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HPV VACCINE: PANACEA OR PANDORA'S BOX? THE COSTS AND DECEPTIVENESS OF THE NEW TECHNOLOGY

BY SUSAN HAACK, MD, MA, ASSOCIATE FELLOW

Introduction:
The United States has the most affluent and technologically advanced healthcare system in the developed world, offering increased life-expectancy and quality of life to many. Yet it is also the most inequitable system in the developed world, with many of its own residents lacking access to this system of care—a fact which weighs heavily on our national conscience. Consequently, healthcare reform is again an urgent political issue, with the most recent reform package estimated to cost over $3 trillion to institute.

It is in this context that one of the newer technological advances, HPV (human papilloma virus) vaccination, must be evaluated. The first quadrivalent vaccine was licensed for use in 2006 but not widely utilized until the completion of phase three trials in 2007.[1] Even though the clinically relevant endpoint of this trial was the prevention of CIN (cervical intraepithelial neoplasia) II and III,[2] it was quickly marketed as the first cancer vaccine: if administered to preadolescent girls, before the onset of sexual activity, it would prevent the later development of cervical cancer. This was rapidly followed by an egregiously premature move to make vaccination against HPV a mandatory requirement through the school system, a move which lacked the empirical foundation necessary to withstand critical opposition, except in the state of Texas.[3]

What is HPV?
Human papilloma virus is a DNA virus that is transmitted by skin-to-skin contact, and is similar to papilloma viruses that cause "warts" on other areas of the body. There are approximately 40 species that specifically infect the genital tract, causing genital warts and—in the presence of other co-factors, such as smoking or immune deficiency—cancers of the cervix, vagina, and vulva.[4] While the virus is more prevalent in men, they rarely develop significant consequences of infection. The virus has been isolated on sperm,[5] but skin-to-skin contact is the primary means of transmission with scrotal skin serving as a passive reservoir for male-female transmission.[6] It is the incorporation of viral DNA into the genome of the infected cell that produces cellular changes leading to clinical "disease."

Historical Perspective
Our understanding of the mechanism of infection with HPV has changed significantly over the past 30 years, from permanence to transience; from general to specific; and from progression to regression. Originally, infection was felt to be a permanent condition, much like that seen with herpes viruses. Conversely, in recent years we have come to understand that infections with HPV are most often transient, with the median duration of infection ranging from 4.8 months for low risk viruses to 8.1 months for high risk viruses, and with clearance rates as high as 92% in 2-5 years.[7] Moreover, the infection is most transient in young girls, with women over 30 less able and less likely to clear the virus.[8] Secondly, whereas all species of HPV were originally thought to carry a risk of cervical cancer, we now know that these genital viruses have differing oncogenic potential; they are therefore categorized as either "low risk" or "high risk" based on the potential to initiate malignant and premalignant changes in the cervical epithelium. It is the oncogenic ("high risk") viruses that raise serious medical concern. The third significant change in our understanding is that just as the infection is not permanent, neither is the disease necessarily progressive: mild precancerous changes do not necessarily and inexorably lead to cancer, as we once believed. Most often the changes are regressive: with clearance of the virus, the virally-induced cellular changes also regress. Therefore, attempting to eradicate all virally-induced changes is no longer believed to be necessary nor is it recommended.[9]

The Burden of HPV
The prevalence of HPV has increased exponentially in recent years concurrent with the exponential increase in promiscuous sexual activity in our culture. There are currently 24 million people in the U.S. infected with the virus, including 26-35% of sexually active couples. Moreover, there is an 80% chance of acquiring the virus by age 50.[10] Generally speaking, subclinical infection, in which virus is present but virally-induced cellular changes are absent, is 10-30 times more common than clinical infection, but often clears spontaneously. Clinical infections include genital warts (~1% of the population), laryngeal papillomatosis, cervical dysplasia, and cervical, vulvar, and vaginal cancers. Cervical cancer is diagnosed in 11,000 women each year with 3500 women dying yearly from the disease. The average age at diagnosis is 45.

The monetary burden of this virus is not insignificant. The cost of screening, testing, and treating HPV in the year 2000 was $3 billion ($3.4 billion if costs of treating cancer were included). In that same year, $167 million was spent to treat genital warts.

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from the director's desk

BY PAIGE C. CUNNINGHAM, JD
Executive Director

The ethics of HPV. Critique of IVF. Human-animal hybrids. *Beyond Therapy.* All of these are bioethical concerns, and CBHD is attuned to the cacophony of bioethical noises, sorting through the issues we refer to as Bioethics 1.0 (*When does human life begin or end, and who decides?*) and Bioethics 2.0 (*What does it mean to flourish as a human being in the biotech century?*). Novelty is not the criterion for relevance. One of the most relevant issues to our everyday lives is an ancient one: how do I end my life well? I am asked variations of this question more than any other. *How do I talk to my parents about end of life care? Can we say 'no' to a respirator?*

These questions push us out of our comfort zone. Most Christians can identify the ethical issues and conclusions at the other end of the spectrum. The pro-life movement has confidently addressed the key question of abortion: is it right to kill human beings in the womb? Our concern for the unborn child extends to include little ones whose lives might be terminated, not because they are inconvenient, but because there is something 'wrong' with them. The fatal criteria might be gender, genetic disability such as Down syndrome, or correctable defect such as cleft palate. The lives of unborn children must never intentionally be destroyed.

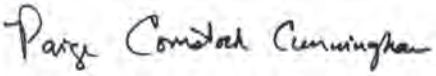
This absolute refusal to discriminate has prompted many pro-lifers to conclude that life must be preserved at all costs not only at its dawn, but also in its twilight. Christians are particularly likely to feel this obligation. A 2009 *Journal of the American Medical Association* study concluded that Christians were nearly three times more likely to seek aggressive medical care, even though they knew they were dying, and that the treatment might not benefit them. In his recently released *The Art of Dying: Living Fully into the Life to Come*, Rob Moll points out that our pro-life commitments might make it more difficult for us to receive counsel on how to die. Moll quotes one Christian gerontologist who observed that "We're so pro-life, we're anti-death." This denial, a kind of vitalism, comes at a great cost: the loss of dying well in Christian hope.

Yet we often "fight the good fight," not in spiritual terms, but on technological grounds. Medical technologies that are risky, painful, burdensome, experimental, or excessively costly, and that do not offer hope of medical benefit, are not mandatory. Refusing another round of chemotherapy, or a resuscitation order, or a fourth surgery, is not necessarily a lack of faith in God's healing. It can be a recognition that living is over, and dying has begun. Whether dying at home, in the hospital, in a nursing home or a hospice, Christians have the opportunity for a final, mute witness. The reality is that most of us will not die suddenly. We will have an opportunity to consider how we will die.

In the Middle Ages, dying was a public event, with grieving on both sides, the dying person for the loss of the world, friends and family for the loss of their loved one. Words of reconciliation, confession, petition, and assurance filled the sick room. Even in modern times the circumstances at the end of life cannot be predicted with certainty. But, we can decide what we want our dying to look like.

CBHD has a wealth of resources that inform both ethical reflection and practical decision-making. Here's a sampling from my CBHD bookshelf. Prior to his association with the Center, John Kilner explores a God-centered ethic for caring for the elderly and dying in *Life on the Line* (1992) and *Who Lives? Who Dies? Ethical Criteria in Patient Selection* (1994). Building on our 1995 summer conference, *Dignity and Dying: A Christian Appraisal* (1996) was crafted by seventeen writers who walk through the challenges of suffering, medical futility, and forgoing life support. Arthur Dyck's *Life's Worth: The Case against Assisted Suicide* (2002) gazes at human suffering and the deeper truths of life's inherent worth. *Aging, Death, and the Quest for Immortality* (2004) building on our 2001 summer conference again enlists multiple perspectives on aging, rationing, dementia, and medical decision-making. More recently, Robert Orr's *Medical Ethics and the Faith Factor* (2009) uses case studies from his vast clinical experience to give practical counsel at all life stages, particularly the end of life.

Yes, death comes to us all. Novel? No, but every death is unique. Since life and death issues are not going away, CBHD remains committed to engaging the wide spectrum of issues at the nexus of bioethics and human dignity.



The Center for Bioethics & Human Dignity (CBHD) is a Christian bioethics research center of Trinity International University.

"Exploring the nexus of biomedicine, biotechnology, and our common humanity."

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BIOETHICS AT THE BOX OFFICE: 2005-2008 EDITION

COMPILED BY ALICE KONG
2010 Summer Intern

CBHD often receives requests from educators and other individuals involved in engaging bioethics regarding popular resources (fiction, film, and television) that present materials relevant to bioethical discussions. In a two part series, we offer a recap of the past five years of relevant materials that have premiered on the silver screen. Readers are cautioned that the films represent a wide variety of genres and may not be appropriate for all audiences. Before viewing or screening for educational purposes, individuals are encouraged to read synopses of the films available through such websites as www.movieweb.com or www.imdb.com. If we have missed some films that you think should be listed here, please let us know.

BIOTECHNOLOGY
Repo! The Genetic Opera! (Released 11/08, R for strong bloody violence and gore, language, some drug and sexual content)
I Am Legend (Released 12/07, PG-13 for intense sequences of sci-fi action and violence)

CLONING
The Island (Released 7/05, PG-13 for intense sequences of violence and action, some sexuality and language)

DISABILITY ETHICS
Praying with Lior (Released 2/08, Not Rated, Documentary)
Music Within (Released 10/07, R for sexual references and some drug content)
Away from Her (Released 4/07, PG-13 for some strong language)
Guarding Eddy (Releases 10/05, PG for thematic elements, language, some mild violent content and brief smoking)

EMERGING TECHNOLOGY
Babylon A.D. (Released 8/08, PG-13 for intense sequences of violence and action, language and some sexuality)
Ultraviolet (Released 3/06, PG-13 for sequences of violent action throughout, partial nudity, and language)

END OF LIFE
Seven Pounds (Released 12/08, PG-13 for thematic material, some disturbing content, and a scene of sensuality)
Away From Her (Released 4/07, PG-13 for some strong language)
Exit: The Right to Die (in French with subtitles) (Released 10/06, Not Rated documentary)

GENETIC ETHICS
Babylon A.D. (Released 8/08, PG-13 for intense sequences of violence and action, language and some sexuality)
In the Family (Released 8/08, Not Rated, Documentary)
I Am Legend (Released 12/07, PG-13 for intense sequences of sci-fi action and violence)
Resident Evil: Extinction (Released 9/07, R for strong horror violence throughout and some nudity)
Isolation (Released 3/06, R for violence/gore, language, and a scene of sexuality)
Memory (Released 3/07, R for language and frightening images)
Ultraviolet (Released 3/06, PG-13 for sequences of violent action throughout, partial nudity, and language)

GLOBAL BIOETHICS
Pregnant in America (Released 12/08, Not Rated, Documentary)

HEALTHCARE
Sicko (Released 6/07, PG-13 for brief strong language)

HUMAN ENHANCEMENT
I Am Legend (Released 12/07, PG-13 for intense sequences of sci-fi action and violence)
Time (Released 7/07, Not Rated)
Ultraviolet (Released 3/06, PG-13 for sequences of violent action throughout, partial nudity, and language)

ORGAN DONATION & TRANSPLANTATION
Seven Pounds (Released 12/08, PG-13 for thematic material, some disturbing content, and a scene of sensuality)
Repo! The Genetic Opera! (Released 11/08, R for strong bloody violence and gore, language, some drug and sexual content)
The Eye (Released 2/08, PG-13 for violence/terror and disturbing content)

NEUROETHICS
Just Another Love Story (Released 9/08, Not Rated)

REPRODUCTIVE ETHICS
Pregnant in America (Released 12/08, Not Rated, Documentary)
Baby Mama (Released 4/08, PG-13 for crude and sexual humor, language and a drug reference)
Miss Conception (Released 3/08, R for language and some sexual content)
A Walk to Beautiful (Released 2/08, Not Rated, Documentary)
4 Months, 3 Weeks and 2 Days (Released 1/08, Not Rated)
Juno (Released 12/07, PG-13 for mature thematic material, sexual content and language)
The Brothers Solomon (Released 9/07, R for language and sexual content)

RESEARCH ETHICS
I Am Legend (Released 12/07, PG-13 for intense sequences of sci-fi action and violence)
Isolation (Released 3/06, R for violence/gore, language, and a scene of sexuality)

Continued from page 1

Concerns with Vaccination

HPV vaccines have proven to be 100% effective in preventing the neoplastic changes associated with HPV 16 and 18, and 100% effective in preventing genital warts resulting from infection with HPV 6 and 11. Yet in spite of these positive statistics, there are significant concerns. In order to be effective, a vaccine must be administered before the onset of sexual activity and hence before exposure to the viruses. The ideal age of vaccination has therefore been determined to be 11-12. But the virus is highly transient in adolescents in whom cervical cancer has never been diagnosed, and the duration of protection from the vaccination is unknown. It is therefore possible that the protective effects of the vaccination will wane at the time when women are most susceptible to the oncogenic effects of the virus (those over 30), providing protection to those who do not need it (adolescents) and failing to provide protection to those who do (women over 30).

Secondly, the quadrivalent vaccine covers only 4 of the approximately 40 papilloma viruses that infect the genital tract (HPV 6, 11, 16 and 18). The newer bivalent vaccine released this past year covers only HPV 16 and 18. HPV 6 and 11 are low risk viruses that will resolve spontaneously within one year, rendering any vaccine against them a waste of valuable resources and healthcare dollars.[11] HPV 16 and 18 have oncogenic potential, but even 80% of these infections will resolve without treatment. Additionally, the four HPV types covered by the vaccine account for only 3.4% of all HPV infections in the U.S., and HPV 16 and 18 account for only 2.3% of the high risk viral infections in the U.S. (HPV 6: 1.3%; HPV 11: 0.1%; HPV 16: 1.5%; and HPV 18: 0.8%).[12] Moreover, not all of those who acquire these two viruses will develop cervical cancer. Even the American College of Obstetricians and Gynecologists states that "very few individuals with an HPV infection will develop cancer."[13] Since the duration of protection is unknown and the average age of diagnosis of cervical cancer is 45, it has not been demonstrated that the vaccination of all 11-12 year olds will prevent cancer at age 45. There is no long term data to support such a program, only speculation based on "knowledge" that is incomplete and ever-evolving.[14]

At age 11 or 12, informed consent is often given to and by the parent or guardian. Is the adolescent being informed? Is she being educated?

Under naturally occurring circumstances, infection with HPV triggers an immune response that provides a natural source of protection against the virus.[15] Vaccination may inhibit this response, and if the vaccination then fails to provide permanent protection, these once-vaccinated young women will also lack any natural immunity, rendering them more susceptible to infection at a time when they are also more vulnerable to the oncogenic potential of the virus. Additionally, there is some concern that vaccination may generate shifts in oncogenic potential, escalating the risk of other viral strains for which there is no vaccine, a phenomenon recognized with influenza viruses.

HPV vaccines are exorbitantly expensive, exceeding the cost of all other vaccinations combined, and making it unfeasible for use in the general population. At a cost of $500-900 for the series of 3 injections, vaccination will be inaccessible to many, thereby diminishing the overall effectiveness through loss of "herd immunity." And in spite of its price-tag, it does not eliminate costs of screening that are currently utilized: due to the large number of other viruses not covered by the vaccine, current screening methods will still be required.

The cost-effectiveness of vaccination is dependent upon a reduction in the rate of cervical cancer, an effect that has not to date been proven, which will not be realized for 4 or 5 decades, and which is dependent on achieving a high level of protection among a substantial portion of the population. And at a time when cost of medical care is under scrutiny, the crucial question is: who will pay? A recent study determined that if the protection the vaccination offered was permanent, vaccination of 11-12 year olds would cost an additional $43,600 per QALY,[16] over and above the cost of current screening methods, a level that was felt to fall within the range of cost-effectiveness.[17] However, if a booster is required, the cost-effectiveness of the vaccination will be further diminished. And logic belies the data: to vaccinate 10 million 11-12 year olds each year will cost approximately $5 billion/year, a cost which will merely diminish the risk of cervical cancer from HPV 16/18 for approximately 4600 women.[18] And these women will still be at risk for cervical cancer from other or new oncogenic strains of virus, as it is estimated that 50% of vaccinated women will still develop high grade cervical lesions due to the other viruses.[19] The high prevalence of these viruses, the transience of infection, the low prevalence of the virus in question, and the low incidence of serious disease would argue against cost-effectiveness of the vaccine and suggest that despite the rigorous statistical analysis employed by this study, a methodological error exists.

One of the cornerstones of modern medical practice is that of informed consent. The risks, benefits, side effects and alternatives of any medical procedure must be discussed with the patient before it is performed. Where a procedure is felt to be "necessary," however, informed consent is often glossed over, if not ignored. And so it is with this vaccine, especially given the speed with which it received FDA approval. But the vaccination is not without associated risks--risks which potentially exceed the theoretical benefit--and these include paralysis, blood clots, Guillain-Barré syndrome, and death. There have been 43 reports of deaths (26 confirmed, 9 under investigation, and 8 unconfirmed) among young women associated with the vaccine,[20] yet death from cervical cancer is unknown in adolescents. At age 11 or 12, informed consent is often given to and by the parent or guardian. Is the adolescent being informed? Is she being educated? While mandates and coercion might be warranted in epidemics where public health and safety is at risk, this is not the case with HPV infection. And what is the ethically appropriate response when disagreement exists between the mother and the daughter with regard to the vaccination or completion of the series? The HPV vaccine has been marketed as a vaccination against cervical cancer, yet there is no data to substantiate that the vaccine prevents cervical cancer or that vaccinating adolescents today will indeed prevent cervical cancer later. Such marketing is deceptive and manipulative. Is this being addressed in our "informed consent"? Furthermore, the marketing techniques deceptively promote a

false sense of security by placing emphasis on the rare oncogenic consequences of infection rather than on the nature of the virus as an STD. In so doing, it fails to acknowledge that the most cost-effective means of preventing cervical cancer is not a vaccine but cessation of smoking (a known co-factor for cervical cancer) and abstinence until marriage for both males and females. It is unlikely that this is part of the informed consent process even though it is one of the alternatives that comprise informed consent and an educational responsibility of healthcare providers.

The burden of this vaccine as well as the infection falls again to the female population. The vaccine has not been tested on males and perhaps for good economic reason: males serve primarily as vectors for the virus, in most cases suffering no significant short- or long-term consequences from infection. It would be a rare young man—or mother of a young man—who would subject himself to the cost, the pain, and the inconvenience of the vaccine for the sake of women 40 years hence.

From a global perspective, HPV vaccination may indeed be a panacea by providing protection where screening is unavailable. But third world countries do not have the resources from which companies can recover their expenses. Conversely, while we in the U.S. have the fiscal resources, we also have a screening program that has proven to be cost-effective in preventing cervical cancer, if utilized. Pap smear screening is also more cost-effective than vaccination, since it is non-discriminatory with respect to viral types.

Conclusion

There has been a subtle but significant paradigm shift in the orientation of American medicine in recent years from preventing and treating illnesses to alleviating the consequences of life-style choices. That shift is costing us greatly, as our choices are boundless and our perceived need insatiable. The rapid, deceptive, and pervasive promotion of the HPV vaccine is illustrative of this shift and raises more questions than answers. Experience in other areas of medicine (osteoporosis, coronary artery disease) has demonstrated that positive changes in clinical markers do not always correlate with disease prevention. With the rapid evolution in our understanding of HPV, it is imprudent to base disease prevention on clinical information that is incomplete and unproven. Given what we do know, the vaccine makes little sense. Why are we vaccinating young women with an expensive, painful vaccine that has not been proven to prevent what it claims? Why are we advocating that all pre-adolescent young women be vaccinated against an uncommon virus that is known to be largely transient? It calls into question the methodological assumptions underlying the research for the vaccine. The original research was initiated in 1991.[21] Was this under the earlier assumption that the viral infection was permanent, before the transient nature of the infection was known? Now that the vaccine has been developed, does it have to be marketed in order to recover the expenses of the research and development? Why has it been marketed when the long-term effects on the immune system of young girls and the oncogenic potential of other viruses are unknown? Are we perhaps creating more problems than we are preventing? And finally, is this an effective use of scarce medical resources and dollars? These are questions that should have been answered prior to FDA approval, but will need to be answered in the days ahead if we are to preserve a system of healthcare that is accessible to all of our citizens.

1 Charlotte J. Haug, "Human Papillomavirus Vaccination—Reason for Caution," *New England Journal or Medicine* 359, no. 8 (August 21, 2008): 861-862.

2 Ibid.

3 See National Conference of State Legislatures data at www.ncsl.org/IssuresResearch/HPVVaccineStateLegislation/tabid/14381/default.aspx. The State of Texas originally passed legislation by executive order that mandated HPV vaccination for school enrollment, but it was overridden by legislators. As of May 2009, there has been legislation to require, fund, or educate the public regarding HPV vaccine introduced by 41 state legislatures, but only 19 have enacted such legislation, and the District of Columbia is the only other district to mandate vaccination.

4 "Human Papilloma Virus Infection," Centers for Disease Control and Prevention, 2009; available at www.cdc.gov/std/hpv/default.htm.

5 Olufemi Olatunbosun, Harry Deneerm, and Roger Peirson, "Human Papillomavirus DNA Detection in Sperm Using Polymerase Chain Reaction," *Obstetrics & Gynecology* 97, no. 3 (March 2001): 357-360.

6 Rachel L. Winer, et al., "Genital Human Papilloma Virus Infection: Incidence, and Risk Factors in a Cohort of Female University Students," *American Journal of Epidemiology* 157 (2003): 218-226. Hands have also been strongly implicated in transmission, with virus cultured from nail beds.

7 ACOG Practice Bulletin no. 61, "Human Papilloma Virus," *Obstetrics & Gynecology* 105, no. 4 (April 2005): 907.

8 Ibid. This is also consistent with the fact that the average age of diagnosis of cervical cancer is 45.

9 Diane Solomon, et al, "The 2001 Bethesda System: Terminology for Reporting Results of Cervical Cytology," *JAMA* 287 (2002): 2114-2117. See also ASCCP practice recommendations available at www.asccp.org/edu/practice.shtml.

10 "Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly, Early Release* 56 (March 12, 2007): 4.

11 This remains a significant question for the developers of the vaccine: why did they determine that a vaccination was needed for viruses that would resolve spontaneously, the costs of which would be passed onto the patient in the form of increased cost of the vaccine?

12 "Quadrivalent Human Papilloma Virus Vaccine: *MMWR*, 4.

13 ACOG Practice Bulletin no. 61, "Human Papilloma Virus," (2005): 907.

14 The speed with which the FDA approved the vaccine raises concerns as well in light of inadequate data regarding its duration, safety, and long-term effectiveness.

15 Deane Medved Harper, "The HPV Vaccine Debate: Public Policy vs. Personal Choice," Devos Medical Ethics Colloquy (March 24, 2008): 30. See also *MMWR* 56 (March 2007): 3.

16 QALY stands for Quality-Adjusted Life Year's measurement and is a method that compares different drugs by measuring their clinical effectiveness.

17 Jane J. Kim and Sue J. Goldie; "Health and Economic Implications of HPV Vaccination in the United States," *New England Journal of Medicine* 359, no. 8 (2008): 821-832. Vaccination of women in other age groups, while believed to be necessary, was not shown to be cost-effective.

18 10,000,000 @ $500/vaccination; 2.3% will contract HPV 16/18, but 80% will resolve spontaneously, leaving 20% of the 2.3% of the 10,000,000 at risk.

19 Harper, "The HPV Vaccine Debate," 26.

20 "Reports of Health Concerns Following HPV Vaccination," Centers for Disease Control VAERS data 2009; available online at www.cdc.gov/vaccinesafety/vaers/gardasil.htm. It must be noted that these risks are associated with the vaccine but the relationship has not been proven to be causal. The concern remains.

21 Christopher P. Crum, "The Beginning of the End of Cervical Cancer?" *New England Journal of Medicine* 347, no. 21 (Nov 21, 2002): 1704-5.

MEDICAL EXPLOITATION AND BLACK MARKET ORGANS: PROFITEERING AND DISPARITIES IN GLOBAL MEDICINE[1]

BY PAIGE C. CUNNINGHAM, JD AND MICHAEL SHAFER, MA, PHD CANDIDATE

"Global social justice." It is an excellent but overwhelming goal. We rightly care about fellow human beings who are cut off from basic goods like clean water, basic education, and healthcare. Their needs are staggering. Yet, those who are most vulnerable to exploitation are often not those who need something, but those who have something that others desperately want. These victims are the poor and disadvantaged who are the targets of organ trafficking.

The Center for Bioethics & Human Dignity has focused attention on this urgent issue for the past two years, beginning with several lectures in 2008, and highlighted in our 2009 conference, *Global Bioethics: Emerging Challenges Facing Human Dignity*. In the coming year, Paige and CBHD research scholar Michael Sleasman will be contributing a chapter on medical exploitation that will explore this issue and others associated with bioethics and social justice to a forthcoming volume tentatively entitled, *Social Injustice: What Evangelicals Need to Know about the World*.

Black market organ transfer is the consequence of a gross imbalance between supply and demand. The waiting list of patients who are in need of an organ vastly outnumbers the organs being donated. Over the last ten years, more than 65,000 transplant candidates in the United States were removed from the waiting list because they died.[2] The desperation of sick patients and shortage of domestic donors has contributed to the emergence of "transplant tourism," connecting those who need an organ with those who have them. Most often, the prized organ is a kidney, but partial-livers and single corneas are also traded. Typically, the sick patient is from a wealthy nation, while the organ donor usually lives in a disadvantaged country. The transplant may take place in the recipient's country, the donor's country, or in a private, boutique hospital in a third location. These hospitals are set up to avoid legal barriers in the home countries of donors and recipients.

The National Organ Transplant Act makes it "unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation."[3] Excluding the buying and selling of the organ itself, this act clearly allows monetary compensation for all other aspects of the transfer including "removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor."

Aside from reimbursement for medical and travel costs these guidelines allow for virtually no benefit to be procured by the donor. The lack of organ donors suggests that for most people altruism is not enough. In their search for an organ donor many have traveled abroad, often to poor countries. Wealthy people with sick organs and poor people with healthy organs tend to gravitate together in hopes of an exchange. Sadly, the exchange is often heavily one sided. Transplant procedures are a bargain for the organ recipient. One Christian physician in India told CBHD that India is the medical tourism destination of the world. In 2007, over 150,000 medical tourists advantaged themselves of the lower prices in India ($200,000 vs. $10,000 for a heart valve replacement), and the readily available market of kidney sellers.

Advocates of social justice might think that this provides a unique way for an impoverished man to care for his family. He can live adequately with one organ, and the price is a princely sum in his community. The reality is less attractive.

First, the power distance between donor and potential recipient is great. The group identified as prospective donors are vulnerable because of their low social status, their ethnicity, their gender,[4] their age, or their incarceration.[5] Even though they are called 'donors,' many part with their kidney under the enticement of the promise of a rich reward. Staggering under a load of debt, they grasp at this hope of improving their lot in life. Others are simply coerced (with brutal force), or deceived. In the hospital for one purpose, they wake up from surgery to discover their kidney has been removed without their consent.

Consider the stark picture of exploitation in India: Kidney recipients often pay $25,000 for the transplant, and the donor may receive $1,250 to $2,500. Kidneys may be sold for as little as $700, but the patient may pay over $180,000 for the transplant. Who is pocketing the difference? The payment is divided among the kidney broker, the harvesting surgeon, and the transplant hospital. Some receive nothing. One Manila transplant surgeon callously remarked that a large bag of rice should suffice, since "donors" are only playing the part of the Good Samaritan.

Even if they do receive payment, few donors improve their lot in life. Within a few months, their situation is even more dire. The payment has vanished into the pockets of those to whom the donor was in debt.

The donor often is physically maimed, and unable to return to his former line of work: heavy manual labor.

However, the relatively small financial compensation should not be the basis for our complaint against organs being bought and sold on the black market. Even if the donor were to receive larger sums of money ethical difficulties would remain and the notion of global social justice would not be advanced. Human organs ought not to be assigned an arbitrary monetary value regardless of the price tag. Whether the black market donor is paid $2,000 or $20,000 he or she is being used as a means to an end rather than being respected as an individual human being.

The ethical problems do not stop there. Tragically, many are outcast within their village, where they are viewed as prostitutes. Viorel, a 27-year-old, unemployed kidney seller from Moldova believes it is worse than that: "We are *worse* than prostitutes because what we have sold we can never get back. We have given away our health, our strength, and our lives."[6]

One of the darkest sides of the organ trade is the physical abandonment of the donors. Once the recipient has the organ, the profiting parties tend to lose all interest in the donor. Few donors have subsequent access to medical care, and many are maimed for life. This is no way for fellow human beings to be treated, even if both parties receive temporary benefits.

Our doctor friend in India reminds us that all people are made in the image of God, from the callous transplant surgeon to the sick kidney patient to the abandoned donor. We must pursue justice and compassion. There *are* ethical ways for transplant patients to receive organs from global donors. The donor must be respected as an individual, must be able to give truly informed consent, must be free from physical or financial coercion, and must be cared for after his organ is harvested.

As Christians, we should demand no less.

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1 This essay is adapted and expanded from a piece entitled, "Black Market Organs" by Paige C. Cunningham that originally appeared in *Trinity Magazine* (Spring 2010): 18-19.

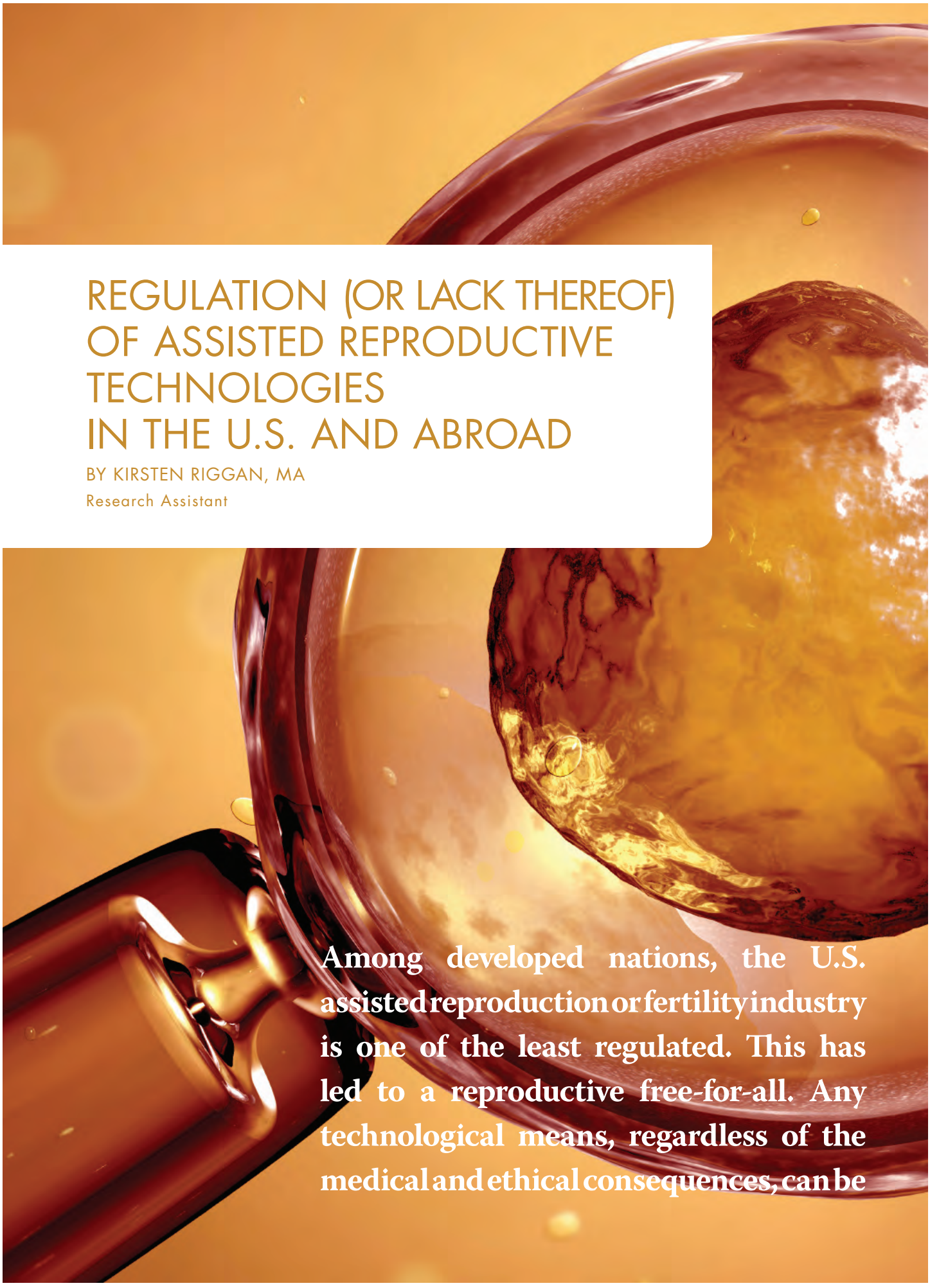
2 "2009 OPTN / SRTR Annual Report: Transplant Data 1999-2009" U.S. Department of Health & Human Services http://optn.transplant.hrsa.gov/ar2009/ (accessed July 23, 2010).

3 "National Organ Transplant Act" http://www.law.cornell.edu/uscode/html/uscode42/usc_sup_01_42_10_6A_20_II_30_H.html (accessed July 23, 2010). The Department of Health & Human Services implemented a Final Rule establishing the regulatory framework for the structure and operations of the Organ Procurement and Transplantation Network in 2000, http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr121_main_02.tpl (accessed July 23, 2010).

4 Even though women may be approached to give a kidney, the majority of donors are men. Virtually all organs go to men; women rarely receive illicit organ transplants.

5 Before China adopted the Human Transplantation Act in 2007, there were reports of as many as 11,000 transplants of organs from prisoners whose execution was timed to meet donor needs. See Debra A. Budiana-Saberi and F. L. Delmonico, "Organ Trafficking and Transplant Tourism: A Commentary on the Global Realities." *American Journal of Transplantation 8 (2008):* 925-929.

6 Nancy Scheper-Hughes, "Rotten trade: millennial capitalism, human values and global justice in organs trafficking." *Journal of Human Rights*, no. 2 (June 2003): 197-226, 200.



REGULATION (OR LACK THEREOF) OF ASSISTED REPRODUCTIVE TECHNOLOGIES IN THE U.S. AND ABROAD

BY KIRSTEN RIGGAN, MA
Research Assistant

Among developed nations, the U.S. assisted reproduction or fertility industry is one of the least regulated. This has led to a reproductive free-for-all. Any technological means, regardless of the medical and ethical consequences, can be

utilized in the pursuit of parenthood if the price is right. Arguments that this industry is effectively self-regulated fall flat in the face of evidence which suggests otherwise.[1] While many of the 400-500 clinics offering assisted reproductive technologies (ART) in the U.S. are members of professional organizations such as the Society for Assisted Reproductive Technology (SART) or the American Society for Reproductive Medicine (ASRM) and follow clinical and ethical guidelines produced by these organizations, the majority do not. A Centers for Disease Control and Prevention study found that only 20% of ART programs follow such guidelines.[2] As the "Octomom" (Nadya Suleman) case publicly demonstrated, there is no legal detriment to clinicians engaging in clinical or ethically dubious practice.[3] Not surprisingly, the U.S. has high rates of multiple pregnancies, which are associated with astronomical healthcare costs and more importantly serious risks to the health of both mother and child. Many European countries have recognized these risks and have moved to legally restrict the number of embryos transferred per reproductive cycle. Additionally, many of these countries have moved to limit some practices that are ethically problematic, such as the use of third-party donor gametes and surrogacy. These legal changes have resulted in a significantly different situation than the current state of the ART industry in the U.S. Additional regulation is needed, whether it be at the state or federal level, to provide additional safeguards.

Multiple Gestations

The U.S. has one of the highest rates of multiple births in the world. This rate is directly attributed to the increased use of ART in achieving pregnancy. In 2003, for example, 31% of pregnancies conceived using *in vitro* fertilization (IVF) were twin gestations and 3% were triplets or higher-order gestations. Only 1% of spontaneous pregnancies are multiple gestations.[4] The health risks of multiple pregnancies to both mother and child are well documented. Women carrying multiple embryos are at a higher risk of pregnancy complications including high blood pressure, preeclampsia, anemia, post-partum hemorrhaging, and increased risk of miscarriage. While multiple gestations account for only 3% of all live births in the U.S., they are responsible for 23% of early preterm births (delivered before 32 weeks) and 26% of very low birth weight infants (less than 1500 g or 3 pounds, 4 ounces). Excess hospital costs for multiple births resulting from IVF cycles is estimated to be $640 million per year in the U.S.[5] Multiple pregnancies also have a higher mortality rate (including still birth and neonatal deaths) compared to singletons. It has been calculated that the mortality rate for twins is seven times greater than singletons, whereas triplet and higher order multiples is twenty times greater.[6] Additionally, children from multiple pregnancies are at a higher risk of long-term medical and developmental problems including cerebral palsy and other neurological complications.

The U.S. is lagging behind European efforts to limit the number of multiple pregnancies following ART. Germany, Italy, Spain, and Switzerland have enacted regulations limiting the number of embryos transferred in one reproductive cycle to 3. In Italy, however, limiting the number of embryos transferred to 3 has actually increased rates of multiples due to the prohibition of embryo cryopreservation, encouraging women to transfer multiple embryos as a means of increasing pregnancy (50.4% of ART cycles involved the transfer of 3 embryos in 2005).[7] The prohibition of embryo cryopreservation has caused the fertility industry in Italy to become a leader in improving methods of egg cryopreservation, an alternative to freezing supernumerary embryos (otherwise referred to as "excess" or "spare" embryos).[8] The Human Fertilization and Embryo Authority in the United Kingdom limits the number of embryos to a maximum of 2 for women under 40 years and 3 for women over 40. As a means of contrast with actual practice, approximately 43% of ART cycles in the U.S. involved the transfer of 3 or more embryos. In 0.5% of ART cycles, 7 or more embryos were transferred.[9]

More recently, the trend in Europe has been to transfer a single embryo per reproductive cycle (*i.e.,* "single embryo transfer" or SET), particularly in Scandinavian countries. Typically a fresh embryo is transferred in the first cycle and single cryopreserved embryos are transferred in subsequent cycles. The pursuit of SET does not eliminate the ethical issues surrounding the fate of surplus embryos or embryo destruction from the freeze/thaw process of cryopreservation, but is ethically preferred to multiple embryo transfer due to the reduction of maternal and fetal health risks associated with multiple pregnancy. Countries such as Belgium and Sweden that have regulations requiring the transfer of singleton embryos for initial ART cycles have seen a marked decrease in multiple births since SET practices were adopted. Clinical studies following SET programs have demonstrated a drop in multiple pregnancies from approximately 30% to 10%, while still achieving high overall pregnancy rates.[10] Sweden has maintained an unchanged delivery rate while decreasing the multiple pregnancy rate to under 10% since enacting SET in 2003.[11] These statistics demonstrate that the transfer of multiple embryos is not necessary to achieve a high pregnancy or delivery rate.

In addition to decreasing the health risks inherent in multiple pregnancies, single embryo transfer may be more successful and cost effective than multiple embryo transfer. The transfer of multiple embryos in a single reproductive cycle gained notoriety as a cost saving measure by increasing pregnancy rates. In the U.S., the average cost of a standard IVF cycle is approximately $12,500 USD, substantially higher than the majority of international ART programs. In comparison, a standard IVF cycle is $8,500 in Canada, $6,534 in the United Kingdom, $5,645 in Australia, $5,549 in Scandinavia, and $3,956 in Japan (all USD 2006).[12] Due to the expense of IVF in the U.S., patients and their physicians strive to achieve pregnancy in the fewest cycles possible. Many patients also prefer to conceive twins as a means of achieving their desired family size as quickly as possible due to time or financial concerns. Some parents simply have a preference for twins over singletons.[13] These patients may not be aware of the increased health risks and the exponential healthcare costs associated with multiples.

New research has demonstrated that transferring a single embryo at a time may be as effective in achieving pregnancy as transferring multiple embryos at once.[14] While it may take more cycles to achieve pregnancy with the transfer of single embryos than the transfer of multiple embryos, SET drastically reduces the financial burden associated with multiple gestations and it also reduces the maternal and fetal health risks thus increasing the live birth rate. Without some form of subsidization, however, IVF may initially be more expensive for SET patients due to the repeated cycles. These repeated cycles

may also pose additional health risks for women associated with controlled ovarian hyperstimulation if eggs or embryos are not cryopreserved. In countries where IVF is partially or completely covered by insurance or governmental health programs (*e.g.,* Australia, Sweden), there is less financial pressure to obtain pregnancy in the fewest cycles possible. This has resulted in both greater utilization of ART and a decrease in the overall rate of multiples.[15] Belgium in particular is unique in the fact that it explicitly links public funding for ART with good clinical practice. In order to receive federal funding, patients and their physicians must subscribe to established limits on the number of embryos transferred in one cycle. From a societal perspective, SET greatly reduces the overall financial burden to the healthcare system due to the reduction of medical complications associated with multiples. Belgium has calculated that the money they have saved by avoiding half of the multiple pregnancies finances all IVF and intracytoplasmic sperm injection (ICSI) in one year.[16]

It is imperative that the U.S. follows the lead of European countries and takes measures to reduce what has rightly been called an epidemic of multiple births. In doing so, the serious maternal and fetal risks involved in multiple pregnancies will be significantly diminished. Decreasing multiple births will also have a societal benefit, by reducing the overall financial burden on the healthcare system. The media attention given in the U.S. to high order multiple births following ART can be misleading. Multiple gestations often end in tragedy, not in celebrated successes. Given the advances of assisted reproduction it is no longer necessary to place women and their children at risk of developing serious, lifelong, and in many cases deadly, medical complications through the transfer of multiple embryos.

Encouraging Ethical Practices

In addition to the inherent health risks involved in current U.S. ART practices, the U.S. permits many ART practices considered by many to be ethically problematic, specifically the use of donor gametes and surrogacy. This is in contrast to several of the G12 countries, which more strictly regulate such practices and in many cases restrict their utilization. In the U.S., egg and sperm donors can be commercially compensated for their donation, a practice that lends itself to coercion of donors and makes the term "donation" somewhat of a misnomer. This has led to high-paying advertisements[17] for egg donors in college newspapers and more recently through social networking sites such as Facebook, targeted as a way for young women to earn money by "giving the gift of life." This trend is especially alarming given the serious medical risks associated with the process of egg donation, including risks of infection and ovarian hyperstimulation syndrome.[18] Sperm donors are traditionally medical students who are given a small compensation ($30-100 USD) per donation. Many clinics do not place limits on the number of times sperm donors can donate or the number of children that can be conceived from a single donor, even though the American Society for Reproductive Medicine suggests a general limit of 25. It is not uncommon for the sperm from a single donor to be used to conceive dozens of children or more. This has caused concern, particularly in countries with smaller populations and communities that frequent a select number of sperm banks, that half-siblings may grow up as neighbors or in rare cases may unwittingly date or marry each other. Additionally, there are concerns that sperm donors, even though screened, will pass on rare genetic disorders as is the case of a 22 year old donor who passed on a rare genetic heart disease to 9 of his 24 known offspring, 22 of which were the result of sperm donation.[19] The protection of donor anonymity and lack of a central registry tracking donors and their offspring has made contacting potentially affected offspring difficult and in many cases impossible.

Many have suggested that egg and sperm donation is analogous to "half-adoption," a wonderful means of providing a child to an infertile couple. The experience of children conceived through donation suggests otherwise. A recent study by the Institute of American Values comparing the psychosocial well being of offspring from sperm donation, adopted children, and biological offspring found that in many categories, donor offspring struggle with their origins and identity, are confused by who is a "real" member of their family, and are more likely to have substance abuse and legal problems compared to biological offspring.[20] Approximately half of donor offspring agree that they "feel sad" when they "see friends with their biological fathers and mothers" and 65% agree that their "sperm donor is half of who I am," suggesting that donor offspring experience the loss of not knowing their biological parent and view their donor as contributing more to their identity than a haploid cell.[21] A significant number (45%) of donor offspring are bothered by the fact that money was exchanged to conceive them. Registries such as Donor Sibling Registry exist to help connect donor offspring with their donor parents and half-siblings, helping donor offspring understand their origins and increasing their sense of family. Donor conceived offspring, however, tend to lose interest as the number of offspring of a particular donor increases.

The ethical issues surrounding egg and sperm donation have led countries such as Germany, Italy, Japan, and Switzerland to prohibit the use of donor eggs and sperm for assisted reproduction. In countries that allow egg and sperm donation, the United Kingdom, Switzerland, Sweden, the Netherlands, Germany, and certain parts of Australia prohibit donor anonymity. The loss of donor anonymity in these countries has resulted in an overall reduction of the number of donors willing to donate egg and sperm to ART programs. In Western Australia for example, it has been reported that after anonymity was prohibited, only 35 sperm donors were available out of a population of 1.4 million.[22] In the United Kingdom, the number of women treated with donor sperm dropped 20% in 2006, a year after donor anonymity was abolished.[23] Both Spain and the United Kingdom have limited the number of children that can be born from a single donor to 6 and 10, respectively. Australia, Belgium, Canada, the Netherlands, and the United Kingdom prohibit the commercial purchase of donor eggs and sperm, which is also believed to have led to a reduction in donors.

Like the use of donor eggs and sperm, surrogacy has serious ethical, legal, and social implications. The introduction of a third party in reproduction can complicate the relationships between all parties involved, including the relationship of the parents utilizing a surrogate, between the parent and child, and between the surrogate and the child they are carrying. This practice also treats the human body as a commodity, especially when some form of payment is exchanged for surrogacy services. Commercial surrogacy in particular, where a surrogate is given payment beyond covering

expenses incurred from the pregnancy, can be coercive and exploitative of impoverished women. Even altruistic surrogacy can have a coercive element due to the encouragement of contracting parents to pamper their surrogates with gifts and vacations. It is also important to note that pregnancy can have serious medical complications, especially when multiple pregnancy is involved, which places the surrogate at risk for long-term complications, including infertility.

Additionally, surrogacy is legally problematic in terms of identifying the legal parents of a child born to a surrogate. Surrogacy can be genetic, meaning the surrogate donates the egg and is artificially inseminated by the contracting father, or gestational, meaning an embryo created by the contracting parents through IVF is transferred to the surrogate's uterus. Surrogacy complicates the matter of who should be granted legal parenthood: the intended or contracting parents, genetic parents, or birth mother. In the U.S., surrogacy is regulated at the state level. The majority of states do not have any statutes regulating surrogacy. Some states prohibit commercial surrogacy, whereas others do not recognize surrogacy contracts at all. The most permissive state regarding surrogacy is California, which grants legal parenthood to the intended parents. Due to the ethical and legal concerns surrounding surrogacy, France, Germany, Italy, Sweden, and Switzerland prohibit this practice. Spain does not outright prohibit surrogacy, but does not recognize surrogacy arrangements as valid and considers the birth mother to be the legal mother. Canada, the Netherlands, the United Kingdom, and some states in Australia prohibit commercial surrogacy. The prohibition or legal difficulty of arranging surrogacy agreements in these countries has increased local interest in overseas reproductive tourism in countries where surrogacy is legal, such as India and the U.S.

The goal of many ART clinics and their patients is to achieve a clinical pregnancy utilizing all available means, including the use of donor eggs/sperm and surrogacy. These practices, however, are ethically suspect at best. Egg donation and surrogacy in particular are exploitive of women and unnecessarily place women's health at risk, including their own fertility. The experiences and thoughts of donor offspring are seriously troubling and suggest that "the kids are not alright." Additional regulation is needed in order to limit or at the very least monitor the outcomes of using donor eggs and sperm, including the physical and psychological well-being of the donors, parents, and children involved. It would also be best to prohibit all forms of surrogacy due to the ethical and legal complications involved. Industry self-regulation, however, simply does not work. The drive to have children and the opportunity for monetary gain makes a deadly combination. Steps must be taken to ensure that the health and safety of women and children are protected and do not take a backseat to the end goal of producing children.

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1 American Society for Reproductive Medicine, "Oversight of Assisted Reproductive Technology," *ASRM Bulletin* 12, no 18 (2010): 4-11.

2 Centers for Disease Control and Prevention, American Society for Reproductive Medicine, Society for Assisted Reproductive Technology, *2006 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports* (Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2008).

3 Nadya Suleman's physician was dismissed from the ASRM, but this does not prevent him from continuing his ART practice.

4 Bradley J. Van Voorhis, "In Vitro Fertilization," *New England Journal of Medicine* 356 (2007): 382.

5 Ibid, 382.

6 Eli Y. Adashi, et al. "Infertility Therapy-Associated Multiple Pregnancies (Births): An Ongoing Epidemic," *Reproductive BioMedicine Online* 7 (2003): 518-519.

7 A. Nyobe Andersen, et al. "Assisted Reproductive Technology and Intrauterine Inseminations in Europe, 2005: Results Generated from European Registers by ESHRE," *Human Reproduction* 24 (2009): 1268.

8 For more information see Kirsten Riggan, "Egg Cryopreservation: An Update on an Emerging Reproductive Technology," available at http://www.cbhd.org/content/egg-cryopreservation-update-emerging-reproductive-technology.

9 Centers for Disease Control and Prevention, 44.

10 Jan M.R. Gerris, "Single Embryo Transfer and IVF/ICSI Outcome: A Balanced Appraisal," *Human Reproduction Update* 11 (2005): 105-121. Pregnancy rates must be distinguished from live birth or delivery rates, which are typically lower than pregnancy rates. In other words, many women become pregnant after multiple embryo transfer, but not all deliver a live infant due to the increased risk of miscarriage and fetal death.

11 Christina Bergh, "Single Embryo Transfer: A Mini-Review," *Human Reproduction* 20 (2005): 326.

12 Georgina M. Chambers, et al. "The Economic Impact of Assisted Reproductive Technology: A Review of Selected Developed Countries," *Fertility and Sterility* 91 (2009): 2281-2294.

13 Van Voorhis, 383.

14 Zdravka Veleva, et al., "Elective Single Embryo Transfer with Cryopreservation Improves the Outcome and Diminishes the Costs of IVF/ICSI," *Human Reproduction*, 24 (2009): 1632-1639.

15 Chambers, 2292.

16 Gerris, 115.

17 The average payment for egg donors is $4,000 USD, although some advertisements have been reported to offer payments of up to $100,000 USD for "elite" donors.

18 For more information see Kirsten Riggan, "Ovarian Hyperstimulation Syndrome," available at http://www.cbhd.org/content/ovarian-hyperstimulation-syndrome-update-contemporary-reproductive-technology-and-ethics (accessed November 10, 2010).

19 Barry J. Maron, et al., "Implications of Hypertrophic Cardiomyopathy Transmitted by Sperm Donation," *Journal of the American Medical Association* 302 (2009): 1681-1684.

20 Elizabeth Marquardt, Norval D. Glenn, and Karen Clark, *My Daddy's Name is Donor: A New Study of Young Adults Conceived Through Sperm Donation* (New York: Institute for American Values, 2010).

21 Ibid.

22 Liza Mundy, *Everything Conceivable: How Assisted Reproduction is Changing Our World* (New York: Anchor Books, 2007): 187.

23 Mark Henderson, "Childless Couples Denied As Anonymity Loss Scares Egg and Sperm Donors," *The Times*, June 26, 2008. (accessed June, 24, 2010 http://www.timesonline.co.uk/tol/news/science/article4215440.ece)

Would you like to offer comments or responses to articles and commentaries that appear in *Dignitas*? As we strive to publish material that highlights cutting-edge bioethical reflection from a distinctly Christian perspective, we acknowledge that in many areas there are genuine disagreements about bioethical conclusions. To demonstrate that bioethics is a conversation, we invite you to send your thoughtful reflections to us at info@cbhd.org with a reference to the original piece that appeared in *Dignitas*. Our hope is to inspire rigorous conversations between our readers and those who contribute material to this publication.

announcing CBHD's new communities of influence

Upon strategic evaluation of CBHD's varied engagement in the many interdisciplinary spheres of bioethics, the Center has undertaken a reorganization to interact more effectively with each group and collaborate on resources that align more closely with their interests. As a result, the Center is pleased to announce that several communities of influence have emerged at various stages of development. While a given community may emphasize a discrete area of engagement, individuals who participate within a given community may find that their interests actually draw them simultaneously to several communities.

ACADEMY OF FELLOWS

CHAIR: DÓNAL P. O'MATHÚNA, PHD

At the Center's annual conference this past July, our new Academy of Fellows was finalized and our first group of inductees was announced. The Academy of Fellows is an interdisciplinary community of scholars in bioethics who engage in thoughtful discussion, charitable engagement, and mutual support. As an expression of the Center's commitment to ensure that a distinctly Christian conception of bioethics is attended to by the academic community, the Academy of Fellows was formed to:

i) Advance scholarship in bioethics across the disciplines of law, medicine, nursing, public policy, philosophy, and theology with particular attention to Judeo-Christian Hippocratism.
ii) Produce publications that will positively influence public discussion of bioethics and remain faithful to Christian principles and values.
iii) Promote and protect the dignity of all human beings at all life stages, from conception to death.
iv) Educate and mentor the next generation of Christian bioethicists.

The Academy is led by an executive committee that consists of Dónal O'Mathúna, Paige C. Cunningham, and Michael Sleasman. Fellows are appointed to three-year renewable terms. CBHD is a Christian bioethics research center of Trinity International University committed to the academic freedom of our Fellows as an indispensible aspect of excellence in Christian scholarship. All of those affiliated with the Academy hold in common a commitment to CBHD's core values and principles. Because bioethics is an ongoing conversation, a range of interpretations is likely to exist within the Academy.

SENIOR FELLOWS
C. Christopher Hook, MD
William Hurlbut, MD
Henk Jochemsen, PhD
John F. Kilner, PhD
C. Ben Mitchell, PhD
Robert D. Orr, MD
Daniel Sulmasy, MD, PhD

DISTINGUISHED FELLOWS
Eugene F. Diamond, MD
Arthur J. Dyck, PhD
Dennis P. Hollinger, PhD
Gilbert Meilaender, PhD
Edmund Pellegrino, MD

SENIOR RESEARCH FELLOW
William P. Cheshire, Jr., MD

ASSOCIATE FELLOWS
Mary B. Adam, MD, MA
Matthew Eppinette, MBA, MA
Sharon A. Falkenheimber, MD, MPH
Susan Haack, MD, MA

FELLOWS
Farr Curlin, MD
Bart Cusveller, PhD
Claretta Y. Dupree, PhD
David B. Fletcher, PhD
Calum MacKellar, PhD
Scott B. Rae, PhD
Gregory W. Rutecki, MD
Agneta M. Sutton, PhD
Brent Waters, DPhil

The Center expresses our profound gratitude to all who have served as fellows of CBHD over the years. We are grateful for their friendship, support, and most importantly their active participation in the thought work and activities of the Center that allowed our combined efforts to thrive. Several of our former fellows are serving in the new Academy, while others are contributing their professional interests and passions to one or more of the other communities of influence.

RECENT PUBLICATIONS FROM OUR FELLOWS:

Dyck, Arthur J. *Rethinking Rights and Responsibilities: The Moral Bonds of Community*. Revised. Washington, D.C: Georgetown University Press, 2005.

Hollinger, Dennis P. *The Meaning of Sex: Christian Ethics and the Moral Life*. Grand Rapids: Baker, 2009.

Meilaender, Gilbert. *Neither Beast nor God: The Dignity of the Human Person*. New York: Encounter Books, 2009.

Meilaender, Gilbert, and William Werpehowski, eds. *The Oxford Handbook of Theological Ethics*. New York: Oxford University Press, USA, 2007.

Mitchell, C. Ben. "The Vulnerable: Abortion and Disability," in *The Oxford Handbook of Evangelical Theology*, ed. Gerald McDermott. (New York: Oxford University Press, 2010.)

Mitchell, C. Ben. "Technology, Biotechnology," in *A Science and Religion Primer*, eds. Campbell, Heidi, and Heather Looy. (Grand Rapids: Baker Academic, 2009.)

O'Mathúna, Dónal P. *Nanoethics: Big Ethical Issues with Small Technology*. New York: Continuum, 2009.

HEALTHCARE ETHICS COUNCIL (HEC)

CO-CHAIRS: ROBERT D. ORR, MD, CM & FERDINAND D. YATES, JR., MD, MA

Through the leadership of Co-Chairs, Bob Orr and Nick Yates (formerly holding the titles of Consultant on Clinical Ethics and Consultant on Pediatric Ethics for CBHD respectively), the Healthcare Ethics Council held several preliminary planning meetings, including a formal steering committee meeting during the proceedings of CBHD's summer conference. The nomenclature of the "Healthcare Ethics Council" was agreed upon to express the invitation for all healthcare professionals to participate in this community of influence, extending from the broad clinical/medical community on to the chaplaincy and hospital administrators. The steering committee decided that the Clinical Ethics Working group would be folded into the new HEC, though the emphasis upon creating case studies for peer-reviewed publication will continue.

Participants in the initial steering committee meeting included the co-chairs and CBHD staff Paige C. Cunningham and Michael Sleasman, as well as the following individuals: Robert Cranston, John Dunlop, Joseph Gibes, Joe Kelley, Janet Liljestrand, and Christine Toevs.

During these meetings the steering committee developed a draft mission statement: *A community of healthcare professionals in affiliation with The Center for Bioethics & Human Dignity that recognizes and engages in dignified medical healthcare and professional education in the Judeo-Christian tradition.* A key aspect of this community's work will be to assist CBHD in its commitment to "scholarship with a purpose" through the dissemination of pertinent clinical, medical, and ethical information.

If you are interested in being involved in the HEC, please contact us at info@cbhd.org and we will forward your information on to the HEC Co-Chairs.

CHURCH BIOETHICS NETWORK (CBN)

CO-CHAIRS: SARAH FLASHING, MA | SUSAN M. HAACK, MD, MA, FACOG | KEITH PLUMMER, PHD

During the CBHD conference, another initial planning meeting was held regarding the developing Church Bioethics Network. Led through the efforts and passion of the Co-Chairs, this community is still in the early phases of formation. A core aspect of this community's purpose is to foster CBHD's vision that a distinctly Christian conception of bioethics be lived out by the church. Through conversations at the initial planning meeting it was discerned that additional work is necessary to identify key issues in developing an effective engagement of bioethics within the local church. As a result there will be several focus groups involving pastors and clergy to gain a better awareness of their understanding of bioethics in the everyday life of the church. Emphasis will be given to exploring constructive ways to help those in the pew to make wise choices regarding these pressing issues. This community is open to all individuals interested in engaging bioethics through their denomination, local church, or individual ministry. If you would like to get involved, please contact us at info@cbhd.org and we will forward your information on to the CBN Co-Chairs.

OTHER COMMUNITIES . . .

Law, Science Policy, and Emerging Issues in Research Ethics. CBHD leadership has consulted with several individuals and has begun initial steps in planning a community of influence that emphasizes the engagement of science policy and research ethics as well as the assessment of public policy on traditional bioethical issues. Stay tuned for more information as this community begins to take greater shape.

LIGERS, TIGONS, AND SPLICE: HUMAN-ANIMAL HYBRIDS

BY PAIGE C. CUNNINGHAM, JD

When the great naturalist Joseph Kolreuter painstakingly and methodically cross-pollinated hundreds of plants in the 18th century, he could not have foreseen the 21st century version of hybrids: human-animal (HA) hybrids. HA hybrids confront us with a technology which eludes a ready-made ethical conclusion. In "doing bioethics," particularly with emerging technologies, we find that it takes time to understand, consider and reach an ethical conclusion. An open bioethics conversation among those who share our Judeo-Christian commitments also means that we may be uncertain about preliminary observations as well as ultimate conclusions. HA hybrids is one of those situations. In this column, I'll address just one aspect of HA hybrids: the insertion of human neurons into animal brains. But first, what are we talking about?

Understand the biotechnology. In the popular understanding, "hybrids" includes three biotechnologies: chimeras, hybrids, and cybrids. Chimeras are entities created by mixing cells of different animals, usually two different species; each cell retains its original genetic identity. Think of a graft, such as replacing an aging human heart valve with one grown in a pig. Other chimeras are created at a much earlier stage by mixing two embryos, changing the appearance of the new organism. While the centaur is a mythological version, unusual animal hybrids exist, for example, the liger (a combination of a male lion and female tiger), the tigon (offspring of a male tiger and female lion), and the beefalo, a bison/cattle breed designed for beef production.

Splice, a 2010 summer movie release, tells the dark tale of Dren, a half-human, half-animal lab-created chimera that unpredictably grows and terrorizes people. Actual human chimeras may not raise the same fears. Their new heart valve does not acquire human DNA. Nor does it change their fundamental humanness.

True hybrids are created by integrating some genetic material from one species into an animal of a different species, perhaps by fertilizing the egg of the former with sperm from the latter. Human "cybrids" are hybrids created by a cloning process: human DNA is inserted into a non-human egg that has been enucleated (the animal nucleus has been removed), usually from a cow or rabbit. Cybrids contain more than 99% human DNA; the rabbit or cow mitochondrial DNA in the cytoplasm surrounding the nucleus remains. The United Kingdom, one of few places to permit cybrid research, requires the cybrid embryo to be destroyed after fourteen days. Chinese scientists apparently created a human-animal hybrid by inserting human DNA into rabbit eggs for the purpose of extracting the embryonic stem cells.[1]

HA hybrids are produced for a variety of purposes: to observe how transplanted cells differentiate in the host (*What kinds of cells do they become?)*, to test human cells (*Are these early cells pluripotent?*), to find out what cells will do (*Will these become cancerous?),* to reveal how these cells are affected by different control systems, to test new drugs for medical treatment, and to grow replacement tissues or organs for xenotransplantation. As the Chinese have claimed, embryonic stem cells might be harvested from cybrid embryos. Their research, which has not been proven elsewhere, would produce human embryos in bulk, to create made-to-order tissues for patients.[2]

Identify potential benefits and risks. HA hybrids might be used to study the causes and development of diseases such as cystic fibrosis, Parkinson's, AIDS and heart disease, pointing toward new therapies. Genetically engineered mice hybrids with human DNA inserted can generate antibodies to treat cancer that will not be rejected by the human recipient's body. Researchers may also develop HA hybrids to test new drugs.

Despite their significant research potential, HA hybrids carry some risks. The lessons of history warn of the risk of zoonotic infection. That is, diseases which have been confined to the animal kingdom may cross over to humans. We have witnessed the worldwide calamities triggered by the introduction of HIV, avian virus, and H1N1 influenza (swine flu). A single genetic or protein fragment might be sufficient for crossing the species boundary, causing diseases such as cancer, leukemia, and mad cow disease.

Additional risks include the creation of human diseases and the reality that no one knows how the HA hybrids will develop. When animal viruses cross the species barrier, new strains can emerge which may be carried only by human hosts. Furthermore, while many animal hybrids are sterile, closely related species, such as a mule and a donkey, have been known to reproduce. The "what if" allure of inseminating a primate, such as a chimpanzee, with human sperm may be irresistible. The sensationalized attempt of an early 20th century Soviet scientist to create "humanzees" dramatically illustrates this potential.

Ethical observations. Ethical inquiry often begins with questions about consequences. As HA experiments proceed, what would be the moral status of these new creatures? Are they protected by animal welfare regulations, or do they deserve human subject research protection? Are there limitations on how much human DNA can be inserted into an animal? How are the risks of zoonotic infection controlled? Would this open the door to using primates to grow donor-specific replacement organs, as did the mad scientists in Robin Cook's *Chromosome 6*?

While consequences are important considerations, our ultimate concern should involve a deeper level of ethical analysis. Three moral and theological questions immediately come to mind: species boundaries, bodily integrity, and human identity. All of these are aspects of our human dignity. We will explore species boundaries, and touch upon human identity with respect to one specific technology. Although it is easier to state categorically that no human female should be inseminated with animal sperm and vice versa, or that cloning with a rabbit ovum and human nucleus is wrong, other HA possibilities are not clear cases of impermissible mixing of species. One of these is the insertion of human brain cells into animal brains.

It is obviously difficult to study the development of the human central nervous system in human subjects, but it is possible to transplant human brain cells into embryonic, fetal or adult animals, typically mice. Researchers can then track and observe how these cells develop and interact. These HA hybrids are technically chimera, because the human cells do not acquire the mouse DNA; they remain distinct and traceable.

Does this cross a boundary between the human species and the animal? If so, what is the criterion or basis for that boundary? Most people believe that there is a difference, a qualitative difference, between a human being and a tortoise, or even a circus-trained chimpanzee. Christians in the US would describe this as "human dignity." In the UK, "full moral status" is more commonly used. Both expressions signal that human beings are exceptional, distinct from other creatures.

Human exceptionalism is a difficult problem for biologists who are nominalists. Nominalist theory concludes that only concrete things exist, and that abstract ideas, such as "species," do not. To illustrate: the nominalist biologist points out that there is no single, universal DNA sequence among human beings; there is no conclusive standard for determining the species of an organism based on its DNA sample. Or, they tout the evolutionary connection of human beings with a common ancestor. According to this perspective, human beings are nothing more than dust and ashes, a particularly clever architecture of molecules and cells.

Science cannot answer why any biological organism is of greater value than another. Admittedly, "species boundary" is a difficult problem, particularly from a biological perspective, but the mere fact of difficulty does not mean that species identities and boundaries do not exist. Think about it: it is hard to define the precise boundary between night and day, but that imprecision does not imply that night and day do not exist. Therefore, while Christian ethicists can and do disagree about where to locate the boundary line in these matters, boundaries do exist, and it is an important part of ethical reflection to strive to discern them.

Matter causes brain causes mind? The nominalist presupposes that the human mind derives only from the brain, which is composed solely of matter, and that the mind is the basis for possessing human dignity. The nominalist would be concerned about a change in the *structure* of the brain that might cause a change in its *function*. When an undefined threshold is reached, that is, a critical number of neurons have been inserted and have integrated themselves into the mouse brain, the mouse brain might demonstrate human-like cognitive characteristics. For the nominalist, this is the threshold of unease, if not outright certainty, that a species or moral barrier has been breached.

If unease is based on "humanlike" cognition alone, it appears to condition species membership and our concomitant moral worth on mental abilities. If we stop to consider a radical, logical extension of this ethical position, the ramifications are chilling. Those with significantly impaired cognitive function—the uncle in a persistent vegetative state, the daughter with serious developmental delays, the elderly grandmother with dementia, the anencephalic newborn boy—are judged to have less moral worth than the Rhodes scholar or moral philosopher. What is respected here is not human *dignity*, but human *cognition*. While cognitive capacity is one evidence of our singularity, it is not the basis of the ontological reality, the truth about our status as creatures made in the image of God. There are many other capacities which are distinctively human, for example, humor, preservation of history, artistic creativity, imagination, self-awareness. No single human being fully expresses all mental capacities, and some humans lack one or more entirely. Yet, it would be wrong to conclude they are not human beings with dignity.

Some advocates of human dignity are concerned about transplanting human neurons into animal brains on different grounds. Because of the brain's intimate connection with personal *identity*, on this view, brain transplantation—a theoretical possibility for now—would be clearly immoral. The insertion of human cells into an animal brain could be problematic in two ways. The first concerns the origin of the cells: bone marrow stem cells might not be problematic, but neuronal progenitor cells, which raise the "possibility of humanlike connections between the neurons," are troubling.[3] The second concern has to do with the potential of the inserted cells to change the architecture of the brain, that is, its weight, shape, and size. It is not clear what percentage of human neurons constitutes a "significant" alteration. Thus, prudence counsels that we *not* engage in a procedure which potentially alters identity.

It is important to note that not all HA hybrid research may violate species boundaries. Inserting a small fragment of human DNA into a mouse to develop a cancer-fighting drug, for example, might not implicate human dignity. Growing a human-tolerant pig valve for a heart patient is therapeutic, not threatening.

Thus, we have two different arguments against integrating human DNA into animal brains, one based on nominalist grounds, and the other on dignitarian grounds. A whole host of ethical concerns remain. What about concerns for animal welfare? The host animal and its offspring may suffer terribly. Could "human dignity" apply to HA hybrids? Are they human, or actually something else? In addition to neurons, are there other types of cells that raise specific concerns, such as gametes, or organs, such as the uterus? Does it matter at what stage of biological development the species mixing occurs? It could be at fertilization, at the embryonic stage, or somewhat later. How is this relevant?

Humanzees or Dren from *Splice* may be fanciful creations. The mass production of human-animal embryos may not. Somewhere in between we may find the highest and best purposes of research, those therapeutic goals that do not violate ethical standards. We still lack a Christian consensus on all aspects of the HA hybrid question, but we must persevere and continue the difficult work of thinking through ethical issues, principles, and their application. A premature conclusion may initially satisfy, but ultimately prove to be a barrier to both encouraging ethical research and respecting human dignity in all its stages, ages, and variations.

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1 Sharrie Gossett, "Chinese Scientists Create First Human-Animal Embryo." http://archive.newsmax.com/archives/articles/2003/8/14/153902.shtml (accessed Sep. 22, 2010).

2 David Derbyshire, "Experiments fail: Controversial human-animal hybrid embryos 'will not deliver medical benefit.'" http://www.dailymail.co.uk/sciencetech/article-1134483/Experiments-fail-Controversial-human-animal-hybrid-embryos-deliver-medical-benefit.html (accessed Sep. 22, 2010).

3 Tara L. Seyfer, "An Overview of Chimeras and Hybrids," *The National Catholic Bioethics Quarterly* (Spring 2006): 37-49, 47.

CBHD continues to expand its reach to the next generation of leaders in Christian bioethics. This summer we were pleased to host three interns through internships that were tailored to their specific career trajectories and topical interests. Focused around the annual conference, our summer internships provide a venue for interns to engage with bioethics students and scholars and to be challenged with an approach to bioethics that emerges out of the Center's commitment to Judeo-Christian Hippocratism.

Paula Neiweem received a BA in Biology and Religion from Augustana College in Rock Island, Illinois and spent a semester in Washington, D.C. with the Evangelical Lutheran Church in America Advocacy Office prior to spending the summer with CBHD. Paula worked primarily on the continued development of a denominational bioethics research project we will be unveiling as a part of wiki on our soon-to-be-released website www.everydaybioethics.org. She recounts that prior to her internship with the Center, her approach toward bioethical issues had been primarily scientific; however, through her work she gained new theological perspectives that have enhanced her view of bioethics. She is thankful for the time that she spent interning with the Center and the experience that she gained. "One of the highlights was being able to attend the summer conference where I heard several speakers and had the opportunity to meet even more people interested in bioethics."

Alice Kong recently entered her senior year at Yale University majoring in Religious Studies with a concentration in Bioethics and plans to attend medical school after graduation. Alice's internship at CBHD involved review of archived audio and print resources, as well as research on films with bioethical content and development of various bibliographies. One of the highlights of Alice's experience was leading a staff brown bag session discussing ethical issues surrounding artificial reproductive technologies. Above all, Alice says that the Center has equipped her with reason, critical thinking, and logic to guide her as she faces bioethical issues in her future career. "The most valuable thing that I have learned is not what to think, but rather how to think." She is grateful to the Center for the "immense amount of encouragement and guidance" that she received during her internship.

Matthew Krueger is currently in his second year at Regent University School of Law and is a graduate of Taylor University. Matthew spent much of his internship working with Paige to research legal issues surrounding surrogacy and embryo donation and adoption. Matthew noted, "Working alongside Paige Cunningham has helped me to develop my legal thought and dive deeper into the heart of an issue." He enjoyed the ability to work on projects with the Center and to be involved in thinking through integrating several of the discrete streams of bioethical thought. "The Center's constant drive and passion for intellectual thought and analysis of today's most pressing bioethical issues has been a process that I feel I was privileged to be a part of."

Internship opportunities continue throughout the year as well. For the Fall, CBHD is currently hosting seven interns and volunteers. If you are interested in applying to be an intern or know of someone who should be considered for an internship with CBHD, please contact us at info@cbhd.org. Some have expressed interest in sponsoring interns. If you would like to learn more about those opportunities for support, please contact CBHD's Director of Development, Joel Dillon at jdillon@tiu.edu or 847.317.7006.

CALL FOR PAPERS AND POSTERS: "THE SCANDAL OF BIOETHICS"

The Center for Bioethics & Human Dignity
18th Annual Summer Conference
July 14-16, 2011
Trinity International University, Deerfield, IL

THE SCANDAL OF BIOETHICS RECLAIMING CHRISTIAN INFLUENCE IN TECHNOLOGY, SCIENCE, & MEDICINE

Forty years after the concept of "bioethics" was introduced, it has emerged as the moral umpire in the fields of medicine, science, and technology. The bioethics of today is a broader enterprise than the familiar realm of medical ethics. Originally conversant with Christian moral reflection, bioethics has emigrated from bedside consultations to interdisciplinary research, public policy debates, and wider cultural and social conversations that all privilege secular discourse. *The Scandal of Bioethics* glances backward to ask questions about the legacy of Christian thought in bioethics, while facing the future, the purpose, and the place of Christian thought in bioethics. The time has come to address the tough questions: Has 'Christian bioethics' made any difference? Will Christians lead with moral courage and imagination? Is there a future for right of conscience in medicine and research? This conference will also address related trends in women's health and reproductive ethics, the growing role of empirical research, global health, and a vision of biotechnology that affirms both human dignity and human flourishing.

There will be an opportunity to present professional papers and posters during the upcoming CBHD summer conference *The Scandal of Bioethics: Reclaiming Christian Influence in Technology, Science, & Medicine*. All serious proposals relevant to the study of bioethics are welcome. To be considered for presentation, papers and posters must be submitted as abstracts of 250-300 words along with a CV/resume. For the requirements, guidelines and deadlines of abstracts, papers and posters and conference dates, please visit www.cbhd.org/events/the-scandal-of-bioethics.

BEYOND THERAPY CONFERENCE

BY JENNIFER MCVEY

Every summer a group of individuals passionate about engaging bioethics in all walks of life descends upon the campus of Trinity International University seeking knowledge about the newest thought and developments in the field. For some, this is a first time experience; others partake of the tradition on a yearly basis. Many things are predictable: more than likely it will be unbearably hot and humid; wraps and pasta salad will be served at the opening reception. Old friends gather together and greet, new professional relationships are established. The unknown is always what the plenary speakers bring to the table and how they will challenge the audience to respond.

The Center for Bioethics & Human Dignity continued a rich seventeen year history of conferencing with the July 15-17, 2010 summer conference: *Beyond Therapy: Exploring Enhancement and Human Futures*. CBHD played host to seven distinguished plenary speakers from across the country: William P. Cheshire, Jr., Maureen Condic, Amy Laura Hall, William B. Hurlbut, Dorothy Roberts, Michael Sleasman, and Brent Waters.

The purpose of *Beyond Therapy* was to investigate both the opportunities and perils of scientific discoveries and technological innovations that are transforming the nature of biomedicine and revolutionizing the expectations for biotechnology. The intention of the program was to probe some of the toughest questions in bioethics where, as Paige Cunningham, our Executive Director has pointed out, the "boundaries are not neat and tidy." These questions surrounding the shift from therapy to enhancement are some of the most important for the future of our humanity. It was our hope that attendees would deeply consider and engage the moral and ethical questions surrounding the move from therapy to enhancement, what it means to be human, and the impact on human dignity.

This conference was an opportunity to hear from some of the top experts who dedicate time to think extensively about the questions presented by this shift. What are the prospects and challenges to human futures in light of advances within science and technology? What is the role of race and ethnicity in race-based biotechnologies? What are the contributions of regenerative medicine to science and medical research, as well as ethical, legal, and social concerns? Can the ability to pursue perfection lead to a rhetoric of shame?

Dr. William B. Hurlbut (former President's Council on Bioethics member) eloquently set the stage for the weekend in his opening address entitled "Embodiment, Biotechnology, and Human Dignity." Dr. Hurlbut commented that enhancement is at the heart of the deepest dilemmas we face as a society, because of its close link with the future of humanity. This link is not just tied to the practical outcomes and potential physical side effects of various types of enhancement, but is rooted in a deeper ethical, philosophical, and spiritual understanding of what it is to be human and what it means to live authentically in our humanness within our natural limitations. In order to reflect well upon these changes, Dr. Hurlbut proposed that we need to have a more radical understanding of the meaning of "beyond therapy," one that includes the whole of life and is not only seen through the lens of medicine, sickness, and healing: an understanding of "beyond therapy" that incorporates psychological, moral, and spiritual lenses.

The speakers that followed Hurlbut's opening address used these expanded lenses to address issues and opportunities that will affect human futures. The bioethics conversation regarding therapy and enhancement continues, but I believe that those who attended left with both a better understanding of the issues that dot this landscape and the moral framework for engaging lingering questions. At the very least, that was my experience.

I would like to invite you to the Center's 18th Annual Summer Conference: *The Scandal of Bioethics: Reclaiming Christian Influence in Technology, Science, & Medicine*. I am pleased to announce a distinguished schedule of plenary speakers: H. Tristram Engelhardt, Jr., Kevin FitzGerald, Dennis Hollinger, C. Christopher Hook, Edmund Pellegrino, David Stevens, and Daniel Sulmasy. During the conference we will glance backward to ask questions about the legacy of Christian thought in bioethics, while facing the future, the purpose, and the place of Christian thought in bioethics. Do not miss the opportunity to address the tough questions: Has 'Christian bioethics' made any difference? Will Christians lead with courage and moral imagination? Is there a future for right of conscience in medicine and research? I would invite you now to begin considering how you might contribute to the conversation through paper and poster sessions. Once again, individuals passionate about engaging bioethics in all walks of life will descend upon campus of Trinity International University and more than likely there will be wraps and pasta salad as we greet our friends at the opening reception, but the unknown will be how the plenary speakers will inspire us to engage our world. Mark your calendar now for July 14-16, 2011. I will see you there!

TOP BIOETHICS STORIES: JANUARY-JUNE 2010

BY KIRSTEN RIGGAN, MA

1. "**First U.S. Stem Cells Transplanted Into Spinal Cord**" by Miriam Falco, *CNN*, January 21, 2010.

> For the first time in the United States, stem cells have been directly injected into the spinal cord of a patient, researchers announced Thursday. Doctors injected stem cells from 8-week-old fetal tissue into the spine of a man in his early 60s who has advanced ALS, or amyotrophic lateral sclerosis. It was part of a clinical trial designed to determine whether it is safe to inject stem cells into the spinal cord and whether the cells themselves are safe. http://tinyurl.com/ydshrrd

This is the first time fetal stem cells have been injected into a patient in the U.S. The neural stem cells were derived from an aborted fetus, considered by many to be an unethical source of stem cells.

2. "**Researchers Directly Turn Mouse Skin Cells into Neurons, Skipping IPS Stage**" by Krista Conger, *PhysOrg*, January 27, 2010.

> Even Superman needed to retire to a phone booth for a quick change. But now scientists at the Stanford University School of Medicine have succeeded in the ultimate switch: transforming mouse skin cells in a laboratory dish directly into functional nerve cells with the application of just three genes. The cells make the change without first becoming a pluripotent type of stem cell - a step long thought to be required for cells to acquire new identities. http://tinyurl.com/2b5f37v

This is the second demonstrated example of direct cell reprogramming, a promising and ethical avenue of regenerative medicine. The researchers are currently working to replicate this experiment in human cells.

3. **"Stem Cell Alternatives Show Early Aging Abnormalities**" by Dan Vergano, *USA Today*, February 12, 2010.

> A first head-to-head comparison of human embryonic stem cells with ones grown from skin cells, reported Thursday by biologists, revealed early aging and other abnormalities in the less-controversial alternatives. http://tinyurl.com/2dpu8l7

This study demonstrates that induced pluripotent stem cells (iPS) may have certain growth and aging abnormalities compared to embryonic stem cells. iPS cells are being investigated as a source of pluripotent stem cells that avoid the ethical and immune rejection issues of embryonic stem cells.

4. "**US Judge Strikes Down Patent on Cancer Genes**" by Larry Neumeister, *Associated Press*, March 29, 2010.

> In a ruling with potentially far-reaching implications for the patenting of human genes, a judge on Monday struck down a company's patents on two genes linked to an increased risk of breast and ovarian cancer. http://tinyurl.com/26mybma

This decision invalidated the patents held by Myriad Genetics for the BRCA1 and BRCA2 genes and threatens the legality of other existing gene patents. Many believe that gene patents greatly hinder scientific research and that the patenting of DNA leads to the commodification of the human body.

5. "**Panel to Take Broad View of Bioethics**" by Brendan Borrell, *Nature News*, April 13, 2010.

> US President Barack Obama last week announced the full membership of his bioethics advisory council, unveiling a more diverse body and one that is likely to have a greater impact on policy than its predecessor. http://tinyurl.com/22u932q

While the 12-member panel is professionally diverse, it features only two formal bioethicists. This has caused concern that comprehensive analysis of ethical issues may be overlooked in favor of developing pragmatic policy.

6. "**House Launches Investigation into Genetic Tests"** by Rob Stein, *Washington Post*, May 19, 2010.

> The House Energy and Commerce Committee and its subcommittee on oversight and investigations sent letters to Pathway Genomics Corp. of San Diego, 23&Me Inc. of Mountain View, Calif., and Navigenics Inc. of Foster City, Calif., requesting information about their tests. The move was prompted after Pathway announced plans last week to sell its genetic test through drug stores nationwide for the first time "despite concern from the scientific community regarding the accuracy of test results," the letters stated. http://tinyurl.com/26arrnb

The investigation was launched after concerns were raised that home genetic testing for serious medical conditions would lead to consumer confusion, violations of privacy, and genetic discrimination. The accuracy of these genetic tests has also been under question.

7. "**Scientists Create First Synthetic Cell**" by Robert Lee Hotz, *Wall Street Journal*, May 21, 2010.

> Heralding a potential new era in biology, scientists for the first time have created a synthetic cell, completely controlled by man-made genetic instructions, researchers at the private J. Craig Venter Institute announced Thursday. http://tinyurl.com/3xrrhvy

This "proof-of-principle" experiment is considered to be a major step forward in the field of synthetic biology. Many have objected that engineering a synthetic cell raises deep questions about the proper limits of scientific endeavor that, at the very least, deserve to be aired and carefully thought through within the scientific community and the broader public. There is also concern that the use of synthetic cells outside the laboratory may have serious environmental consequences.

8. "**NIH to Tighten Rules on Conflicts**" by Meredith Wadman, *Nature News*, May 20, 2010.

> After a wave of financial scandals over the past few years involving biomedical researchers, the US National Institutes of Health (NIH) proposed far-reaching changes today that would lead to much tighter oversight of agency-funded extramural investigators and their institutions. http://tinyurl.com/3685dof

The NIH has proposed revisions to current regulations to prevent financial conflicts of interest and increase transparency of NIH-funded investigators. These changes shift the responsibility for determining and disclosing financial conflicts of interest from the individual researcher to their institution.

9. "**Doctors Reverse Stand on Circumcision**" by Pam Belluck, *New York Times*, May 26, 2010.

> The American Academy of Pediatrics has reversed its decision last month regarding the practice of female circumcision by immigrants from some African, Middle Eastern and Asian cultures. The academy had suggested in a policy statement that doctors be given permission to perform a ceremonial pinprick or nick on girls if it would keep their families from sending them overseas for the full circumcision. http://tinyurl.com/37jjkeo

Originally supported as a means of compromise to prevent families from seeking full female circumcision overseas, the decision was reversed due to opposition by those who believe that the decision tolerates an unethical and harmful practice.

10. "**First Human 'Infected with Computer Virus'**" by Rory Cellan-Jones, *BBC News*, May 27, 2010.

> Dr Mark Gasson from the University of Reading contaminated a computer chip which was then inserted into his hand. The device, which enables him to pass through security doors and activate his mobile phone, is a sophisticated version of ID chips used to tag pets. http://tinyurl.com/29wmtes

This was a "proof-of-principle" experiment to demonstrate that computer viruses could be transferred to implanted medical devices such as pacemakers and cochlear implants, highlighting an important safety concern.

**Each of these articles was accessed June 25 - July 1, 2010*

updates & activities

EDUCATION

CBHD hosted a special lecture by Nancy L. Jones, PhD on April 21st, entitled, "Talk to the Animals: Animal Experimentation, Research Ethics, and Human Goods." The afternoon lecture was held on the Deerfield campus of Trinity International University.

PARTNERSHIP

On October 8th, CBHD along with Tennessee Center for Bioethics and Culture co-sponsored the 2nd Fall Foliage Dinner Discussion presented by Cabrini Institute, Inc. The event was held in the Radisson Hotel, Manchester, New Hampshire and focused on the topic of "Nutrition and Hydration at the End of Life." CBHD Fellow, Gregory W. Rutecki, MD was one of the featured speakers. For more information on the event, please visit Cabrini Institute's website at: http://www.cabriniinstitute.com/Upcoming_Events.html.

RESOURCES

MP3 CDs from our recent summer conference are available for sale on our website. Please visit www.cbhd.org/beyondtherapy-cd.

Conference attendees will receive a special discount offer by email.

RESOURCE LIBRARY

CBHD continues to invest in our resource library, housed in the Center's offices. We are providing a study center environment to facilitate collaborative and cutting-edge bioethics scholarship. Visiting scholars from Canada (Carina Majaesic, MD, PhD, FRCPC) and Australia (Sam Chan, MB BS, PhD) made use of these facilities during March and July. Recent improvements to the Resource Library included cataloguing the holdings in an online database, the creation of an archive of topical, legal, and historical print materials, and the addition of over 75 volumes and periodicals.

STAFF

PAIGE CUNNINGHAM, JD

- Interviewed by *Christianity Today* in December 2009 on whether or not Christian doctors should leave the AMA.
- Fulfilled two interviews in January with *Moody Radio* regarding general bioethics issues and one with the *St. Louis Post Dispatch* on embryo adoption.
- Completed interviews with the San Francisco Chronicle and Contra Costa Times in April on the issue of frozen embryos.
- Interviewed by both *KGRH Radio* and *Moody Radio* in May on synthetic biology.
- Guest lectured in June at this year's Blackstone Legal Fellowship meeting held in Phoenix
- Taught CBHD's Intensive Pre-Conference Institute in July.

HANS MADUEME, MD, PHD CANDIDATE

- "Nip & Tuck: A Parable" Dignitas 17(1) Spring 2009 and *The Bioethics Podcast* episode 126 served as the basis for Mollie Ziegler Hemmingway's article, "Is Cosmetic Surgery Immoral? Even More Importantly: Why Do You Want to Know?" *Christianity Today*, March 2010, 56. Available electronically at http://www.christianitytoday.com/ct/2010/march/18.56.html.
- Moody Radio interview regarding cosmetic surgery in April.
- Taught the Graduate Conference Wrap-Around Course during CBHD's conference in July.

MICHAEL SLEASMAN, PHD

- Interviewed regarding embryonic and adult stem cell research by Family News in Focus in May, 2010.
- Guest lectured in CBHD's pre-conference institutes in July.
- Delivered a plenary entitled, "Virtual Paradise? Being Human in a World of Digitized Reality and Artificial Life" at CBHD's July Conference.
- Taught "Bioethics and Moral Theology" as a CBHD post-conference seminar in July.

ON THE CBHD BOOKSHELF

For those interested in knowing what books the Center staff have been reading.

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