A Publication of the Medical Humanities Program of Davidson College

The Ethical View

April 2014

Research Ethics Consultation

Inside this Issue

An Ethical Analysis of the 2009 Mild Gestational Diabetes Trial ..................................2

The McMath Case: Continuing Confusion, Unease and Distrust About “Brain Death” ..................................4

An Ethical Analysis of Physician Reimbursement in Clinical Trials ..................................6

Parental Right to Discretion in the Decision to Circumcise ..................................9

Contraceptive Coverage within the Affordable Care Act ..................................11

Letter from the Editors
Ashley Parker ‘14 and Hailey Cleek ‘16

The Ethical View is released annually by the Medical Humanities Program of Davidson College in an effort to raise awareness about healthcare issues and their ethical ramifications.

The theme of the publication corresponds to that of the annual Frederick Womble Speas Symposium. The event will bring disciplinary experts together on campus to discuss a particular healthcare theme, which this year is Research Ethics Consultation.

The articles in this publication were written by Davidson students and professors. The subjects cover a broad range of topics in bioethics, including but not limited to exploring Research Ethics Consultations.

Should physicians be reimbursed for enrolling patients in clinical trials? Should corporations be mandated to provide contraceptive coverage in insurance policies?

These questions, along with several others, are addressed within these pages.

The Bioethics Society would especially like to thank Dr. Lance K. Stell for his contribution to this publication in his last semester at Davidson. After nearly forty years of teaching at Davidson, Dr. Stell and his thought-provoking classes will be very much missed.

To respond to any article presented in this publication, please see the contact information on page 13.

About the Editors...

Ashley Parker ‘14 is a French and Francophone Studies major with a Medical Humanities concentration from Warwick, RI. She and Hailey are co-presidents of the Bioethics Society. Next year Ashley will be teaching English in France.

Hailey Cleek ‘16 is a Psychology major with a Medical Humanities concentration from Goodlettsville, TN. This summer she will be working as a Vann Fellow at the Mayo Clinic.
Gestational diabetes is defined as “any degree of glucose intolerance with onset or first recognition during pregnancy” (U.S. Preventive 2008). In 2009, Landon et al. conducted a trial in order to determine whether mild gestational diabetes mellitus (GDM) should be treated in order to improve pregnancy outcomes such as decreased mortality, fetal overgrowth, shoulder dystocia, cesarean delivery, and hypertensive disorders. Women were assigned to either a treatment group in which they received treatment for GDM, such as diet and exercise counseling or insulin in some cases, or a control group in which participants received regular prenatal care. Women assigned to the control group were tested for mild GDM, but the results of this test were not disclosed to the participants or their doctors unless the results were severe enough for exclusion from the study (Landon et al. 2009). This raises ethical concerns because researchers withheld information from the participants, and critics claim that by doing so the researchers were denying the participants care and causing harm to the control group. These actions can be justified based on principles of clinical equipoise and the necessity of the study due to a lack of previous knowledge about the effect of mild GDM treatment on pregnancy outcomes.

The stakeholders in this trial are the researchers, the mothers involved in the study, the babies of the mothers in the study, the larger community of pregnant women who may or may not have GDM, the doctors of the mothers in the study, the families of the study participants, the institution where the study was conducted, the funding institution, and the broader research community.

Several points of conflict exist between these various stakeholders. The first major conflict of interest is obtaining significant results versus the mothers having a right to know whether they have GDM. Researchers, the institution, the funder, and both the broader research community and the broader community of mothers are primarily interested in obtaining significant results from this trial. A significant result with minimized confounding variables creates generalizable scientific knowledge. One of the confounding variables in this trial and a limitation of a previous pilot study is the possibility of self-treatment in the control group. If women in the control group were told that they had GDM, they would possibly self-treat at home by modifying diet and exercise, which could make the results of the study invalid because there isn’t a standard group to compare outcomes of the treatment group to (Landon et al. 2009). It has been accepted in the research community that it is ethical to withhold information as long as you don’t exploit the study participants. Withholding information is necessary in many trials in order to generate valid results. This is a utilitarian argument that the benefit of many, meaning the larger community of pregnant women or women expecting to become pregnant who may develop GDM, outweighs the interests of a few, meaning the study participants. On the other side of this conflict is the mothers enrolled in the trial, particularly those involved in the control group, their babies, and their families. These stakeholders are primarily interested in obtaining treatment for the enrolled mother in order to improve personal pregnancy outcomes, while also minimizing harm to the mother and child. Therefore, these stakeholders feel the mother and her doctor have a right to know whether she has mild GDM in order for the doctor to determine whether additional care is necessary and should be provided. By not sharing this information with the participants in the control group, the researchers are ensuring that the mothers will not get care such as diet and exercise counseling specific to GDM and these stakeholders believe that by restricting this care “excess harm was allowed to accumulate in the control group” (Stell 2010).

There was insufficient scientific evidence, however, at the time of this trial to suggest that screening and treatment of GDM would cause either harm or benefit to patients. Scientific evidence was lacking even more so on the benefits or harm of treatment of the mild form of GDM. In 2008, prior to the publication of the Landon study in 2009, the U.S. Preventive Services Task Force (USPSTF) published a recommendation statement regarding the necessity of screening for GDM. This recommendation stated “the current evidence is insufficient to assess the balance between the benefits and harms of screening women for GDM either before or after 24 weeks gestation.” In addition, there was no evidence at the time that GDM treatment, such as diet and exercise counseling or insulin prescriptions, would improve health outcomes (U.S. Preventive 2008). This genuine uncertainty over whether screening and treatment is equal or superior to standard care satisfies the ethical principle of clinical equipoise.

Researchers cannot intentionally harm their study participants, and therefore a genuine uncertainty over the benefits and harm is ethical because there is no intent of harm. The prospect of discovering benefit outweighs the prospect of minimal harm (Miller & Brody 2003).

Because there was not sufficient evidence at the time, this study was conducted to determine whether screening or treatment of GDM would improve pregnancy outcomes. Practices such as weight management and exercise counseling for GDM, particularly the mild cases, were common before this study was conducted but there was insufficient evidence to show that these practices were actually benefiting patients. It could have been equally likely that patients were being harmed by these practices. For example, overcorrection of mild GDM with significant diet and exercise changes could lead to hypoglycemia, or low blood sugar, leading to negative effects on pregnancy such as small for gestational age babies (Landon et al. 2002). Therefore, the Landon study was necessary in order to determine whether screening and treatment of GDM should be standard treatment in mild cases. Because blinding was essential to producing significant results in this trial and due to the necessity of this study, it was therefore ethical to use this method to produce significant results. Generalizable scientific knowledge resulting from this trial helped to shape standard care for mild GDM, which benefits the larger community in showing that screening and treatment for the mild form of GDM is beneficial and improves pregnancy outcomes.

If this counseling was not proven to benefit patients and improve pregnancy outcomes, it can be argued that it would be detracting from other, more necessary or pressing patient care. This is a conflict of interest between mothers with the mild form of GDM and mothers with the more severe form of GDM. The time spent counseling these mothers with a mild form of gestational diabetes could be spent on mothers with a more severe form of the...
Continued from page 2

condition, thereby maximizing benefit for the same amount of time caring for patients. Therefore, it was necessary to carry out the Landon trial in order to determine whether screening and treatment for mild GDM was in fact beneficial, rather than the possibility of spending this time with patients when the treatment is having no effect. It is unethical for doctors to spend unnecessary time with patients if the treatment is not beneficial when there are other patients with whom their time would be efficiently spent.

Yet another point of conflict is necessity of the study versus unnecessary cause of stress and potential harm of participants. Researchers must establish the necessity of their study and prove that it will generate useful knowledge. Unnecessary stress will be caused on participants if data from this study does not generate useful knowledge. Prior to the 2009 study, there had been one study conducted on the effect of treatment of gestational diabetes mellitus on pregnancy outcomes called the Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) Trial Group (Crowther et al. 2005). The USPSTF recommended that further randomized trials be conducted in order to “add weight” to the results of the ACHOIS trial (U.S. Preventive 2008). This study was a phase II clinical trial, which continues to test treatments for safety and begins to test for effectiveness (ClinicalTrials). Phase II trials are conducted on a homogenous population with limited diversity. Phase III trials are then necessary in the process of establishing standards of care because they continue to test safety and effectiveness of a drug or treatment on a large, diverse population and at different dosages.

Over 70% of the participants in the ACHOIS study were white with the small remaining percentage being Asian (Crowther et al. 2005). The Landon study enrolled participants of a wider ethnic background, including a more even spread of black, white, Asian, and Hispanic mothers. The Landon study also took other factors into account such as smoking and alcohol use. This is necessary in order to verify that results are generalizable, meaning that the results can be applied to different groups of people. In addition, a second trial was necessary in order to verify the results of the ACHOIS study and ensure reproducibility. Reproducibility and generalizability are necessary in research in order to assure that the results of a study or trial can be trusted as accurate. Furthermore, there were several limitations in the ACHOIS study, necessitating a second study to overcome these limitations and determine whether the results could be reproduced. While the outcomes of the two studies were similar in that they claim benefit of treatment of GDM, the pregnancy outcomes that were improved differed between the two studies. In the ACHOIS study, researchers did not focus exclusively on the mild form of GDM, and they concluded that treatment of gestational diabetes reduced “serious perinatal morbidity” (Crowther et al. 2005). In the Landon trial, researchers focused on women who had mild gestational diabetes and concluded that treatment did not significantly reduce perinatal morbidity, but it did have positive effects on secondary outcomes such as fetal overgrowth, shoulder dystocia, cesarean delivery, and hypertensive disorders (Landon et al. 2009).

Generalizable scientific knowledge resulting from this trial helped to shape standard care for mild GDM, which benefits the larger community in showing that screening and treatment for the mild form of GDM is beneficial and improves pregnancy outcomes. The withholding of information in this trial was not unethical, as researchers satisfied the principle of clinical equipoise and there was no proven treatment for GDM prior to conduction of this trial, so there was no evidence to show which participants would have benefitted from knowing they had GDM. Randomization in controlled trials in this case was both ethical and necessary in order to generate valid, generalizable, and reproducible results.

References


Thibaudeau ‘14 is a biology major from Charleston, SC. This summer she will be working as an ocean rescue first responder and applying to medical school.
## The McMath Case: Continuing Confusion, Unease and Distrust About “Brain Death”

Lance K. Stell

On December 9, 2013, Jahai McMath, a 13-year-old obese female, underwent extensive throat and airway resection for treatment of potentially life-threatening sleep apnea at Oakland (CA) Children’s Hospital. The operation was not a simple tonsillectomy/adenoidectomy as was widely reported at the time. Her surgery involved three procedures: a tonsillectomy, removal of the nasal tubinates and a uvulopalatopharyngoplasty (UPPP). The latter procedure, the most commonly performed operation for sleep apnea, removes excess tissue in the throat to widen the airway. It may include excision of the small finger-shaped piece of tissue (uvula) that hangs down from the back of the roof of the mouth into the throat, part of the roof of the mouth (the soft palate) and other throat tissue determined to be excessive, such as the back of the tongue, adenoids and the pharynx. The op-note from McMath’s surgery is not publicly available, so it is uncertain precisely what was done or what intraoperative difficulties may have been encountered. Recovery from UPPP is unpleasant. It takes about three weeks. Only 60% of those having the procedure say they would undergo it again.

Such an extensive surgery (elective? urgent?) in a child is not routine. Bleeding and death can occur, as it did in Jahai McMath’s case. It is unknown how her surgical risk was characterized for purposes of informed consent. A large study in the VA population by Kazarian found a non-fatal but serious complication rate of 1.5% and a mortality rate to be .2%. Obesity among children approaches epidemic status in the United States. Sleep apnea is associated with obesity. The morbidity and mortality rates for UPPP in the obese pediatric population is not known. A cautionary disclosure might have characterized her risk as “high.” A reassuring but paternalistic disclosure might have lowered the estimate.

While she was in recovery, approximately 30 minutes post-op, Jahai began bleeding heavily. She suffered a cardiac arrest. Perhaps she choked on her own blood, aspirated it into her lungs and stopped breathing thereby depriving her brain of oxygen. Alternatively, her blood loss may have been so great that her pressure dropped below what was required adequately to perfuse her brain resulting in irreversible damage. Either of these scenarios may have caused her heart to stop. Regardless the actual causal pathway, Jahai’s brain injury was devastating. CPR was performed successfully but her brain damage was irreversible and fatal.

On December 11th, Jahai’s attending physician consulted a neurologist, Dr. Shanahan “to determine whether or not Ms. McMath had sustained irreversible cessation of all functions of the entire brain.” This is a legal criterion for death in California. Dr. Shanahan’s exam concluded that there was no brain function, in others words, Jahai’s exam for brain death was “positive”. Jahai’s mother, Nailah Winkfield, was notified. She rejected the diagnosis. As is customary when a diagnosis is challenged, and most especially with children whether or not the diagnosis is challenged, the brain death exam was repeated the following day by another neurologist, Dr. Heidersbach. His conclusion was the same. Consistent with the Hospital Policy, Jahai was declared “dead” and her death certificate was issued. Yet again, Jahai’s mother rejected the diagnosis. She protested the validity of the death determination. She retained Christopher Dolan, a self-described “cafeteria Catholic” to represent her. On what basis? That the concept of brain death was invalid? California law recognizes it. On the basis that Jahai’s diagnosis was wrong? Two specialists had concurred. Dolan’s personal view was that removal of life-support should not belong exclusively to physicians, but rather, family concurrence should be required. Ms. Winkfield had emphatically withheld it. Can a dead person be maintained by “life support”? That confusion would infect media and other commentary throughout. Isn’t it fraud to treat a corpse as if it were alive? Whatever, Dolan brought suit in Superior Court seeking to enjoin the hospital’s removal of the ventilator and other supportive measures (“life support”).

Consulting neurologist, Dr. Shanahan urged against granting Ms. Winkfield’s request. She testified: “There is absolutely no medical possibility that Ms. McMath’s condition is reversible or that she will someday recover from death.” Another neurologist, Dr. Fiori, deposed “While allowing post mortem bodies to be supported for over three weeks appears to be unprecedented, it is the team’s complete conviction that nothing can be done to stop the natural progression of Ms. McMath’s post-mortem deterioration which is already underway – or the bodily deterioration of any deceased individual.”

However, Ms. Winkfield’s had secured her own expert, Dr. Paul Byrne, a forensic-intelligence expert from Ohio who testified that, on his exam, Jahai had “responded” to her family, hence she could not be dead. Dr. Byrne is well-known for his rejecting brain death as “real death.” Indeed he registered his disagreement with the Oakland Children’s neurologists’ diagnosis even before performing his own exam. Faced with conflicting experts, and probably dogged by some confusion of its own, on December 31, the court granted Winkfield’s request that supportive measures be continued, but only until January 7.

Both the hospital and Winkfield had economic interests in play. A diagnosis of death might limit the hospital’s liability in an anticipated lawsuit - $250,000 for death of a child under California law. On the other hand, Winkfield’s damages would be potentially much greater if Jahai were later found to have survived her post-op complication, albeit with a permanent brain injury.

On January 6, 2014, Jahai’s body was released to her mother. A tracheostomy had been performed and a feeding tube had been placed. It is unclear who performed these procedures. Performing them on someone declared “dead” might be grounds for professional discipline. Representatives from the Terri Schiavo Foundation provided assistance in locating an (unidentified) facility to accept Jahai’s body in transfer. On January 25, Ms. Winkfield
Continued from page 4

released a video apparently showing Jahai moving her toes and foot. The National Right to Life website reported on April 1 that Winkfield remains convinced that Jahai will recover. She described Jahai, who is undergoing physical therapy, as moving her head side to side, bending at the waist and changing positions when she is uncomfortable.

Brain Death:
The Harvard ad hoc Committee introduced Americans to the concept of brain-death in 1968. Since then, California, indeed all the states and the District of Columbia, have recognized the legal validity of a physician’s using neurological criteria to diagnose death. For example, North Carolina law provides:

§ 90-323. Death; determination by physician.
The determination that a person is dead shall be made by a physician licensed to practice medicine applying ordinary and accepted standards of medical practice. Brain death, defined as irreversible cessation of total brain function, may be used as a sole basis for the determination that a person has died, particularly when brain death occurs in the presence of artificially maintained respiratory and circulatory functions. This specific recognition of brain death as a criterion of death of the person shall not preclude the use of other medically recognized criteria for determining whether and when a person has died. (1979, c. 715, s. 3.)

How is Brain Death Diagnosed?
The diagnosis is based on a clinical exam – a series of tests performed at the bedside that require skillful interpretation. Some tests look for signs of awareness. Others test for cranial nerve function and others for brain stem function. Sometimes special additional studies are ordered, such as a brain-perfusion scan, an EEG or a CTA or an MRI. The goal is to arrive at a determination whether whole-brain function has been destroyed.

Increasingly, the diagnosis of death by neurological criteria is reserved to neurologists, neurosurgeons and critical care specialists. Why? Because the diagnosis of death, like all diagnoses, is probabilistic not absolute. We should want as few false-positives (falsely concluding “dead”) with this diagnosis as possible. These errors are minimized when specialists with extensive experience do the exam. They can discern the difference between reflexes and purposeful behavior, between brain death, the minimally conscious state, the vegetative state, locked-in syndrome and other remarkable neurological conditions. Making these distinctions is not only beyond the skill of laypersons, it over-masters the abilities of non-specialty untrained, inexperienced medical personnel.

To lay observation, a corpse connected to a monitor may display heartbeat and a blood pressure. She may look too good to be dead, despite that her brain has been destroyed. The ventilator keeps the heart beating, chemicals may support blood pressure, perfusing the tissues, pinking her. A blanket keeps her warm. But the “vital signs” displayed on the monitor are deceptive. They manifest the power of supportive medical technology, not that of life itself. These appearances understandably baffle people, hence the oxymoron: “brain dead, on life-support.”

From an ethical point of view, we should appreciate that the circumstances of brain death put trust in medical authority on trial. How so? A medical authority is asking or insisting that the inexperienced person substitute an expert’s judgment for what her own senses plainly tell her, namely, “vital signs” = alive. Withdrawal of “life-support” will cause death. The level of trust required for a suspicious next-of-kin to think otherwise may be absent, as it apparently was in the McMath case.

Questions:

Is brain-death a comparatively new way to be dead? Can one be dead in two ways – in a heart-sort-of-way and a head-dead-sort-of-way? Can one die twice? First when the brain dies and second when the heart stops? What relationship is there between using traditional, cardio-pulmonary criteria for diagnosing death and using neurological criteria? 

Answer: All traditional, bedside tests for death (non-responsiveness, apnea, cessation of heartbeat) implicate brain functions directly, except for heartbeat that implicates brain function indirectly, because of its dependence on breathing. A unifying physiological theory says that the brain is the master organ, orchestrating the complex processes that enable somatic integration. The theory predicts that, when the whole brain is destroyed, somatic disintegration is rapid (within a few days) and inexorable, irrespective respiratory and other support. Neurology expert, Dr. Fiori based her professional opinion on this theory.

Problems: In the journal Neurology (1998), Alan Shewmon, M.D., documented somatic survival of brain-dead individuals well beyond a few days. He found 175 cases of survival of week or more, in one case more than 14 years. Indeed, ventilator & feeding tube supported brain-dead individuals may exhibit homeostasis, proportional grown, wound healing, lactation, and gestation. Susan Repertinger, M.D., a pathologist, reports having performed “a brain autopsy of a boy who at 4 years of age suffered fulminant Haemophilus influenzae type b bacterial meningitis resulting in massive brain destruction and the clinical signs of brain death. Medical intervention maintained him for two decades. Autopsy revealed a calcified intracranial spherical structure weighing 750 g and consisting of a calcified shell containing granular material and cystic spaces with no recognizable neural elements grossly or microscopically. The case represents an example of long survival of brain death with a living body.”

A dogmatic, foot-stomp response says “all these so-called somatic survivors were false-positive diagnosed.” Perhaps. But a scientific cast of mind and an ethics that begins with good facts isn’t so absolutist. New Jersey is currently unique among the United States for allowing a patient’s next-of-kin to veto physicians’ using neurological criteria to diagnose death.

26:6A-5. Death not declared in violation of individual’s religious beliefs.
The death of an individual shall not be declared upon the basis of neurological criteria pursuant to sections 3 and 4 of this act when the licensed physician authorized to declare death, has reason to believe, on the basis of information in the individual’s available medical records, or information provided by a member of the individual’s family or any other person knowledgeable about the individual’s personal religious beliefs that such a declaration would violate the personal religious beliefs of the
An Ethical Analysis of Physician Reimbursement in Clinical Trials

Andrew Charap ’16

In the United States today, approximately 85% of clinical trials are sponsored by the private sector.1 With the costs of these sponsorships exceeding hundreds of billions of dollars every year, the role of industry-sponsored research in the investigative medical field cannot be understated. However, after the exposure of numerous failed industry-sponsored clinical trials to the public, the precise role and influence of the pharmaceutical industry in clinical research has been called into question. Specifically, ethicists and investigators have begun to scrutinize the partnership between physician-scientists and pharmaceutical representatives. Practices such as speaking at conferences, consulting and gift giving—though common—now foster public distrust of industry-physician ties. In this paper, I will analyze the common practice of payment-for-enrollment, or “finder’s fees”, for physicians conducting industry-sponsored clinical research. In essence, these financial incentives are offered to investigators in hopes of expediting the time frame inherent in drug development. Using the framework outlined in Muriel J. Bebeau’s article “Developing a Well-Reasoned Response to a Moral Problem in Scientific Research”, I will analyze the relevant ethical various, various stakeholders, actions, consequences and parties involved in payment-for-enrollment schemes, and will subsequently reach a decision as to whether payment-for-enrollment systems are ethical and appropriate in industry-sponsored research.

1. Ethical Issues and Points of Conflict

The ethical issues in this case can stem chiefly from the Belmont Report, which historically serves as an ethical guideline for human-subjects research. In the Belmont Report, the authors outline three basic ethical principles for conducting morally correct research: beneficence, respect for persons, and justice. Within the context of paying physicians for subject enrollment, we can focus primarily on beneficence and justice. The Belmont Report defines the goals of beneficence as “do not harm…and maximize possible benefits and minimize possible harms.”2 Critics of the “finder’s fee” argue that paying physicians for the enrollment of patients creates a culture of clinical trials where the primary purpose, rather than producing generalizable knowledge or ensuring patient safety, is to accelerate the development process of a drug. In an article released in the American Academy of Neurology’s journal Neurology Now in 2012, a patient involved in industry-sponsored multiple sclerosis drug trials reported “feeling pressured to take certain medications that she was unsure were in her best interest.”3 Only after investigation into the financial ties of her doctor did she realize that they were receiving several hundred thousand dollars from an affiliated drug company. Though physicians are obligated to disclose financial conflicts of interests before enrolling a patient in the trial, this has not remedied the distrust felt by patients. In a similar investigation created by ConsumerReports, 77% of patients said that they would feel “somewhat or very concerned” about the quality of treatment they would receive from a doctor taking payments from a drug company.4 Thus, beneficence, from a patient’s point of view, appears to stand at odds with the practice of paying physicians for enrollment.

Proponents of industry-sponsored research have responded to these claims by highlighting the various safety protocols required by clinical trials, as well as the lengthy disclosure process of conflicts of interest prior to obtaining informed consent. Indeed, potential conflicts of interest for each physician are well documented, and available through open websites such as ProPublica. Additionally, physicians are required to disclose any financial arrangements with pharmaceutical companies amounting to greater than $10,000 dollars during the informed consent process. But, even in light of this disclosure, recent studies have shown that the levels of patient concern about payment-for-

References


Dr. Stell is the Thatcher Professor of Philosophy and the Director of the Medical Humanities Program at Davidson College. He is also a Professor of Medicine at the University of North Carolina School of Medicine.
enrollment systems are exaggerated. In the study “Effects of Disclosing Financial Interests” published in 2008, investigators reported “with the exception of researcher owning equity, disclosure of most financial interests in research…is unlikely to affect the willingness of potential research subjects to participate in research,” with per-capita enrollment payments “reflecting a greater willingness to participate in the trial.” In sum, the investigators found that the willingness of a patient to participate in a trial increases when it is disclosed that their physician is receiving payment for their enrollment.

But critics of the system argue that the real dangers lie in what the patients do not know. Returning to the Belmont Report, the principle of respect for persons obligates researchers to disclose all relevant information so that their patients are able to act autonomously and make meaningful, informed decisions about their participation. However, with a potential payout on the line, some argue that physicians are incentivized to obtain authorization at all costs by subverting proper information disclosure. In a report released by the Department of Health and Human Services in 2000, they term this phenomenon the “erosion of informed consent.” After interviewing members of IRB’s across the nation, they summarized that “many people expressed to us their concern that the pressure-filled and competitive research environment may lead investigators or their staff to encourage hesitant subjects to participate.” In a relevant Op-Ed published in the New England Journal of Medicine, the secretary of the Department of Health and Human Services, Donna Shalala, voices her concern that “as researchers are pressured to recruit subjects quickly in order to discover the next blockbuster drug, they may misrepresent the true nature of a trial, or they may simply appeal to their patients’ trust.”

II. Stakeholders and Interested Parties

Though various peripheral stakeholders in this case can be acknowledged – such as institutions, review boards and patient-advocacy groups – I have selected the top three stakeholders in this case to be physician-scientists, potential research subjects, and the pharmaceutical industry. These three have been selected because of their expanded investment into the process of clinical-trial enrollment, whether on monetary, professional or personal grounds.

Beginning with the pharmaceutical industry, it is clear what stake they hold in the execution of a swift clinical-trial. With patents and marketing exclusivity clocks ticking, pharmaceutical companies are pressured to minimize the time it takes for a drug to travel from lab to market. Currently, major pharmaceutical companies, on average, must spend an astronomical 5 billion dollars per medicine that reaches a market. This pressure, in combination with the expected 90% failure rate of early-phase clinical trials, creates a research-and-development process aimed at ‘success at all costs.’ If it is decided that paying physicians for enrollment of patients into a clinical trial is an unethical practice, it may make the process of creating a novel drug an even bigger risk for a pharmaceutical company. Without the presence of industry-sponsored, there is no doubt that the progress of medical exploration would decelerate.

Physicians also hold considerable stake in the process of patient recruitment. The Belmont Report, as well as various other ethical guidelines, places the onus on physician-scientists to ensure that clinical trials are conducted ethically and safely. During the process of obtaining informed consent, it is a physician-scientist’s obligation to analyze participant capacity and comprehension to ensure that patients can make meaningful decisions about their treatment. The addition of a conflict of interest, such that the physician is incentivized to obtain authorization, may shift the focus of informed consent from patient to physician. If we continue to allow physicians to receive payment for patient enrollment, it may set a harmful precedent for biased disclosure to patients. In fact, there is evidence that physician-industry conflicts of interest already affect how physicians speak about the benefits and risks of industry drugs. According to a study conducted by Su Golder and Yoon Loke on the biased reporting of adverse affects of drugs, “authors with industry funding were more likely than authors without pharmaceutical funding to interpret and conclude that a drug was safe, even among studies that did find a statistically significant increase in adverse effects for the sponsored product.”

Finally, we can recognize the crucial stake that patients hold in this decision. Human subjects have a natural expectation that their participation in a clinical trial will coincide with the utmost professionalism on the part of the investigators. This professionalism involves a commitment to safety, and an assessment of the study protocol that is free from conflicts of interest. Though it is not reasonable for participants to expect that all the investigators in the trial will completely detach themselves from industry, they do expect that any conflicts of interest will not pose any unnecessary risk of physician poor judgment or carelessness. In the case of physician incentives for patient enrollment, patients that are members of vulnerable populations may be incurring a higher risk of exploitation by physicians. In the previously mentioned report from the Department of Health and Human Services, the authors noted, “nearly all of the investigators we spoke with told us that they first tried to enroll any of their patients that were eligible.” This practice may be ethically questionable because of the unique level of trust involved in a doctor-patient relationship. Patients may be more likely to participate in a trial because of the perceived trustworthiness of their physician, without adequately assessing the benefits and risks of enrolling in the trial or the motivations of their physician.

In addition to the increased risk of exploiting vulnerable populations of patients, the report also discussed the potential for investigators to recruit patients that are ineligible for services. One particular investigation into a trial surmised “some investigators [had] stretched enrollment criteria…just to get subjects into the trial.” This phenomenon is particularly troubling, because it would undermine the viability of the clinical trial to produce generalizable knowledge, thereby putting the greater scientific community at risk of using bad data to conduct future trials with equally at-risk patients. Thus, the result of the decision to allow or disallow physician incentives for enrollment could have profound effects for the future of clinical trial safety and viability.
III. Actions, Consequences and Decision

With the ethical issues established and the stakeholders identified, we can now move on to possible courses of action, and then make a decision as to which is the most ethical solution to the case study. As it stands, the two clear courses of action are to either continue to allow physicians to accept payments for enrolling physicians, or using a combination of institutional reform and legislation, ban the process entirely on the grounds that it is an unacceptable conflict of interest.

I believe that the correct decision is to forbid physician earnings for patient recruitment. The justifications for my decision are couched in modern and historic ethical guidelines for human research that, above all, emphasize the importance of patient safety during the course of a clinical trial. I believe that the financial incentive for patient recruitment represents an unacceptable breach of private industry into the domain of science, and that existing methods of disclosure do not adequately control this conflict of interest. It is worth noting that the use of the phrase “conflict of interest” is not meant to suggest that all conflicts between a physician’s primary duty to treat a patient and their secondary interest to increase their personal income are inherently unethical. However, in this specific case, the biases created by financial incentives that are intricately connected to the pace of the trial cannot simply be left at the door. Such incentives represent a partnership between physician and industry that occur at the expense of the patient. Not only does this qualify as malfeasence, but the concomitant pressure to recruit patients as quickly as possible pose a threat to the principle of respect for persons.

Of course, it is also necessary to examine how this decision may affect each of the three chief stakeholders. It is doubtful that being barred from offering incentives to physicians for patient enrollment will affect the pace of clinical trials. Recent studies into the effects of payment on clinical trial enrollment show that such incentive systems, despite their ethical cost, are generally ineffective at increasing recruitment speed. Thus, pharmaceutical companies can expect little change in the pace of their clinical trials. For physicians involved in research, such a change would set a precedent for increased government oversight over the safety of recruiting practices in clinical trials. Physicians may receive decreased supplementary salaries, but will gain the opportunity to champion recruiting processes that protect the safety of the patients and produce more valid, representative subject groups.

But the most important benefits of this decision are to the potential clinical trial participants. Their decision to participate in a clinical trial could be made without the fear that their physician may have ulterior motives. They would receive more accurate disclosure, plagued by less conflict of interest, in an environment free from their physician’s pressure to participate. Such a change to clinical trial recruiting practices would shift the focus once more to the population with the most to gain and lose from participation: the patients.

“it is doubtful that being barred from offering incentives to physicians for patient enrollment will affect the pace of clinical trials.”

References
11. Glass, H.E. “Higher Payments to Investigators Don’t Speed Study Completion,” Applied Clinical Trials

Charap is a sophomore Biology major from White Salmon, Washington interested in medical humanities and pre-medical studies at Davidson. This summer he will be researching as a fellow for the Duke-Davidson Immunology Partnership with Dr. Sophia Sarafova in the Biology Department.

The Medical Humanities Program at Davidson College

The Medical Humanities minor promotes an interdisciplinary understanding of health and health care. It enables students to appreciate the strengths and limits of the natural sciences, social sciences, and humanities as they seek to explain and to achieve a measure of control over disease, illness, and suffering.

The interdisciplinary minor helps students grasp how legal, economic, and political institutions influence the production, distribution, and delivery of health care services. It also provides students with the analytical and ethical skills necessary to apply the principles of scientific integrity in biomedical research.
Male circumcision is a common, though controversial, procedure usually performed during the newborn period in a male’s life (in the United States). Yet, should parents be able to consent to the procedure for their child without the child’s input? In this essay, I contend that parents are ethically allowed to decide whether or not to have their infant son(s) circumcised as long as their consent to the procedure is informed and the decision is made with the child’s best interests at heart. I will show that parents are the most able to decide how to act for their child’s welfare when considering factors not only of medical benefits but also of religious and cultural background, family implications, and maximal opportunity and choice in the future for the child. In the case of older males, “children who are able to express views about circumcision should be involved in the decision-making process” (Great Britain 1). Even if the boy in question is young and not considered lawfully competent to make a decision, the child’s expression of views should be taken into account when considering his best interests, and parents should act accordingly. In all cases of non-therapeutic (not medically necessary) circumcision, parents should make every effort to justify circumcision on the premise that it is best for their son.

In addition, both parents need to consent to the procedure if both are living and accessible. Informed consent of the parents requires information about both short and long-term benefits and risks of circumcision. The American Academy of Pediatrians (AAP) writes, “Evaluation of current evidence indicates that health benefits of newborn male circumcision outweigh the risks and that the procedure’s benefits justify access to this procedure for families who choose it” (“Circumcision Policy Statement” 585). However, in the Netherlands specifically and other regions of the world, there is less of a consensus on whether circumcision actually reduces risk of disease. The considerations parents should be informed of include: benefits of social connectedness associated with circumcision, decreased risk of some diseases, loss of autonomy and choice for the child, loss (or gain) of sexual function and procedural risks, psychological complications, and alternative treatments (ex. HPV vaccine to reduce risk of HPV instead of circumcision). It should be noted that complications are rare, but there are many studies that draw different conclusions about the benefits and drawbacks to circumcision, so parents should be exposed to a wide range of opinions and facts in order to make the most informed decision. Even Jews and Muslims, who practice circumcision for faith reasons, should be informed of the potential drawbacks of circumcision, just so they know what they subject their son(s) to and to make informed consent uniformly obtained from all parents deciding for their children. It is best for parents to make the circumcision decision on an individual basis, and in making the ultimate decision, parents need to demonstrate that choosing to circumcise is in the child’s best interests.

It is common practice in medicine to assume an infant’s incompetence in decision-making and delegate that authority to parents. In rare cases where parents and sons disagree (such as when a child rejects his parents’ religion and its practices), and sons are legally competent, “the wishes that children express must be taken into account. If parents disagree, non-therapeutic circumcision must not be carried out without the leave of a court” (Great Britain 3). There are some discrepancies about when a child becomes legally competent. There are instances, however, in which this parental right to make decisions for the child can be removed if the decisions made would be significantly detrimental to the child. In Britain, the BMA recognizes that “where children cannot decide for themselves, their parents usually choose for them” (Great Britain 3). There appears to be, in other countries as well, a trend of allowing parents to make medical decisions for their children before their children come of age. Consider the fact that parents already make many other (arguably less
controversial) decisions for their children’s medical care. Immunization is comparable in some ways to circumcision because it carries potential risks but also potential long-term benefits. Like immunization, many parents consent to circumcision, a somewhat painful (at least post-anesthesia) and risky procedure, on their children’s behalf without second thought. Applied to the United States specifically, parents must consider other factors besides medical benefits that go with circumcision such as ethnic, cultural, and religious traditions. Parents have the right to make medical decisions for their children, provided the decisions are informed, unanimous between parents (or else decided by a court of law), and work in the children’s best interests (briefly defined here as zero/little pain, no loss of function, sociocultural cohesion, and potential health benefits). Because circumcision is one of the most commonly performed medical procedures on the planet, parents’ right to decide for their children extends to it.

It could be argued that circumcision should be postponed until the child is ready to make that decision for himself. A premier medical society of the Netherlands, Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst (KNMG), takes the strongest stance in support of this opinion. The KNMG concludes that “there is no convincing evidence that circumcision is useful or necessary in terms of prevention or hygiene” (Netherlands 5). It finds even therapeutic circumcision in the face of adequate alternative treatments to be unethical. Surprisingly, the KNMG states that no doctor should perform a medical procedure on a child that has no therapeutic or preventative value, claiming, “After all, there is no culture that preventative deals with dirty ears by cutting them off” (Netherlands 12). Rightly, it is mentioned that urinary tract infections and HPV infections can both be treated by modern healthcare, either in the form of antibiotics or vaccines. The KNMG also elaborates on the medical and psychological complications that can result from circumcision, and it even makes a point that the death rate from the procedure is estimated to be 1 in 500,000. A child’s rights to autonomy and physical integrity are brought into question, and the comparison is made between female genital mutilation and male neonatal circumcision. Lastly, the KNMG points out that the right to religious freedom is also extended to children, so that they may choose to practice a different faith than their parents. Circumcision for religious reasons would violate a child’s religious freedom of choice. Thus, the Netherlands does not ban parents from choosing circumcision for their sons, but it does present the information in such a way that could bias parents toward choosing not to circumcise. This violates the parents’ ability to make informed consent, and it could harm children because parental decisions are not made in their best interests, but in the state’s.

In waiting to circumcise until adolescence or older, some of the benefits of circumcision are lost and new risks are gained. It may be true that circumcision need not be routinely recommended, but its possible medical benefits and religious purpose justify parents’ access to it for their son(s). Even the KNMG understands that because the practice is religiously rooted, it may never be fully eradicated, even if law prohibits it. Parents are best able to decide whether or not circumcision will help incorporate a child into a community; some even choose it because they want their sons to be like their fathers. Parents have a right to want this for their children, and it would seem that these desires are also in the best interests of their sons. Using the example of Jewish parents, the inability to decide at infancy (the 8th day of life) whether or not to circumcise their son would interfere with a tenet of Jewish life. Their son would be differentiated from his Jewish community, and a ban on parents’ right to decide would disrupt thousands of years of culture and would “essentially make the practice of Judaism illegal” (“German…” 1). To remove the discretion of parents in this matter would seem like an attack on this religious practice (Cypess 2). A last argument for parents’ right to decide to circumcise their son(s) is the fact that later life circumcision is a more complicated and risky procedure. “Waiting until the boy is twelve years old or more may mean losing benefits that circumcision was intended to produce” (Australia 15). Therefore, parents should retain the right to discretion in this case, because infancy may be the best time to circumcise, and a child cannot legally consent at that age. In most cases, giving decisional authority to parents on the subject of circumcision for their male children does not appear to wrongly violate the child’s autonomy, nor does it defy current ethical norms. Because most parents are able and indeed want to make choices that reflect their children’s best interests, and because the ethical guidelines of many regions of the world set a precedent that parents have the right to make medical decisions for their minor children, parents should have discretion in the instance of circumcision as long as their son is not of legal age. Arguments could be made against circumcision, and these could be used to persuade parents to wait and let their children decide for themselves, but these kinds of arguments may create unfair bias and block informed consent. In some cases, it may be more beneficial to the child in the long run to be circumcised as an infant, and whether or not the child agrees with the decision later on is irrelevant because the decision of the parents to act in the best interest of their child at the moment was inherently ethical. Parents can, should, and are ethically allowed to jointly offer informed consent for their male child to be circumcised or to withhold this kind of medical treatment.

References


Hunter is a junior Psychology major with a Medical Humanities concentration from Wilmington, NC. This summer he will be working as
On March 23, 2010, Congress adopted the Patient Protection and Affordable Care Act (ACA), a broad legislative initiative to overhaul the nation’s health-care system and regulations. One feature of the act is that it requires a general requirement that employer-sponsored group health care plans cover “preventive care and screenings,” as recommended by the Health Resources and Services Administration. These include approved contraceptive methods, sterilization procedures, and patient education and counseling for women in relation to reproduction. While some may contest that legislation like the ACA weakens individual liberties by disregarding business owners’ religious liberties, the ACA actually helps to promote individual liberties and does not infringe upon business owners. Contraceptive coverage should be mandatory for all health insurance policies, irrespective of business owners’ religious beliefs. Businesses should accept the ACA mandate for contraceptive coverage because it does not infringe upon First Amendment Rights, does not violate the Religious Freedom Restoration Act of 1993, and promotes competent scientific practices. Because the ACA does not infringe upon constitutional rights, supports valid scientific practices, and strengthens the patient-physician relationship, contraceptive coverage should be mandatory.

Since the nation’s founding, the Constitution has dutifully protected religious liberties as a personal right for citizens, yet businesses cannot take part in this constitutional tradition due to conflicts with the Free Exercise Clause within the First Amendment. Businesses lack reason, dignity, and conscience, distinctly separating them from fundamental human pursuits and the central pursuit of free exercise of religion (Wydra, 1-3).

For John Stuart Mill, a conscience is a force powerful enough as something that inflicts personal, internal harm if it is not followed (Mill). Consequently, a conscience is not the same as autonomy, for the being may risk guilt, shame, or pain from a lack of disregarding one’s conscience, whereas autonomy simply asserts that an individual has sovereignty. In Citizens United, the Supreme Court held that government entities cannot suppress political speech for corporations in accordance with the Free Speech Clause, but in July of 2013, the US Court of Appeals for the Third Circuit determined that “for-profit, secular corporations cannot engage in religious exercise” in Conestoga Wood Specialties Corporation v. Sebelius. As noted in Conestoga’s outcome reasoning, the purpose of the Free Exercise Clause is to secure religious liberty in individuals by prohibiting interventions from civil authorities. The court notes, “religious belief takes shape within the minds and hearts of individuals, and its protection is one of the more uniquely human rights provided.” This assertion of religious beliefs is deeply intertwined with Mill’s definition of a conscience, for individuals may feel that they have violated their conscience by violating a religious belief. Yet, the Tenth Circuit Court concluded in concurrence in 2013 regarding Hobby Lobby Stores, Inc. v. Sebelius that corporations simply do not exercise religion, for businesses are unable, apart from the actions of their owners and employees, to take religiously-motivated actions. Although business owners may hold personal religious convictions, Free Exercise protections do not extend to for-profit, secular cooperations. “Artificial being(s), invisible, intangible, and existing only in contemplation of law” are distinctly different from United States citizens seeking to exercise human rights with a defined conscience (Dartmouth Coll., 17 U.S. 518). Because the ACA does not require individuals who own businesses to personally provide health care coverage but rather only corporate entities, these businesses cannot be harmed by Free Exercise infringements or violate personal conscience.

Opponents of ACA note that the steep fines and penalties associated with failure to comply with the provisions of the contraceptive mandate infringe upon provisions set forth by the Religious Freedom Restoration Act of 1993 (RFRA). Making contraception coverage mandatory, however, is not in violation. RFRA is a federal law that seeks to prohibit laws that “substantially burden” a person’s free exercise of religion (RFRA, Sec. 3). The government may not substantially burden this exercise unless the violation is in accordance with approved exceptions. These exceptions are broadly defined that the law “is in furtherance of a compelling governmental interest” and “is the least restrictive means of furthering that governmental interest.” The Free Exercise Clause protects only beliefs rooted in religion; thus, the First Amendment would not cover sincere secular beliefs in this context (McConnell, 1417). Upon passing the ACA, debates regarding religious-employers received the most coverage, for while the law allows for churches and houses of worship to bypass the legislation, it does not leave room for conscientious objections. In order to understand the applicability of RFRA to corporations, religion itself must be defined. In a dissenting opinion in the US 7th Circuit, Justice Sykes writes:

“All of this reinforces what one would otherwise intuit about religion: that it is inextricably intertwined with characteristics that are uniquely human: conscience, belief, faith, and devotion” (Korte v. Sebelius, Nos. 12-3841 & 13-1077).

Although Justice Sykes dissented from the majority opinion, the reasoning poses unique implications. In this reasoning, corporations are unable to generate autonomous decisions in that religious faith cannot be incorporated as legal construct. This ideological backing is similar to Planned Parenthood v. Casey where it was asserted that, “At the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.” RFRA does not compel the individual owners to alter their own personal practices, but rather, it compels them to provide corporate health plans that in turn fund the insurance employees use to purchase contraception. As the American Civil Liberties Union notes in their amicus brief to the Supreme Court for Hobby Lobby Stores, Inc., v. Sebelius, the owners are only required to cover health insurance. Providing insurance plans does not place a “substantial burden” on the owners, and the decision to obtain contraception lies therein with the employee. RFRA does not protect individuals seeking to suppress the free-exercise powers of individuals who differ in religious or personal beliefs from the business owner.
Contestants of the ACA mandate claim that contraceptive coverage should not be supported as many forms of contraceptive are linked to abortive practices. In October 2013, Senator Ted Cruz of Texas told attendees of the 2013 Values Voter Summit that the ACA was “forcing... businesses like Hobby Lobby to provide ‘abortifacients’” (Bassett, 1-2). In 1976, Congress drafted and passed the Hyde Amendment in order to ensure that abortion is not covered through Medicaid health care services, a federal government program (National, 1). Although the ACA does require employers to cover birth control and emergency contraception, businesses are not required to cover RU-486, the abortion-inducing medication that is often mistaken for emergency contraception. Many politicians contest that emergency contraception causes abortions by preventing implantation in the uterus, but this is rooted in outdated and incorrect understandings of contraception. Most drugs under the ACA delay ovulation; thus, these drugs prevent the creation of fertilized eggs. In its amici curiae brief on behalf of petitioners for Sebelius v. Hobby Lobby, Inc., the Physicians of Reproductive Health et al. defined abortifacient as the termination of a pregnancy. They state “contraceptives that prevent fertilization from occurring, or even prevent implantation, are simply not abortifacients” (Sebelius v. Hobby Lobby Stores, Inc., No. 13-354). Although there was initial confusion regarding contraceptives, these products are now understood to prevent fertilization. Emergency contraception methods are not abortifacients, and abortifacients are not covered under the ACA.

Providing contraceptive coverage furthermore strengthens the patient-physician relationship and individual autonomy, for the mandate emphasizes that medical decision-making should occur between patients and their physicians. Autonomy is defined as sovereignty over one’s body and is often cited as a basis for promoting conscientious objections; thus, business owners may feel that due to personal autonomy, they are able to ethically refuse coverage for employees (Wicclair, 212). Yet, this principle also applies for employees. In a statement regarding Sebelius v. Hobby Lobby Stores, Inc., White House press secretary Jay Carney noted, “As a general matter, our policy is designed to ensure that health care decisions are made between a woman and her doctor. The president believes that no one, including the government or for-profit corporations, should be able to dictate those decisions to women” (Office, 1). The ACA ensures that women’s personal health and beliefs cannot be subjected to business owners’ beliefs and allows for women to make medical decisions with their families and primary physician. Only physicians have the capability to maintain expert, diagnostic knowledge, self-regulation to understand what is best for the patient, and the historic understanding regarding the principle of duty to treat for their patients. Businesses cannot make personal health decisions on behalf of their employees or intervene within the special relationship between patients and physicians, as they do not have the relevant professional knowledge to decide what is best for patients. The medical profession is distinct from business professions.

Contraceptive coverage should be mandatory for all health insurance policies irrespective of business owners’ personal religious beliefs. Because business owners may use their own religious beliefs to deny health insurance benefits to their employees, conflicts regarding autonomy emerge. Should the US enforce the contraception mandate, it should continue to not cover RU-486 under the ACA or other abortion-inducing medications. While some may view the position of a corporation as modeling that of a human similarly in relation to infringement on religious liberties, it is evident that corporations cannot enjoy full protection of constitutional liberties, as they lack certain defining characteristics to be considered “human.” Consequently, the ACA does not infringe upon provisions set forth by the First Amendment or RFRA, as the businesses and corporations subject to the contraceptive mandate hold distinct behaviors and traits that distinguish them from acting as parties that can be placed under “substantial burdens” under law. Employers and employees alike can view the incorporation of the contraception coverage mandate as an expansion of professionalism for doctors and enhancement of the special relationship shared between patients and physicians. Thus, it is within the interests of both business owners and their employees throughout the United States to support the contraceptive mandate within the ACA.

References
Conestoga Wood Specialties Corp. v. Sec’y of the United States HHS, No. 13-1144, UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT, 724 F.3d 377; 2013 U.S. App. LEXIS 15238
Hobby Lobby Stores, Inc. v. Sebelius, No. 12-6294, UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT, 723 F.3d 1114; 2013 U.S. App. LEXIS 13316
Tn. of Dartmouth College v. Woodward, SUPREME COURT OF THE UNITED STATES, 17 U.S. 518; 4 L. Ed. 629; 1819

Cleck is a sophomore Psychology major with a Medical Humanities concentration from Goodlettsville, TN. This summer she will be working as a Vann Fellow in Bioethics at the Mayo Clinic.
Since 1988 Davidson College and the Carolinas Health Care System have jointly sponsored the Frederick Womble Speas Symposium funded through the generosity of the R. Dixon Speas Family.

April 30th, 2014 at 4:30pm in the Semans Auditorium of the Visual Arts Center, Davidson College

Keynote Speaker:

Marion Danis, M.D.
Head of the Section on Ethics and Health Policy in the Department of Clinical Bioethics in the Clinical Center of the National Institutes of Health
Chief of the Bioethics Consultation Service at the Clinical Center

The event is free and open to the public.

If you would like to respond to any of the articles or issues presented in this edition of The Ethical View, please send responses to:

The Ethical View
c/o The Medical Humanities Program
Davidson College
P. O. Box 7135
Davidson, NC 28035-7135

Or if you prefer, send e-mail to medicalhumanities@davidson.edu

If you know someone who would like to receive The Ethical View, please contact the Medical Humanities Program by mail or e-mail.