Journal*: “Normally we use the term ‘person’ as a synonym for ‘human beings,’ people like us. However we are also familiar with the idea

that there are nonhuman persons, and humans who are not, or may not be persons or full persons.... Human nonpersons or humans who are not fully fledged [sic] persons may include zygotes and embryos, or individuals who are 'brain-dead,' anencephalic infants, or individuals in a persistent vegetative state." What is disturbing is that influential secular bioethicists like Harris are making statements that call for a radical revisioning of our understanding of human personhood. In the same vein, consider the following statement by one of the most respected secular bioethicists of our time: "Although nonhuman animals are not plausible candidates for moral personhood, humans too fail to qualify as moral persons if they lack one or more of the conditions of moral personhood."<sup>3</sup>

Perhaps because I married into a German family and spent the early years of marriage living in (former West) Germany, where the first of our children was born, I am particularly sensitive to the character of moral atrocities that lie in the not-too-distant past. (Perhaps, too, because my father-in-law—an exceedingly good man whom I loved dearly and who died in 1984—spent the five years of the Second World War working for the German railroad, in Poland.) In the following essay, I wish to consider the evolution of the notion of *lebensunwertes Leben* ("life unworthy of living") in German academic thought that occurred in the forty-year period roughly between 1890 and 1933, when National Socialism officially took power. Thereby I hope to illustrate that "revolutionary" and totalitarian tendencies require *preparation*. This ideological preparation is particularly significant as we undergo shifts in our social understanding of the notion of human *personhood*.

## **The Biological and Economic Arguments**

One of the tragic legacies of social Darwinism is that it assisted in giving justification to the elimination of *lebensunwertes Leben*, life that is unworthy of living, or, in the language of Darwinists, life that is simply unfit.<sup>4</sup> While it is commonly assumed that the moral atrocities associated with the Holocaust were the exclusive domain of Adolf Hitler and those loyal to him (people such as Joseph Goebbels, Hermann Goering, Heinrich Himmler and Albert Speer), this was only the final act.<sup>5</sup> Indeed it would appear, as authors with such diverse backgrounds as Alexander Mitscherlich,<sup>6</sup> Robert Jay Lifton,<sup>7</sup> Robert Proctor,<sup>8</sup> Michael Burleigh,<sup>9</sup> and Wesley Smith<sup>10</sup> have documented, the path to medical evil was prepared long before Nazism was even a cloud on the German horizon.

In addition to the ascendancy of biological determinism,<sup>11</sup> an important step in legitimizing the killing of the weak, the infirm, the terminally ill, and the incompetent was the shift in ethos among medical doctors and psychiatrists several decades prior to WWII. Historian Robert Proctor has argued persuasively that the Nazi experiment was rooted in *pre-1933 thinking* about the essence of personhood, racial hygienics and survival economics, and that physicians were instrumental both in pioneering research and in carrying out this program.<sup>12</sup> In fact, Proctor is adamant that scientists and physicians were *pioneers* and not pawns in this process. By 1933, however, when political power was consolidated by National Socialists, resistance within the medical community was too late.

Proctor notes, for example, that most of the fifteen-odd journals devoted to racial hygienics were established long before the rise of National Socialism.<sup>13</sup>

Few accounts of this period are more thoroughly researched than Michael Burleigh's *Death and Deliverance: 'Euthanasia' in Germany ca. 1900-1945*.<sup>14</sup> Particularly important is Burleigh's discussion of psychiatric reform and medical utilitarianism during the Weimar period.<sup>15</sup> During the years of WWI, it is estimated that over 140,000 people died in German psychiatric asylums.<sup>16</sup> This would suggest that about 30% of the entire pre-war asylum population died as a result of hunger, disease or neglect.<sup>17</sup> Following the war, evidence indicates that a shift in the moral climate was in progress. In the Spring of 1920, the chairman of the German Psychiatric Association, Karl Bonhoeffer,<sup>18</sup> testified before Association members at the GPA annual meeting that "we have witnessed a change in the concept of humanity"; moreover,

in emphasizing the right of the healthy to stay alive, which is an inevitable result of periods of necessity, there is also a danger of going too far: a danger that the self-sacrificing subordination of the strong to the needs of the helpless and ill, which lies at the heart of any true concern for the sick, will give ground to the demand of the healthy to live.<sup>19</sup>

According to Burleigh, Bonhoeffer went on in the 1930s to offer courses that trained those who in time would be authorized with implementing sterilization policies introduced by the National Socialists.<sup>20</sup>

Already in the 1890s, the traditional view of medicine that physicians are not to harm and only to cure was being questioned in some corners by a "right-to-die" ethos. Voluntary euthanasia was supported by a concept of negative human worth—i.e., the combined notion that suffering negates human worth and the incurably ill and mentally defective place an enormous burden on families and surrounding communities. It is at this time that the expression "life unworthy of being lived" seems to have emerged and was the subject of heated debate by the time WWI had ended.<sup>21</sup>

One notable "early" proponent of involuntary euthanasia was influential biologist and Darwinian social theorist Ernst Haeckel. In 1899 Haeckel published *The Riddle of the Universe*, which achieved an enormous amount of success and became one of the most widely read science books of the era.<sup>22</sup> One of several influential voices contending for the utility of euthanasia, Haeckel combined the notion of euthanasia as an act of mercy with economic concerns that considerable money might be thereby saved.<sup>23</sup>

Further justification for euthanasia in the pre-WWI era was provided by people such as social theorist Adolf Jost and Nobel-Prize-winning chemist Wilhelm Ostwald. According to Ostwald, "in all circumstances suffering represents a restriction upon, and diminution of, the individual and capacity to perform in society of the person suffering."<sup>24</sup> In his 1895 book *Das Recht auf den Tod* ("The Right to Death"),<sup>25</sup> Jost set forth the argument—an argument almost forty years in advance of Nazi prescriptions—that the "right" to kill existed in the context of the higher rights possessed by the state, since all individuals belong to the social organism of the state. Furthermore, this was couched in

terms of “compassion” and “relief” from one’s suffering. Finally, and not least importantly, the right to kill compassionately was predicated on biology, in accordance with the spirit of the age: the state must ensure that the social organism remains fit and healthy.<sup>26</sup>

## **The Legal and Medical Arguments**

Well before the outbreak of WWI, multiple influential voices appear in the literature agitating for a legalization of assisted death. One such legal proposal is spelled out as follows:

1. Whoever is incurably ill has the right to assisted death.
2. The right to assisted death will be established by the patient’s petition to the relevant judicial authorities.
3. On the basis of the petition, the court will instigate an examination of the patient by the court physician in association with two qualified specialists.
4. The record of the examination must show whether the examining doctors were scientifically convinced that the illness was more likely to follow a terminal course than that the patient would recover permanent ability to work.<sup>27</sup>
5. If the examination finds that a terminal outcome is the most probable one, then the court should accord the patient the right to die. In contrary cases, the patient’s request will be firmly denied.
6. Whoever painlessly kills the patient as a result of the latter’s express and unambiguous request is not to be punished, provided that the patient has been accorded the right to die under clause 5 of the law, of if posthumous examination reveals that he was incurably ill.
7. Whoever kills the patient without his express and unambiguous request will be punished with hard labour.
8. Clauses 1 to 7 are equally applicable to the elderly and crippled.<sup>28</sup>

In many respects the most significant contribution to the debate over euthanasia was the publication in 1920 of *Die Freigabe der Vernichtung lebensunwerten Lebens: Ihr Mass und ihre Form*,<sup>29</sup> by esteemed law professor Karl Binding and psychiatrist Alfred Hoche.<sup>30</sup> By 1920 the subject of euthanasia was no longer merely a matter of academic debate. Binding and Hoche argued with considerable precision that the medical profession had the responsibility not only of promoting health but, where necessary, facilitating death (*Sterbehilfe*) as well. The Binding-Hoche book is significant for several reasons. One is the way in which the authors seek to mainstream the distinction between *lebenswertes Leben* (“life worth living”) and *lebensunwertes Leben* (“life not worth living”).<sup>31</sup> Binding attempts to extrapolate from what he believes to be a “weakness” in the German criminal code by suggesting that certain life, e.g., someone who is “deathly ill or fatally wounded,”<sup>32</sup> “no longer merits full legal protection.”<sup>33</sup> Binding laments the fact that this distinguishing between worthwhile

and unworthwhile life “has made no progress”<sup>34</sup> in the actual practice of German criminal law, although in the academic literature it has “gained a lively reception.”<sup>35</sup>

What’s more, Binding and Hoche stressed that ending “life unworthy of living” had a *therapeutic* goal. But in what instances was the facilitation of death necessary? The authors carefully reason that certain categories of persons were living “unworthy” lives but also that assisting in their death is ethically, medically, and economically justifiable. These categories include the retarded, the deformed, the mentally ill,<sup>36</sup> and the severely disabled.<sup>37</sup>

*Freigabe* consists of two essays, the first being a “legal explanation” by Binding, whose reflections followed forty years of teaching law at the university level, and the second a “medical explanation” by Hoche. What follows is a summary of their two-fold argument—an argument that is remarkably similar to the one being advocated by present-day proponents of assisted death.<sup>38</sup>

Binding, one of Germany’s leading constitutional scholars, restates a question that has “much occupied” his thinking for many years, “but which most people timidly avoid because it is seen as delicate and hard to answer.”<sup>39</sup> His question is this: “Should permissible taking of life be restricted, except in emergency situations, to an individual’s act of suicide as it is in current law, or should it be legally extended to the killing of fellow human beings, and under what conditions?”<sup>40</sup> Binding is a passionate and deeply-committed secularist. Foreclosing any debate, he asserts unequivocally:

Religious reasons have no probative force in law for two reasons. First, in this instance, they rest on a wholly unworthy concept of God. Second, law is thoroughly secular and is focused on the regulation of our external common life. Additionally, the New Testament says nothing about the problem of suicide.<sup>41</sup>

Binding’s prejudice against religion allows him to re-cast traditional Christian morality as the true villain, thereby paving the way for a universal “right to die”:

After an extended, deeply unchristian, interruption in the recognition of this right [the right to end one’s life] (an interruption demanded by the church and supported by the obscene idea that the God of love could wish that human beings not die until they undergo endless physical and spiritual suffering)..., it has now been fully reestablished (except in a few backward countries) as an inalienable possession for all time. Natural law would have grounds for calling this freedom the primary “human right.”... For the law, nothing else remains except to regard the living person as the sovereign of his own existence and manner of life.<sup>42</sup>

Based on the above presuppositions, Binding reasons that the right of persons to kill themselves is to be protected legally.<sup>43</sup> Moreover, this “right” is “transferable” to “all so-called accomplices who act with the suicide’s express consent.”<sup>44</sup> The practical rationale for euthanasia is that it “replaces a death which is painful...with a less painful death.”<sup>45</sup> To reassure his audience,

Binding adds: "This is not 'an act of killing in the legal sense' but is rather the modification of an irrevocably present cause of a death which can no longer be evaded. *In truth it is a purely healing act.*"<sup>46</sup> Such "healing intervention" must extend even to "unconscious patients," since, according to Binding, "the permission of the suffering patient is not required."<sup>47</sup>

## **The "Compassion" Argument**

Anticipating objection among his readers, Binding assures them that "in truth it [the previous question] arises from nothing but the deepest sympathy."<sup>48</sup> "The act of euthanasia," he intones, "must be a consequence of free sympathy."<sup>49</sup> Thus, given the combination of his illustrious career teaching law and his thinking about "the hopelessly ill" that is motivated by the "deepest sympathy," Binding seems well-positioned to pose questions that "raise an uneasy feeling in anyone who is accustomed to assessing the value of individual life."<sup>50</sup> One such question is this: "Are there human lives which have so completely lost the attribute of legal status...that their continuation has permanently lost all value, both for the bearer of that life and for society?"<sup>51</sup> Binding's own response has the ring of authority as well as common sense:

It is impossible to doubt that there are living people to whom death would be a release, and whose death would simultaneously free society and the state from carrying a burden which serves no conceivable purpose, except that of providing an example of the greatest unselfishness.<sup>52</sup>

Binding's reflections compel him to tread—and agitate—where German society heretofore has not legally trod:

Is it our duty actively to advocate for this life's asocial continuance...or to permit its destruction under specific conditions? One could also state the question legislatively, like this: Does the energetic preservation of such life deserve preference...? Or does permitting its termination, which frees everyone involved, seem the lesser evil?<sup>53</sup>

Because his logic appears to be air-tight, Binding is resolute:

I cannot find the least reason—legally, socially, ethically, or religiously—not to permit those requested to do so to kill such hopeless cases who urgently demand death; indeed I consider this permission to be simply a duty of legal mercy (a mercy which also asserts itself in many other forms).<sup>54</sup>

Binding then proceeds to discuss "the necessary means" of carrying this "duty of legal mercy." "With good reason," he observes, "permission always presupposes a clinical diagnosis." This diagnosis, moreover, "requires competent objective verification, which cannot possibly be placed in the agent's own hands."<sup>55</sup> Two steps are recommended by Binding:

1. "The initiative must take the form of an application for permission from a qualified applicant."<sup>56</sup>



2. "This application goes to a government board, whose primary task is limited to investigating whether the presuppositions for permission are met."<sup>57</sup>

According to the Binding prescription, each case was to be evaluated by a three-person panel consisting of a physician, a psychiatrist, and a lawyer, who "alone have the right to vote."<sup>58</sup> This "Permission Board" shall decree that

after thorough investigation on the basis of current scientific opinion, the patient seems beyond help; that there is no reason to doubt the sincerity of his consent; that accordingly no impediment stands in the way of killing the patient; and that the petitioner is entrusted with bringing about the patient's release from his evil situation in the most expedient way.<sup>59</sup>

Death, according to this process, was to be "expertly" administered by a physician, in whom the right to grant death was a "natural extension of the responsibilities of the attending physician"; the "final release<sup>[60]</sup> must be completely painless, and only qualified persons are justified in applying the means."<sup>61</sup> And what about the possibility of error? Binding is confident that scientific consensus operates beyond the realm of error. Of course, he realizes that because of the morally promiscuous era of which he is apart, objections to "mercy killing" will be many. Proof of "alleged error by the Permission Board would be very difficult to come by," he assures the potential "Permission Board" member; nonetheless, "the possibility of error by the Permission Board is undeniable."<sup>62</sup> Indeed,

Error is possible in all human actions, and no one would draw the foolish conclusion that, considering this possible defect, we must forego all useful and wholesome activities. Even the physician in private practice can make errors which have serious consequences, but no one would bar him from practice because he is capable of erring. *What is good and reasonable must be done despite the risk of error.*<sup>63</sup>

Ultimately, even the possibility of fatal mistakes should not stand in the way of carrying out the "good and reasonable" prescription of Prof. Binding, which is the elimination of "life unworthy of living." Prof. Binding's self-proclaimed "deepest sympathy" for "valueless lives" comes to full expression at the conclusion of his essay: "But humanity loses so many members through error that one more or one less really scarcely matters."<sup>64</sup>

In the second essay of *Freigabe*, Alfred Hoche examines the medical relationship of physicians to their patients and physicians' relationship to killing. Hoche opens the essay by observing that a "code of medical ethics is nowhere explicitly established":

There is no medical moral law set out in paragraphs, no *Moral Service Regulations*. The young physician enters practice without any legal delineation of his rights and duties—especially regarding the most important points. Not even the Hippocratic Oath..., with its generalities, is operative today.<sup>65</sup>

In practice, what physicians “may do, or ought to do, emanates from peer opinion.” Indeed, writes Hoche, in some instances physicians “are compelled to destroy life”—for example, in “killing a living child during delivery for the purpose of saving the mother, terminating a pregnancy for the same reason.” This is done “in the interest of serving a higher good.”<sup>66</sup> Furthermore, “in all surgical procedures, one tacitly counts on a certain percentage of fatal outcomes,” and these “can never be wholly avoided. Our moral sensibility is completely reconciled to this.”<sup>67</sup>

One recurring “inner dilemma” that “not infrequently touches the physician” is whether or not, through “passive acquiescence,” to yield to the “temptation to let nature run its course” in matters of dying. Hoche is convinced that in certain cases such “passive acquiescence” to natural death is to be resisted. For example, “when the patient is incurably mentally ill,” then “death is at all events preferable.”<sup>68</sup> Hoche emphasizes how “immensely complicated it has already become for doctors to balance, in daily life, the rigid basic principles of medical ethics and the demands of a higher conception of life’s value,” and when these two stand in conflict, the physician “must recognize” that “he has no absolute relation to this [latter] obligation in all circumstances.”<sup>69</sup> Rather, “this relation is merely relative, alterable under new conditions, and always open to question.” Medical ethics, as Hoche understands it, “cannot be viewed as an eternally fixed pattern.”<sup>70</sup> For example,

If killing incurables or eliminating those who are mentally dead should come to be recognized (and generally acknowledged) as not only unpunishable, but as desirable for the general welfare, then, from that very moment, no opposing grounds for excluding this could be found in medical ethics.<sup>71</sup>

Hoche is not unmindful of practical concerns as he ponders the ethical duties of the medical profession. Extreme cases of “hopeless illness” that require the continuation of life, in Hoche’s view, render “nonsensical” the need for life-saving measures. In posing the question, “Is there human life which has utterly forfeited its claim to worth...that its continuation has forever lost all value both for the bearer of that life and society?,” Hoche answers “with certainty: Yes.” One example of this is what Hoche calls “mental death,” i.e., the condition of people who are deemed “complete idiots,” those “whose existence weighs most heavily on the community.”<sup>72</sup>

### **When All Else Fails: Economics as Trump Card**

Hoche instinctively moves to the economic dimensions of caring for those who are said to “burden the community.” He calculates, based on the number of “complete idiots” cared for in German institutions in his day, the amount of money and resources that would be saved. His calculations: Were Prof. Binding’s recommendations acted upon, “it is easy to estimate what *incredible capital* is withdrawn from the nation’s wealth for food, clothing, and heating—for an unproductive purpose.”<sup>73</sup> This great loss due to “such dead weight” of “valueless lives” calls for “the liberation of every available power for productive ends.”<sup>74</sup>

Hoche is by no means naïve in realizing that overturning conventional thinking, especially at the popular level, takes time and conditioning. Legislative as well as religious roadblocks serve as an additional impediment to the advancement of scientific thinking. Hoche waxes realistic:

The enormous difficulty of trying to address these problems legislatively will continue for a long time. Likewise, the ideas of gaining relief from our national burden by permitting the destruction of wholly worthless mentally dead persons will (from the start and for a long time) encounter lively, strident, and passionately stated opposition. This opposition will draw its strength from many different sources: resistance to the new and unfamiliar, religious ideas, sentimental feelings, and so on.<sup>75</sup>

Up to now, he laments, when the “the individual’s subjective right to exist” has clashed with “objective expediency and necessity,” the former has typically won. This “difficult” problem has been a result of “the essential participation of Christian ideas.” But “alien perspectives” should not prevent us from realizing—and acting on the conviction—that “valueless lives” and “dead weight existences” are a drain to society as a “civil organism.”<sup>76</sup>

### **Putting Euthanasia in Perspective: The Preparation of an Idea**

In 1933, with the accession of the National Socialists to power, two developments that had reached their critical mass were promptly codified into law. One was the long-discussed sterilization program, which had been debated but had not achieved majority support. The second was authorized euthanasia. The proposal, issued by the German Ministry of Justice, was reported on the front page of *The New York Times* and stated:

“It shall be made possible for physicians to end the tortures of incurable patients, upon request, in the interests of true humanity.” Moreover, the Ministry ensured, “no life still valuable to the state will be wantonly destroyed.”<sup>77</sup>

Andrew C. Ivy, M.D., asked in 1946 by the Board of Trustees of the American Medical Association to serve as a consultant at the Nuremberg trial of Nazi physicians who had been indicted for “crimes against humanity,” reflected on his difficult experience with the following observation:

It was inconceivable that a group of men trained in medicine and in official positions of power in German governmental circles could ignore the ethical principles of medicine and the unwritten law that a doctor should be nearer humanity than other men... [W]e had assumed that the sacred aspects of medicine and its ethics would certainly remain inviolate.<sup>78</sup>

Although, according to Ivy, “fewer than two hundred German physicians participated directly in the medical war crimes,” it became clear to Ivy that these atrocities were only “the end result” of the “complete encroachment on

the ethics and freedom of medicine” by those in positions of influence.<sup>79</sup> But where did this process begin? Indeed, the encroachment of crass utilitarianism on ethics and medical science, not to mention psychiatry and law, had begun to surface 40 years before National Socialism ascended to power in 1933. Its propagators displayed an artful and calculated mix of intellectual justification and popular agitation. Where the influence of the church and Christian intellectuals was during these preparatory years is a matter that should give us pause.

This utilitarian strain of thinking, perhaps dormant for several brief decades, would appear to have emerged once more in full force. Unquestionably, it dominates current bioethical debates, where we find it most conspicuously on display in contemporary discussions of what constitutes personhood. Moreover, utilitarian thinking about ethics is ubiquitous; it is the air we breathe, surfacing among and propagated by ethicists, health-care practitioners, social theorists, and sundry consultants, all of whom weigh the value of personhood against the economics of health care and the cumulative “burden” on society.<sup>80</sup> Lacking any strong commitment to the sanctity of life, utilitarian ethicists and practitioners adopt a “quality-of-life” ethic. The inevitable question that follows is this: At what point does an individual no longer have a “quality of life” that is “worthy of life” itself? Rightly bioethicist Leon Kass has warned: “There is the very real danger that what constitutes a ‘meaningful life’ among the intellectual elite will be imposed on the people as the only standard by which the value of human life is measured.”<sup>81</sup>

Consider the following dilemma, “Problem 97,” found in a German mathematics textbook published in 1935:

A mental patient costs about 4 RMS<sup>[82]</sup> a day to keep, a cripple 5.50 RMS, a criminal 3.50 RMS. In many cases a civil servant only has about 4 RMS, a salaried employee scarcely 3.50 RMS, an unskilled worker barely 2 RMS for his family. (a) Illustrate these figures with the aid of pictures. According to conservative estimates, there are about 300,000 mental patients, epileptics, etc. in asylums in Germany. (b) What do they cost together per annum at a rate of 4 RMS per person?... How many marriage loans at 1,000 RMS each could be awarded per annum with this money, disregarding later repayment?<sup>83</sup>

The solution to “Problem 97” follows:

Assuming an average daily outlay of 3.50 RMS there hereby results:

1. a daily savings of RM 245.955
2. an annual saving of RM 88,543.98
3. assuming a life expectancy of ten years [...]

...eight hundred and eighty-five million four hundred and thirty-nine thousand eight hundred Reichmarks...will have been, or has already been, saved by 1 September 1951 by reason of the disinfection of 70,273 persons which has been carried out to date.<sup>84</sup>

Historian Robert Proctor has argued that the primary argument for forcible euthanasia in the 1930s was economic; assisted death was justified as a kind of “preemptive triage” to free up beds.<sup>85</sup> Persons who were considered a burden on German society included handicapped infants, the mentally ill, the terminally ill, the comatose, and the criminal element. By 1941, euthanasia had become part of normal hospital routine.<sup>86</sup> This disposal or “disinfection” of human lives, however, was to be done “humanely and economically.”<sup>87</sup>

Writing in 1989, the late Cardinal John O’Connor of New York City, an ardent pro-life advocate, predicted that euthanasia would “dwarf the abortion phenomenon in magnitude, in numbers, in horror.”<sup>88</sup> When one considers the sheer number of abortions that are performed each year and that have been performed over the last three decades, this statement borders on fantastic. But Cardinal O’Connor’s are not the words of someone given to exaggeration. While there is nothing inevitable about human predictions, O’Connor’s words are haunting. What is it that can hinder this “prophecy” from coming to pass?<sup>89</sup>

Such, I dare say, will be the true test of Christian moral vision.

## Notes

- 1 This is a version of an essay that appeared in *The Unformed Conscience of Evangelicalism: Recovering the Church’s Moral Vision* by J. Daryl Charles. Copyright © 2002 by J. Daryl Charles. The article is published with permission of InterVarsity Press, P.O. Box 1400, Downers Grove, IL 60515, USA. [www.ivpress.com](http://www.ivpress.com).
- 2 Hence, the “end of democracy” debate that surfaced several years ago among some political and legal theorists, while controversial and offensive to some, raised questions nevertheless that demand our consideration. There is a form of tyranny that democratic pluralism is capable of engendering, precisely when it is wed to the ethical relativism against which John Paul warns.
- 3 “The Concept of the Person and the Value of Life,” *Kennedy Institute of Ethics Journal* 9/4 [1999]: 293. Tom L. Beauchamp, “The Failure of Theories of Personhood,” *Kennedy Institute of Ethics Journal* 9/4 [1999]: 309.
- 4 What writer Hugh Gregory Gallagher rather succinctly states as the essence of Darwinian thinking a century ago—genetic determinism—could very easily be applied to our own day: “The eugenicists and Darwinists, for all their pretensions, made no distinctions within the fitness category. Crooks and prostitutes, the blind, the paralyzed, the retarded, all were degenerate, all were unfit. These were people with weak genes. The degeneracy of their character, as well as the flawed nature of their bodies, was seen to be inherited” (*By Trust Betrayed: Patients, Physicians, and the License to Kill in the Third Reich*, rev. ed. [Arlington, Va.: Vandamere Press, 1995], p. 50).
- 5 Perhaps the best resource for understanding not only the indispensable role that Hitler’s assistants played in propping up the Third Reich but also the psychology of totalitarianism as it was played ethically out in their individual lives is Guido Knopp’s *Hitlers Helfer* (Muenchen: Wilhelm Goldmann Verlag, 1996). Unfortunately, this book remains untranslated from the German.
- 6 Alexander Mitscherlich (with Fred Mielke), *Doctors of Infamy: The Story of the Nazi Medical Crimes* (New York, N.Y.: Henry Schuman, 1949).
- 7 Robert Jay Lifton, *The Nazi Doctors: Medical Killing and the Psychology of Genocide* (New York, N.Y.: Basic Books, 1986).
- 8 Robert Proctor, *Racial Hygiene: Medicine under the Nazis* (Cambridge, Mass./London: Harvard University Press, 1988).
- 9 Michael Burleigh, *Death and Deliverance: ‘Euthanasia’ in Germany ca. 1900-1945* (Cambridge: Cambridge University Press, 1994).
- 10 Wesley J. Smith, *Forced Exit: The Slippery Slope from Assisted Suicide to Legalized Murder* (New York, N.Y.: Times Books, 1997), and more recently, *Culture of Death: The Assault on Medical Ethics in America* (San Francisco, Calif.: Encounter Books, 2000).
- 11 It is telling that National Socialist leaders commonly referred to the phenomenon of National Socialism as “applied biology.” An example of this in the literature is Fritz Lenz, *Menschliche Auslese und Rassenhygiene* (Muenchen: Beck, 1931), which remains untranslated from the German. (The title of this volume translates: “Human Selection and Race-Based Health.”) Significantly, the

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- 1931 version of Lenz's book was the *third* edition already.
- 12 Robert N. Proctor, "Nazi Doctors, Racial Medicine, and Human Experimentation," in *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*, ed. George J. Annas and Michael A. Grodin (New York, N.Y./Oxford: Oxford University Press, 1992), pp. 19-31.
  - 13 *Ibid.*, p. 20.
  - 14 See n. 8 above.
  - 15 The Weimar Republic corresponds to the period extending from 1919, the year of a German constitutional assembly at Weimar, and 1933, when the Republic was dissolved with Hitler becoming chancellor.
  - 16 Hans-Ludwig Siemen, *Menschen bleiben auf der Strecke. Psychiatrie zwischen Reform und Nationalsozialismus* (Guetersloh: Guetersloher Verlag, 1987), pp. 29-30.
  - 17 This is Burleigh's calculation (*Death*, p. 11).
  - 18 Karl's well-known son would study theology at Union Theological Seminary in New York City and, to his credit, return to Germany to identify with the so-called "confessing church."
  - 19 Bonhoeffer's address was published in the *Allgemeine Zeitschrift fuer Psychiatrie* 76 (1920/21); the citation is from p. 600 (an English translation of which appears in Burleigh, *Death*, pp. 11-12).
  - 20 Burleigh, *Death*, p. 12.
  - 21 This is the view of historians Burleigh, *Death*, pp. 12-13, and Proctor, *Racial Hygiene*, pp. 177-222 ("The Destruction of 'Lives Not Worth Living,'" which is Chapter 7 of Proctor's book).
  - 22 According to historian Daniel Gasman, *The Scientific Origins of National Socialism: Social Darwinism in Ernst Haeckel and the German Monist League* (New York, N.Y.: American Elsevier Pub. Co., 1971), p. 14, *Riddle* sold more than 100,000 copies in its first year, went through ten editions by 1919, had sold over 500,000 copies by 1933, and in time was translated into 25 different languages. Gasman has called Haeckel "Germany's major prophet of political biology" (p. 150).
  - 23 See Walter Schmuhl, *Rassenhygiene, Nationalsozialismus, Euthanasie. Von der Verhuetung zur Vernichtung 'lebensunwerten Lebens' 1890-1945* (Goettingen: Vandenhoeck & Ruprecht, 1987), esp. p. 109.
  - 24 This was part of an exchange that was published in Wilhelm Boerner, "Euthanasie," *Das monistische Jahrhundert* 2 (1913): 251-54. An English translation of this text appears in Burleigh, *Death*, p. 14.
  - 25 Adolf Jost, *Das Recht auf den Tod: Sociale Studie* (Goettingen: Dietrich'sche Verlagsbuchhandlung, 1895).
  - 26 English-language assessments of Jost can be found in Lifton (*The Nazi Doctors*, p. 46) and Burleigh (*Death*, pp. 12-15), with a more thorough untranslated examination in Klaus Doerner, "Nationalsozialismus und Lebensvernichtung," *Vierteljahrshfte fuer Zeitgeschichte* 15 (1967): 121-52.
  - 27 Note here the emphasis on utility: the patient's "ability to work."
  - 28 This "draft" was originally published in volume 2 of *Das monistische Jahrhundert* (1913): 170-71. A written translation appears in Burleigh, *Death*, pp. 13-14.
  - 29 (Leipzig: Felix Meiner Verlag, 1920), with the title normally translated from the German as *The Permission to Destroy Life Unworthy of Life*. This translation, cited in most historical accounts of this period (see the following footnote), does not adequately capture the nuance and the euphemism that inhere in the German original. A better rendering would be "Release for the Extermination of Life Unworthy of Being Lived." The German verb *freigeben*, from which the noun *Freigabe* is derived, can mean "permit," but more often than not it carries the sense of "release" or "set free." (In my research I came across only one historical source that rendered *Freigabe* as "Release": Robert Proctor's, *Racial Hygiene*, p. 178.) Hence, in the title of Binding and Hoche's volume, it is probably intended to convey a *therapeutic* nuance and not merely descriptive or prescriptive function; from the standpoint of euthanasia advocates, people are "released" or "set free" by the act of "mercy killing." *Freigabe* in this context is a partner-term standing alongside another German euphemism, *Gnadentod* ("mercy death"). This language, it should be emphasized, comports perfectly with the ethos of contemporary euthanasia advocates.
  - 30 This is the view of American Holocaust historian Robert Jay Lifton, *The Nazi Doctors: Medical Killing and the Psychology of Genocide* (New York, N.Y.: Basic Books, 1986), pp. 46-48; German historian Christian Pross, "Nazi Doctors, German Medicine, and Historical Truth," in *The Nazi Doctors and the Nuremberg Code*, ed. George Annas and Michael A. Brodin (New York, N.Y./Oxford: Oxford University Press, 1992), p. 40; American historian Robert Proctor, *Racial Hygiene*, pp. 177-80; British historian Michael Burleigh, *Death*, pp. 15-21; writer Hugh Gregory Gallagher, *By Trust Betrayed*, p. 60; and writer/legal expert Wesley Smith, *Forced Exit*, pp. 73-75.
  - 31 The expression "life unworthy of living" occurs regularly throughout *Freigabe* and is never qualified or questioned—e.g., p. 24 (= p. 244, *Law & Medicine*), p. 51 (= p. 258, *L & M*), and p. 53 (= p. 260, *L&M*).

- 32 German: *einer Todkranker oder toedlich Verwundete* (*Freigabe*, p. 24).
- 33 *Ibid.*, pp. 24-25.
- 34 Here the English translation found in *Law & Medicine*—"has had no continuation" (p. 245)—is awkward and misses the sense of the German original (*hat...im Reichsstrafgesetz keinen Fortgang...gefunden* [*Freigabe*, p. 25]).
- 35 *Freigabe*, p. 25.
- 36 In a remarkable comment confined to a footnote, Binding insinuates that death would prevent the "mentally dead" person or "idiot" from having to endure the shame of being a public spectacle and mistreatment that results from other people's verbal abuse. "The life of such poor people is an unending invitation to die" (my translation of: *Das Leben solcher Armen isst ein ewiges Spiessrutenlaufen*).
- 37 These individuals Binding calls *die unrettbar Kranken*, "the hopelessly ill" (e.g., p. 34, *Freigabe*).
- 38 My own commentary on the Binding-Hoche book is based on the German original, but for the benefit of the reader I locate most of the citations in the English translation of *Freigabe* that appeared in the journal *Issues in Law & Medicine* 5, no. 2 (1992): 231-65. Where the *Law & Medicine* translation is weak or misses particular nuances of the authors' language, I allude in the footnotes directly to the pages of the German original. (In addition, it is distracting that the translators' enumeration of footnotes does not follow that of the authors.) The team of translators who prepared the text of *Freigabe* for *Law & Medicine* consisted of three individuals, one of whom received his medical degree from the Johann Wolfgang von Goethe University of Frankfurt in 1925, where he attended lectures in neurology and psychiatry by co-author Hoche. Reprints of the English translation of *Freigabe* are available from: The Editor, *Issues in Law & Medicine*, P.O. Box 1586, Terre Haute, IN 47808.
- 39 *Ibid.*, pp. 231-32.
- 40 *Ibid.*, p. 232.
- 41 *Ibid.*, p. 233.
- 42 *Ibid.*, pp. 233, 237. This statement is staggering not only for its hubris but in its distortion of language, of Christian belief, and of natural-law thinking.
- 43 Binding acknowledges that in 1885 he had written from the opposite viewpoint, arguing that assisted death should remain illegal (*verboten*, p. 19, n. 32, *Freigabe*). Binding's sole objection to the legality of suicide is the possible loss of potentially valuable members of society.
- 44 *Ibid.*, pp. 236-37. In fact, Binding asserts that "this act must be considered as not legally forbidden even when the law does not explicitly recognize it" (*ibid.*, p. 241).
- 45 *Ibid.*, p. 240.
- 46 *Ibid.* (emphasis his).
- 47 *Ibid.*, p. 241.
- 48 *Ibid.*, p. 246.
- 49 *Ibid.*, p. 252.
- 50 *Ibid.*, p. 246.
- 51 *Ibid.*
- 52 *Ibid.*
- 53 *Ibid.*, pp. 246-47.
- 54 *Ibid.*, p. 248.
- 55 *Ibid.*, p. 251. Note, as well, that this diagnosis cannot be placed in the hands of family members or spiritual leaders.
- 56 *Ibid.*, p. 252. Instigation of the request, however, may originate with relatives or the person's doctor.
- 57 *Ibid.*, p. 252.
- 58 *Ibid.*
- 59 *Ibid.*
- 60 The authors use several German words in the text therapeutically and euphemistically to speak of the patient's "release." The term here is *Erloesung*, which can be translated "solution" or "salvation" as well as "release."
- 61 *Ibid.*
- 62 *Ibid.*, p. 254.
- 63 *Ibid.*
- 64 *Ibid.*
- 65 *Ibid.*, p. 255.
- 66 *Ibid.*, p. 256.

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- 67 Ibid.
- 68 Ibid., p. 257.
- 69 Ibid.
- 70 Ibid., pp. 257-58.
- 71 Ibid., p. 258.
- 72 Ibid., p. 260.
- 73 Ibid., pp. 260-61.
- 74 Ibid., pp. 261, 262. The sheer arrogance and inhumanity of Alfred Hoche is breathtaking. He writes: "Naturally no doctor would conclude with certainty that a two- or three-year-old was suffering permanent mental death. But, *even in childhood*, the moment comes when this prediction can be made without doubt" (ibid., p. 265, emphasis his).
- 75 Ibid., p. 261.
- 76 Ibid., p. 262.
- 77 *The New York Times*, October 8, 1933, p. 1, cited in Gallagher, *By Trust Betrayed*, p. 62.
- 78 Cited in the Forward to Mitscherlich, *Doctors*, pp. ix-x.
- 79 Ibid., pp. x-xi.
- 80 See, for example, Daniel Callahan's book *Setting Limits: Medical Goals in an Aging Society* (New York, N.Y.: Simon and Schuster, 1987), as well as the rather breathtaking essay by John Hardwig, "Is There a Duty to Die?," appearing in the journal edited by Callahan, *Hastings Center Report* (March-April 1997): 37-38.
- 81 Leon Kass, in a personal interview with author Wesley Smith, cited in Smith, *Culture of Death*, p. 9.
- 82 "RMS" stands for *Reichmarks*.
- 83 Adolf Doerner, ed., *Mathematik im Dienste der nationalpolitischen Erziehung mit Anwendungsbeispielen aus Volkswissenschaft, Gelaendekunde und Naturwissenschaft* (Frankfurt am Main: Fischer, 1935), p. 42. (An English translation of the title would be as follows: "Mathematics in the Service of National Political Education with Examples Drawn from Social Science, Folk Art and Natural Science." An English translation of the above citation, with the title untranslated, appears in Burleigh, *Death*, p. ix.)
- 84 From a digest found in 1945 at Schloss Hartheim, one of six killing centers where organized euthanasia was being performed on adults during the war time, this is Exhibit 39T-1021, Heidelberg Dokumente, Roll 18, Item 000-12-463, of the National Archives, Washington, D.C.
- 85 Proctor, "Nazi Doctors," p. 24.
- 86 Ibid.
- 87 Lest we think that that was then but this is now, or that German thinking on the matter was isolated in 1942, an article was published in the *Journal of the American Psychiatric Association* that called for the killing of retarded children ("nature's mistakes"). Elsewhere historian Robert Proctor has noted that until reports of wholesale Nazi exterminations began to appear in American newspapers in 1942, the merits of forced euthanasia were being vigorously debated in various American scholarly journals. See his *Racial Hygiene*, pp. 179-89.
- 88 Cardinal John O'Connor, "A Cardinal's Chilling Warning," *New Covenant* (May 1989), pp. 23-24.
- 89 Following a public referendum in the state of Washington that turned back the permission to assist death, but before Oregon's approval of the same, the Ramsey Colloquium of the Institute on Religion and Public Life in New York City produced an eloquent statement of the Jewish and Christian understanding of euthanasia. The Colloquium, consisting of Jewish and Christian theologians, ethicists, and philosophers and named after Paul Ramsey (1913-1988), the distinguished Protestant ethicist who was a pioneer in the field of contemporary medical ethics, issued a declaration that was published in the journal *First Things* (February 1992): 45-47, and appeared in abbreviated form in the November 27, 1991 issue of *The Wall Street Journal*.

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**J. Daryl Charles, Ph.D.**, is associate professor of religion and ethics at Union University in Jackson, Tennessee, USA. A 2003/4 Visiting Fellow of the Institute for Faith and Learning at Baylor University, Charles is author of *Between Pacifism and Jihad: Just War and the Christian Tradition* (InterVarsity Press, forthcoming), *The Unformed Conscience of Evangelicalism: Recovering the Church's Moral Vision* (InterVarsity Press), and *Virtue amidst Vice* (Sheffield Academic Press). He writes frequently on New Testament ethics, criminal justice, issues surrounding war and peace, and religion and culture.



## BOOK REVIEWS

### **My Sister's Keeper: A Novel**

Jodi Picoult

New York: Atria Books, 2004

ISBN 0743454529; 423 PP., HARDCOVER, \$25.00

Many ethicists are concerned about such the new practice by which a family chooses to conceive a child to help another. Using prenatal genetic diagnosis, an embryo is chosen for its genetic qualities, and is implanted and carried to term so that it can be used to provide cells useful in the therapy of an older sibling. Ethicists have weighed in on either side of the famous 2000 American case of Adam Nash, brought to birth from a prescreened embryo to provide umbilical cord cells to his six-year-old sister Molly to treat her Fanconi anemia. Some point to the fact that this was a miraculous way to save Molly who was expected to have died within a year without this treatment, and they celebrate this development. Others worry about genetically designing a child for even a good purpose, as well as the vexing question of whether the child is being used as a mere means to others' ends. In addition, genetically unsuitable embryos are simply discarded.

Sometimes those of us concerned about this practice have speculated on what it would be like to grow up like Adam Nash. What special problems or blessings would such a child experience?

More so than bioethical argumentation, literature is particularly suited to explore such issues by imaginatively envisioning a family in such a situation. Novelist Jodi Picoult has written a highly readable and moving novel about thirteen year old Kate, who was conceived to be a donor match to her older sister Anna, who struggles with leukemia. Initially only umbilical cord material was to be used from Kate, but as Anna continued to battle her disease Kate was simply expected to make herself available to undergo sometimes frightening and painful procedures and to donate various tissues to help Anna. Finally, at age thirteen, Kate files for medical emancipation so that she will not have to donate a life-saving kidney to her sister.

The novel shows very vividly the mixed emotions that a child like Kate would have towards her sister, her parents, and her brother. Picoult explores the family dynamics that surround a child who frequently is perilously close to death, requiring seemingly endless hospitalizations, and another child who is healthy, genetically matched, taken for granted, and sometimes resentful. Picoult sensitively describes the love between the sisters as well as the feelings that Kate experiences when there is too little time, sympathy, or energy in the family to devote to her own set of problems, concerns, and fears. The chapters of the novel alternate between the perspectives of Kate, Anna, their brother, each parent, and other characters, and provide a rich overview of the effects of bioethical and personal decisions on many affected individuals.

I have been recommending this novel to fellow students of bioethics as an important supplement to the didactic arguments offered. The story is gripping and rewarding, with a genuine surprise ending, and perhaps readers will emerge feeling better able to think carefully and humanely about the unanticipated consequences for good or ill that result from having one child to spare another.

**David B. Fletcher, Ph.D.**, Associate Professor of Philosophy, Wheaton College, Wheaton, Illinois, USA.

## Open Embrace: A Protestant Couple Rethinks Contraception

Sam and Bethany Torode

Grand Rapids, Michigan: William B. Eerdmans, 2002

ISBN 0802839738; 123 PP., PAPERBACK, \$12.00

*Open Embrace: A Protestant Couple Rethinks Contraception* is one couple's theological appraisal of the use of contraceptives within the context of marriage. The Torodes' objective is to promote Natural Family Planning (NFP) as the ideal method for managing family size, and as the sole replacement for current modes of contraception. In the short amount of space that this book takes up, Sam and Bethany Torode also examine the history of the church's view of contraception and posit that the contemporary embrace of contraceptives is the result of an unfortunate marriage of church with culture.

The foreword, written by J. Budziszewski, clarifies the overarching theological problem that guides the conclusions of this book. He says that "some husbands and wives try to sever the procreative dimension from the unitive" for which the marital union was designed. Budziszewski declares that the deliberate intention to avoid conception while having sex is a "collaboration in selfishness" (p. xiv). He says there is "no need to thwart the design, to artificially block fertility during a naturally fertile time. One only has to wait for a few days. If that is too difficult for us, something is wrong" (p. xvi). Budziszewski's previous statement elsewhere that "Deliberate sterility insults the past and destroys the future; it makes us like the animals, who have neither history nor hope" clarifies his position further (*First Things* 88 [December 1998]: 17-29). The forward, as does the entire book, then begs the question as to whether or not NFP is a deliberate method of avoiding conception.

The Torodes ground their views of contraception in their understanding of the image of God, stating that "sexuality reflects God's likeness; from the very beginning man was a sexual being...and blessed with fertility" (p. 16). Appealing to the Trinity as a source for understanding the procreative nature of the marital bond, they view the creation mandate as a way of experiencing the love that exists within the godhead. In light of all this, their position is that if we properly view our spouse as an Image-bearer, then we will recognize that they are worthy of nothing less than selfless love. As a result, the marital embrace will be more than a mutual exchange of pleasure, it will also involve a mutual exchange of bodily fluids, thus permitting man and woman to experience the grace of God and become one flesh.

After building their case against the use of contraceptives for the entire the first half of the book, the authors finally explain the nature of following NFP in chapter six. They state that with NFP "couples can identify the days per cycle...that a wife might become pregnant by monitoring up to three different fertility signs: her body's production of cervical fluid, her oral temperature upon waking, and the position of her cervix. These signs are recorded daily and tracked on a chart. The couple then decides whether to make love during the fertile days or to abstain until they have passed" (p. 45).

NFP, as understood by the explanation provided by the Torodes, functions at least in part for the purpose of avoiding pregnancy. The basal thermometer is no less a barrier to conception than is a prophylactic or diaphragm. Their response to this kind of argument does not settle the issue, however. Maintaining that NFP is not contraception in that it respects the feminine fertility cycle does not necessitate that NFP is not deliberate barrier to conception.

The authors argue that the use of contraception violates God's procreative intent for sex within marriage. For that reason, couples should only defer to using NFP, which, in their view, does not meet the criteria for being a form of contraception. They define contraception as "any process, device, or action whose purpose is to prevent the meeting of sperm and egg when a couple engages in intercourse. This includes things like condoms, diaphragms, and

spermicidal jellies, as well as male and female sterilization” (p. 8). They state, “while sex is not solely for conception, it is not our place to deliberately separate sex from its procreative aspect” (p. 30). But to conclude that NFP does not meet this criterion for what constitutes a contraceptive is erroneous. By tracking physical signs such as body temperature and mucus texture, NFP accomplishes precisely that very separation of sex from procreation.

The difficulty with this book is not the promotion of NFP or the authors’ concern with contraceptives that might function as abortifacients. *Open Embrace* is, in fact, a refreshing resource in its high view of the sacrament of marriage and the fact that it takes seriously the creation mandate of Genesis 1, reiterated again in Genesis 9. It also encourages communication between husband and wife that might not otherwise exist with the use of other forms of contraception because it is properly focused on understanding and respecting her fertility cycle. What this book does not provide is a strong case against the use of other forms of contraception that would not threaten the life of a fertilized egg. This book simply does not establish that NFP is functionally dissimilar to other barrier methods that are currently available, and by that account, the book fails its own purpose.

**Sarah J. Flashing**, Director of Public Relations and Communications, The Center for Bioethics and Human Dignity, Bannockburn, Illinois, USA.



## BIOTECHNOLOGY UPDATE: NEWS AND VIEWS

### How Then Should We Do Medical Research?

ROBERT CARLSON

What is the Declaration of Helsinki and why is it worthy of a doctoral thesis being devoted to it? The Declaration of Helsinki is one of the 20<sup>th</sup> century's most remarkable texts. In this document, the World Medical Association<sup>1</sup> seeks to provide "a statement of ethical principles to provide guidance to physicians and other participants in medical research."<sup>2</sup> Unlike many other much longer international documents,<sup>3</sup> the Declaration of Helsinki sets forth its principles in less than 2000 words. It has risen, over its 40-year existence, to become one of the pre-eminent texts addressing ethical issues in medical research.

Historically, the Declaration of Helsinki has its roots in the Nuremberg Code. At Nuremberg in 1947, over 20 physicians and scientists were on trial for their part in a number of horrific medical experiments carried out under the Nazi regime.<sup>4</sup> The Nuremberg Code was a statement outlining "Permissible Medical Experiments" and was the standard to which those on trial were held.

The World Medical Association, formed in London in that same year, spent most of the next two decades debating its own statement of ethical principles pertaining to medical research. Finally, in 1964, the original Declaration of Helsinki was adopted<sup>5</sup> and stuck fairly closely to the principles articulated in Nuremberg. There was a major revision in 1975, which for the first time set out the requirement that proposed medical research be subject to review by an independent committee. There were minor revisions in 1983, 1989, and 1996<sup>6</sup> but the quarter-century from 1975-2000 really saw the Declaration of Helsinki take a very authoritative position in the international world of medical research.

Yet, with the 5<sup>th</sup> and most recent amendment in October 2000, the Declaration of Helsinki finds itself in the midst of a storm of controversy. Two of the new paragraphs in particular, i.e., paragraphs 29 and 30, are at the centre of the controversy. Essentially these ask the question:

1. In what circumstances is it ethically acceptable to use a placebo (inactive treatment, sometimes called "sham" treatment) in medical research? Placebo-controls<sup>7</sup> have many advantages and often result in a smaller number of subjects being involved in research for a shorter period of time than would be necessary if the control group were receiving active treatment. The drawback is that, for conditions where effective treatment exists, the people who receive placebo do not receive their usual active treatment.<sup>8</sup> A corollary question arises: if active control groups are used, what should be the standard of treatment used in the comparator group? This is particularly pertinent in studies done in resource-poor countries where health care standards may be minimal. If a clinical trial is done in such a population, what should be the standard of care in the control arm? Should it be the usual treatment available in that country? Or should it be the best treatment available anywhere in the world?

These questions depend partly on the nature of the research questions and are still the subject of much debate. Suffice it to say that paragraph 29 in its original form gave rise to so much controversy that the World Medical Association took the unprecedented step of issuing a "Note of Clarification" to this paragraph. It has recently been argued that this "Note of Clarification" does not clarify but rather does just the opposite!<sup>9</sup>

2. Another related controversy arose in paragraph 30 which states: "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study." This addresses the issue of the responsibility of researchers to research subjects after the research is completed. The controversy particularly arises in the context of research sponsors from industrialised countries, undertaking research in resource-poor countries. When the research is over, what happens to those participants who benefited during the clinical trial if they cannot afford the treatment, and their country's public health system cannot (or will not) provide the treatment?

Again the storm of controversy has led the World Medical Association to consider another note of clarification and this will be debated at the upcoming World Medical Assembly in Tokyo in October.<sup>10</sup> It is well known that there are great imbalances in the distribution of the world's health care resources and this imbalance is also reflected in the distribution of research effort in health care. This has been characterised as the 90/10 problem: ninety percent of the world's medical research resources are invested in research into the disease burden affecting 10 percent of the world's population. By venturing into the area of justice with respect to medical research, has the Declaration of Helsinki inevitably courted controversy, and found itself in dispute with some very powerful voices? Or has it simply "missed the mark" in the way it articulates research ethics guidelines?

So, back to the original question: I hope this outline has begun to answer the question of why this Declaration is worthy of a doctoral dissertation. Yet, like any other text, the Declaration of Helsinki gives rise to age-old questions. Does the meaning of the text lie in the author's intent? In this case, how would one determine the author's intent when the text emerges from a long and complicated quasi-democratic process?<sup>11</sup> Three broad approaches to dealing with the question of the interpretation of the Declaration of Helsinki will be taken and they are characterised as follows:

A. How can the Declaration of Helsinki be interpreted? Here, the principles of hermeneutics will be applied to the whole of the document in much the way one would see in a commentary on a biblical text.

B. How should the Declaration of Helsinki be interpreted? Is there an ethical coherence to the entire text? As a document emerging from a global debate and a voting process, are there underlying principles that it consistently follows?

C. How is the Declaration of Helsinki being interpreted? Following semi-structured interviews with over 50 international experts in various aspects of medical research, including many of those involved in drafting the Declaration of Helsinki, a qualitative analysis will seek to demonstrate the variety of interpretations being applied to the Declaration of Helsinki.

By bringing together the results of the above three broad approaches, we return to the question of whether or not the Declaration of Helsinki adequately addresses the question "How then should we do medical research?"

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**Robert Carlson** is Clinical Senior Lecturer in Medical Ethics based in the Clinical Pharmacology Unit at the Western General Hospital in Edinburgh, having initially worked as Locum Consultant in Public Health Medicine (Communicable Disease and Environmental Health) as well as teaching in the Edinburgh University's MSc programme in Public Health. Mr. Carlson has also worked in both public health medicine and general practice, having completed his postgraduate training in public health medicine in Dunedin, and has Masters Degree in theology from Regent College in Vancouver. He is currently completing his PhD on the ethical dimensions and impact on biomedical research of the most recent amendment (Edinburgh, 2000) to the Declaration of Helsinki.

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## Biotechnology News Update

### *California Proposition 71*

In November, voters in California will have to decide on a \$3 billion referendum to fund human cloning and embryonic stem cell research in the state. We are including for our readers links to several articles and organizations who oppose this financially unsound and ethically problematic measure.

<http://www.NoonProp71.com>

<http://www.latimes.com/business/la-fi-golden23aug23,1,4524240.columnn>

[http://home.businesswire.com/portal/site/google/index.jsp?ndmViewId=news\\_view&newsId=20040824005332&newsLang=en](http://home.businesswire.com/portal/site/google/index.jsp?ndmViewId=news_view&newsId=20040824005332&newsLang=en)

<http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2004/08/29/EDGMQ8F9VH1.DTL>

<http://www.sacbee.com/content/opinion/story/10831560p-11749478c.html>

### *France Passes Comprehensive Human Cloning Ban*

The French Parliament recently passed a comprehensive human cloning ban not unlike the one passed earlier this spring in Canada. The bill declares that all human cloning is a "crime against the human species" and includes the controversial uses of human cloning in biomedical research under the ban.

[http://www.channelnewsasia.com/stories/afp\\_world/view/94729/1/html](http://www.channelnewsasia.com/stories/afp_world/view/94729/1/html)

### *UK Oks Human Embryo Cloning*

For the first time in the UK, the Human Fertilisation and Embryology Authority has agreed to grant a 1-year license to researchers who intend to conduct human cloning experimentation. Human cloning for research purposes is legal in the UK, and significant opposition to the HFEA decision has arisen from a variety of groups. In response to the decision, leaders in

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other European nations, particularly in Germany, called for a Europe-wide ban to all human cloning. Human cloning has been banned in Germany since 1990.

<http://news.bbc.co.uk/2/hi/health/3554474.stm>

<http://www.biomedcentral.com/news/20040812/04>

[http://www.dw-world.de/english/0,3367,1432\\_A\\_1297192\\_1\\_A,00.html?mpb=en](http://www.dw-world.de/english/0,3367,1432_A_1297192_1_A,00.html?mpb=en)

### *New Zealand Bans Human Genetic Engineering, Cloning*

New Zealand's parliament has passed a bill banning cloning, inheritable genetic modification, and sex selection for children in that country. While many supporters had hoped that the bill would contain even stronger language to limit embryo selection, such as exists in Australia, it does prohibit many significant unethical practices.

<http://www.scoop.co.nz/mason/stories/PA0408/S00129.htm>

<http://www.nzherald.co.nz/storydisplay.cfm?storyID=3582991&thesection=news&thesubsection=general>

### *Adult Stem Cell Advances*

A broad range of therapeutic advances continues to be made in research utilizing somatic (adult) stem cells. Stem cells derived from bone marrow, umbilical cord blood, muscle tissue, and even fat are showing tremendous promise in providing successful treatments in both human and animal subjects.

<http://www.mdausa.org/publications/Quest/q91stemcell.cfm>

[http://www.biospace.com/news\\_story.cfm?StoryID=16797520&full=1](http://www.biospace.com/news_story.cfm?StoryID=16797520&full=1)

<http://www.nbc4.com/health/3588307/detail.html>

<http://www.washingtonpost.com/wp-dyn/articles/A17047-2004Aug19.html>

<http://www.betterhumans.com/News/news.aspx?articleID=2004-09-03-2>

<http://www.betterhumans.com/News/news.aspx?articleID=2004-09-15-2>

<http://www.reuters.com/newsArticle.jhtml?type=healthNews&storyID=6330756>

<http://www.betterhumans.com/News/news.aspx?articleID=2004-09-30-2>

### *Nanotech Update*

New data are emerging that indicate that size may make a significant difference when nanoscale particles are introduced into the environment or human bodies through commercial products or other means. Researchers in the field are urging caution and further study before more commercial products, which currently include cosmetics and sunscreens, are introduced into the market. Products that utilize nanoscale materials are not currently labeled as such under US law, which would be a strong first step, along with further research into the promises and hazards associated with the tiny particles. The Royal Academy of Science (UK) has published a new report regarding both the opportunities presented by nanotechnology as well as the potential risks to health and the environment.

<http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2004/07/26/MNG767SUKB1.DTL&type=printable>



<http://www.washingtonpost.com/wp-dyn/articles/A25675-2004Jul29.html>

<http://www.nanotec.org.uk/finalReport.htm>

[http://www.the-scientist.com/yr2004/aug/research4\\_040830.html](http://www.the-scientist.com/yr2004/aug/research4_040830.html)

<http://www.biomedcentral.com/news/20040901/01>

<http://www.philly.com/mld/inquirer/news/front/9267202.htm>

### *Drug Makers Fail to Disclose Test Data*

Major drug makers have been found recently to have violated federal law by not disclosing the full scale of their clinical trials. It has been estimated that roughly half of all trials have not been reported to the FDA as required. When this happens and unsuccessful trials go unreported, patients and doctors do not receive important information on new drugs, often information which indicates negative results, lower success rates, and undesirable side effects.

<http://www.washingtonpost.com/wp-dyn/articles/A29576-2004Jul5.html>

<http://content.nejm.org/cgi/content/full/351/4/315>

### *Debate and Hype Over US Cloning and Embryonic Stem Cell Policy*

The debate continues to rage in the US over federal funding for human cloning and embryonic stem cell research. The issue is one in which there is a great deal of hype from those who support expanding federal funding for the controversial methods, and few people, including voters and politicians, have a clear picture as to what is involved or what the realistic hopes may be for cures to arise from the use of human embryonic stem cells from any source, including cloning. The articles linked below provide a fair and substantive analysis of the science and politics in the current embryonic stem cell debate in the US.

<http://www.washingtonpost.com/wp-dyn/articles/A38130-2004Aug3.html>

<http://www.thenewatlantis.com/archive/6/meilaender.htm>

<http://slate.msn.com/id/2104983/>

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### Notes

- 1 The World Medical Association, whose membership comprises the national medical associations of over 80 countries, is the largest international grouping of medical professionals. See <http://www.wma.net/e/members/list.htm>.
- 2 World Medical Association. *Declaration of Helsinki: Ethical principles for medical research involving human subjects* (5th revision, Edinburgh, 2000). <http://www.wma.net/e/policy/b3.htm>.
- 3 For example, Council for International Organisations of Medical Sciences (CIOMS) has over 26,000 words and the European Union Clinical Trials Directive is over 8000 words in length.
- 4 See <http://www.ushmm.org/research/doctors/> for details of the Doctors' Trials and a link to the text of the Nuremberg Code.
- 5 See the *British Medical Journal* of 18 July 1964, p.177 for the innocuous announcement of the adoption of this new Declaration.
- 6 See Carlson RV, Boyd KM, Webb DJ. The revision of the Declaration of Helsinki: past, present and future. See *British Journal of Clinical Pharmacology* 2004; 57: 695-713 for a detailed review of how

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the text of the Declaration has changed with each revision.

- 7 A "control" group in any medical research is the group of people, usually allocated by a random process, who do not receive the new experimental treatment but are compared with the group that do receive the experimental therapy.
- 8 This is an oversimplification as some research study designs, such as "Add-on" studies, where research participants receive either standard treatment plus new treatment or standard treatment plus placebo do not involved withdrawing of active treatment.
- 9 See Ruth Macklin, *"Double Standards in Medical Research in Developing Countries,"* Cambridge University Press, 2004, p.49, for example.
- 10 Details of the proposed Note of Clarification can be found at the WMA website at <http://www.wma.net/e/ethicsunit/helsinki.htm>.
- 11 I use the term "quasi-democratic" because although the final form of the text is the subject of a vote by members of the WMA, the actual voting strength of each national medical association that is a member state of the WMA is weighted according to a complex formula. Modifications to an ethical document of the WMA require a 75% majority at the annual WMA Assembly.

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