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FEATURE ARTICLE

Neuroethics: What It Is, Does, and Should Do

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Neuroethics is an interdisciplinary field that (1) engages scientific investigations of neuro-cognitive processes involved in moral thought and action, and (2) addresses ethical, legal and social issues generated by brain research, its varied applications, uses and misuse. The late Edmund Pellegrino considered neuroethics to be a "hyphenated ethics" in which the prefix subject (here, 'neuroscience') is analyzed with the resources and techniques of ethics. This capacious view certainly allows deliberations about ethical implications of neuroscience and neurotechnology – hereafter, 'neuroS/T' – as well as reflections on neuroscientific implications of our self-understanding as persons bearing moral value.[1] Moral philosophy, virtue traditions, professional ethics, patient advocacy, public policy, and legal perspectives are each intrinsic to the scope and practices of neuroethics.

Neuroethics has close academic company. Similar fields are confronting problems arising in and from cutting-edge human research, and its iterative and inventive uses. Medicine is paired with the ethics of medicine, genetics is paired with the ethics of genetics, and so forth. Research ethics is a well-established field in its own right, capable of addressing many issues fostered by the conduct of brain science. To be sure, there is considerable ethical expertise already well-positioned for dealing with the impact of technology on all areas of society. Placing "ethics of" in front of a scientific discipline might keep things simple; "the ethics of neuroscience" might have sufficed as both fitting under bioethics and ultimately covered by applied ethics. That approach presumes that ethics is a stable and independent field setting principled standards for rightness and goodness, ready for application to particular cases in a deductive manner.

But we believe that neuroethics does not fit well with a mere top-down approach. The brain sciences, from psychology and cognitive science to neurology, are questioning whether the human capacity for ethics is mainly about

principled rules. These fields are also investigating how moral judgment typically functions in real-world situations. How people actually form and act on moral judgments may provide information sufficient to place in doubt those ethical theories still grounded on outdated moral psychology.[2] Neuroethics – as a discipline and set of practices – should avoid an awkward reliance on ideas about moral thinking that ends up discredited by cognitive neuroscience. Sound approaches to ethics need not suffer that fate, so neuroethics will have sufficient ethical resources. Still, the larger question remains, whether neuroS/T can be pursued ethically.

Ethical Challenges

Perhaps the potential for re-configuring humans' (and other organisms') neurological function through the use of new techniques and technologies is what is most worrisome about brain research.[4] Both the methods of brain research, and new neuroS/T applications, are marvels of engineering innovation. Investigating the structures and functions of the brain at ever-increasing levels of granularity requires more capable (if not intrusive) methods, and greater intervention and alteration of neurological processes. So, while important non-invasive assessment tools, such as neuroimaging and neurogenetics, will increase in sophistication, dynamic and real-time alterations of brain network activities will be of equal (if not greater) importance for acquiring more precise insights into neurological architectures and their respective roles.

For example, forms of transcranial modulation, such as transcranial electrical and magnetic stimulation (i.e. tES and TMS) can be employed to modify neural activity to discern effects at targeted and interconnected areas, to discover how and why those areas participate in various cognitive operations and behavioral actions. Even greater specificity of both assessment and control of fine-scale neural networks is being achieved through the use of implantable devices that are capable of recording and stimulating brain structures and functions, the effects of which can be manifest on a variety of levels, from the cellular to the social. Thus, it becomes important to acknowledge the limitations as well as the capacities of these approaches if and when the information they yield is used to infer, describe or define meanings of normality and abnormality that can be used in medicine, as well as legal and political spheres.

This is not unlike monitoring and/or tinkering with a motor's parts to observe how engine performance is affected. If the nervous system is treated like a repairable and adjustable mechanism, then neuroethics can look to topics and methods in engineering ethics that are applicable to "the human machine." Some developments, such as neuroprosthetics and brain-machine interfaces, could clearly be referred to, and gain benefit from, an engineering ethics approach. However, humans, like all organisms, are not machines. Morality won't be reducible to biomechanics. While the use or abuse of technology remains focal to neuroethical address, neuroethical issues will have deeper philosophical implications than most technological problems.

The Need for Watchful Scrutiny

Indeed, we are far more than machines. The point to ethics, one would expect, is to uphold our status as moral agents, worthy of morality's protections against harm and degradation. Technosciences of vast import, such as neuroscience, should arouse thoughtful oversight. That oversight can broaden beyond the amazing applications able to change our lives, to include questions

about how the adoption of those technologies can change conceptions of what human beings are, and what we should be. It is not necessary to view the nervous system as mechanical to understand why alterations to our brains could easily alter who we are as persons. Some neurological adjustments will be welcome, but we must be vigilant about undesirable consequences. NeuroS/T will help alleviate neuropsychiatric disorders, pain, suffering, and sadness, and contribute to optimizing our capabilities. Alterations to brain functioning may also disrupt our mental well-being, and distort our sound self-understanding.[5]

We do not wish to sound too alarmist. It is unnecessary (and probably in error) to suspect that all neuroS/T invites unnatural abominations in order to judge, as we do, that a wary stance of preparedness is warranted. Neuroethics must be part of the watchful scrutiny that checks for unwanted deviations from psychological health and civil conduct.[6] Neuroethics as an academically *and* ethically responsible field must ponder what it means to be a human being, and a personal self.[7] Shall the implementations of neuroS/T be encouraged to the point of transforming this "self" into just another adjustable implement, redesigned for whatever specialized work may be wanted? Perhaps not, but only an adequate theory of the self can explain why not. Neuroethics directly overlaps with, and vitally contributes to medical humanities, philosophy of technology, philosophical psychology, philosophical ethics, and biopolitics.

While neuroethics is a specialized domain of ethics and bioethics, it need not, and should not, be entirely subsumed under these or any other disciplines, any more than mind can be reduced to the brain. Rather, neuroethics works best in conjunction and collaboration with many other fields. Neuroethics belongs wherever neuroS/T is investigated, translated for clinical application, applied in non-medical settings, and adopted into wider use. It is relevant anywhere that the information and tools of neuroscience, from diagnostic methods to medical devices and consumer products, may be beneficially used or dangerously misused within society.[8] Neuroethics can provide timely guidance about the genuine meaning and import of discoveries and advances in the brain sciences. Accurate interpretations to promote public understanding need to keep pace with exciting headlines from science journalism. Clarifying and cautionary neuroethical advice is also highly valuable in policy, legal, and military contexts.[9] It should have both an educational and evaluative role everywhere it is needed.[10]

The Global Context: Toward a Cosmopolitan Palette

The acceleration of exploratory brain research and novel neuroS/T is occurring in many countries. Major governmentally-funded research initiatives are underway, including the U.S. BRAIN Initiative, the EU Human Brain Project, the China Brain Project, the Japan Brain MIND Project, and the South Korea Brain Initiative. Therefore, neuroethical discussions must be international, both in scope and in spirit. No country's moral and legal framework will be able to dictate the plan or pace of another country's research project.[11] Neuroethics should not proceed as if domestically familiar standards are straightforwardly applicable anywhere on the globe. Philosophical ethics can be more sensitive and responsive to differing socio-cultural contexts, values, and contingencies. In that spirit, neuroethics can and should be cosmopolitan.[12]

A cosmopolitan palette of neuroethical capabilities must be applicable at community,

national, and cross-cultural scales. Protecting rights of experimental subjects and recipients of clinical treatments must be prioritized, while developing nuanced ethical analyses that consider local values and norms. Parochial moral rigidity will have little relevance or influence, as brain research and neuroS/T products are rapidly developed and utilized on global scales. What major moral issue, or any health issue, stays confined within a country's borders anymore? Moral imperialism will not work, but neither will simplistic moral relativism. A resigned attitude towards cultural isolation cannot be wise where humanity's self-understanding and future flourishing is at stake.

The academic cooperation that characterizes neuroscientific research, and especially ambitious projects conducted by international teams, provides a teamwork model for cosmopolitan neuroethics. On the 21st century global stage, cultural differences can be a resource of ethical strength, because no single wisdom tradition has yet encountered all the possibilities evoked by emerging developments in neuroS/T. The appropriate application of moral concepts and ethical principles will require continual review and revision. What constitutes effective autonomy, for example, will evolve along with the expanding capacities acquired by users of neuroS/T. The supreme principles inherent to ethical wisdom won't be replaced, but their practical fulfillment will demand creativity, cooperation, and courage.[13]

Dialogues have to be open and inviting. Ultimately, ethics is a matter of public discourse. An authentic neuroethics must both keep pace with the science that is its subject, and remain responsive to the publics that are affected by – and which affect – the scope, conduct and outcomes of brain science. In this way, the endeavor of neuroethics cannot be static: it must entail ongoing education, training, and support of institutions and individuals dedicated to its practices. Efforts toward such support have been encouraging, but must continue and grow. Simply put, there is neither time nor latitude for ethical lassitude, given the pace and breadth of international brain science.[14] The main goal is acquire deeper insights to new developments in neuroS/T, their meanings, probable use, and possible misuse, and to foster preparedness so as to identify, prevent, or at least enable effective response to burdens, risks and harms. Thus, what neuroethics is, and what it does, will, and should remain a work-in-progress.

Acknowledgments

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[2] Testing views in moral psychology, and improving them, through a comparison with neurological findings is neither easy nor uncontroversial, but it is not impossible. Consult differing stances taken by contributors to *Moral Brains: The Neuroscience of Morality*, ed. S. Matthew Liao (New York: Oxford University Press, 2016). See also James Giordano, Kira Becker, and John R. Shook, "On the 'neuroscience of ethics': Approaching the neuroethical literature as a rational discourse on putative neural processes of moral cognition and behavior." *Journal of Neurology and Neuromedicine* 1, no. 6 (2016): 32-36.

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FEATURE ARTICLE

Ethics in Virtual Care: Promoting Catholic Identity through Technology

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"Once we developed telehealth technology, we had an ethical responsibility to use it for the benefit of marginalized persons," said Deanna Larson, CEO of Avera eCARE®. And, with their signature blend of determination, creativity and technological prowess, the Avera eCARE team proceeded to do just that. The result? A multifaceted virtual health ministry which reinterprets Jesus's command "Go and do likewise" by extending services across geographic, socioeconomic and cultural boundaries. Through technology, Avera's mission of positively impacting the lives and health of persons and communities has been realized in new and evolving ways. And Avera's experience is not unique. During recent years, many Catholic systems throughout the country have implemented telehealth programs that provide healthcare services to populations in need.[1]

Fundamentally, ethics is about fidelity to one's identity, and for Catholic healthcare, this means faithfully embodying "Christ's healing compassion in the world."[2] Of particular importance to Catholic identity is the service provided to "those people whose social condition puts them at the margins of society and makes them particularly vulnerable to discrimination: the poor; the uninsured and underinsured; children and the unborn; single parents; the elderly; those with incurable disease and chemical dependencies; racial minorities; immigrants and refugees ... and person[s] with mental or physical disabilities."[3] Not only has telehealth enabled Catholic ministries to reach these special populations, the technology has provided a number of unexpected advantages for doing so.

Immediate Availability of Colleagues: "I knew I would never be alone."

If, as Scripture scholars tell us, the most oft-repeated phrase in the Bible is God's command, "Be not afraid," God's enduring promise, "I am with you," must be a close second. The promise was first manifested in the Old Testament through God's accompaniment of the chosen people, and later took on special significance with the coming of Emmanuel, "God with us." In the midst of the world's suffering, Jesus was "with" humankind, teaching, healing and ministering. And, at the conclusion of his earthly ministry, Jesus commended the promise to all generations proclaiming, "I am with you always, until the end of the age."[4]

Telehealth technology enables healthcare providers to "be with" one another, providing technical expertise and moral support, while

creating "a community that provides healthcare to those in need of it."[5] Hospitals and clinics supported by telehealth have immediate access to board-certified physicians and experienced healthcare professionals from a variety of disciplines. For this reason, many critical access hospitals utilize telehealth in emergency departments to ensure 24/7 provider coverage. A recent survey of Avera's 150 eCARE Emergency sites indicated that in 30 percent of the cases, the local emergency provider was not on site when eCARE was contacted, and that it often took 30 minutes or more for local providers to arrive at the hospital after being called in. Fortunately, the immediate availability of eCARE clinicians ensured that necessary treatment was implemented without delay. The following story from Avera eCARE Emergency bears witness to the power of accompaniment through telehealth.

"We were called by one of our critical access hospitals that was about to receive multiple patients injured in an explosion," said Avera eCARE Emergency Medical Director, Dr. Kelly Rhone. "There were going to be at least five patients, including two who were critically burned and one who had actually been on fire. We knew that the care of these patients would quickly overwhelm that emergency department, so immediately we began calling down their disaster tree and calling in any hospital staff who could lend a hand. At the same time, we dispatched two of Avera's Careflight aircraft in order to provide the hospital with transfer support as well as critical care nurses and paramedics who could assist at the bedside."

"As the patients started to arrive, the ED clinicians put those who were most critical in front of the camera so that the eCARE team could assist the bedside staff with decisions such as where to place an IV in a patient who doesn't have much skin, how to maintain airway support, and the amount of fluid needed for resuscitation. Because we knew that these patients would be transferred to tertiary facilities, the eCARE team notified regional trauma and burn centers about the impending transfers, and the conditions of the patients. This freed up the bedside staff to focus on providing hands-on care."

"A couple months later, we learned that a locum tenens physician who had been working at the hospital during the explosion incident decided to sign a contract with that facility. In explaining her decision, the physician specifically mentioned the 24/7 support available from Avera eCARE stating, 'I knew I would never be alone.'"

Preventing Workplace Violence: "Would you like us to call Nora?"

Healthcare employees are among the occupations most likely to experience workplace violence, which is perpetrated by patients, visitors, intruders and coworkers. Rates of workplace violence in healthcare are significantly higher than for any other industry, and healthcare accounts for nearly as many workplace-violence-related injuries as all other industries combined.[6] Workplace violence results in physical and emotional injury, time away from work, moral distress, burnout, and employee turnover.

During recent years, the Centers for Disease Control and Prevention and Occupational Safety and Health Administration of the U.S. Department of Labor have prioritized efforts to address the rising epidemic of violence against healthcare workers. In 2010, The Joint Commission issued a *Sentinel Event Alert*, "Preventing violence in healthcare settings" which was updated in 2017. The Joint Commission also sponsors a web portal of resources for workplace violence prevention in healthcare.[7] Similarly, the

Ethical and Religious Directives address the responsibility of Catholic healthcare organizations to provide "a work environment that ensures employee safety and well-being."[8]

Because a high percentage of healthcare workplace violence occurs in emergency departments, Avera eCARE Emergency has established a communication code for situations which become volatile or dangerous. The eCARE team will ask the on-site providers, "Would you like us to call NORA?" which stands for "Need an Officer Right Away." If the hospital staff respond affirmatively, the eCARE team notifies local law enforcement about the need for assistance in the emergency department.

Two recent incidents highlight the danger of workplace violence committed by inmates who have been transported to hospitals for medical treatment. On May 13, 2017, an inmate who had been hospitalized at Northwestern Medicine Delnor Hospital in suburban Chicago was unshackled after he requested to use the restroom. While unshackled, he grabbed the attending sheriff's pistol and took two female hospital employees hostage in a treatment area. According to news reports, the hostages were both threatened and beaten, and one hostage was repeatedly raped at gunpoint. During the incident, a section of the hospital was evacuated while hostage negotiators talked for several hours with the inmate. After negotiations broke down, the SWAT team entered the room, then shot and killed inmate. One hostage was struck in the arm by the bullet that killed the inmate.[9]

Less than a month later on June 7, a convicted murderer was taken to Joliet Presence St. Joseph Medical Center for treatment. While at the hospital, the inmate displayed a makeshift weapon and informed the assigned officer and a nursing assistant that they were being held hostage. The Joliet police responded to the incident, apprehended the inmate, and freed the hostages who were physically unharmed.[10]

One way to decrease the security threat posed by inmates is to increase the capability for medical treatment to occur within correctional facilities through telehealth technology. During its initial years of its operation, Avera eCARE Correctional Health has reduced the necessity of transporting inmates to outside clinics and hospitals by 50 percent, saving millions of taxpayer dollars. "We're always looking for new and better ways to keep inmates inside our correctional facilities for security reasons. With eCARE's technological capabilities it's now much easier, safer and more secure, and cost-effective to do that while still providing exceptional healthcare," said Kayla Tinker, Correctional Health Administrator for the South Dakota Department of Health. And, because of the safety and convenience of tele-correctional health, more clinicians have been willing to participate in caring for inmates, thus further promoting quality care.[11]

Although not specifically mentioned as a vulnerable population in the *Directives*, inmates are disproportionally represented by racial and ethnic minorities, persons who are mentally ill, and the poor.[12] Interacting with inmates has been one of the hallmarks of Pope Francis's papacy, beginning with his much-publicized washing of prisoners' feet during a 2013 Holy Thursday Mass, just two weeks into his tenure. Since then, Francis has visited prisons throughout the world, invited prisoners to dine with him, celebrated Mass in prisons, and advocated for prison conditions "that are worthy of human persons."[13] Certainly, ensuring that prisoners have access to timely and exceptional

healthcare contributes to conditions that foster human dignity.

Creating a Safe Space: "It was the first time I had ever seen the whites of his eyes."

As a psychiatric nurse practitioner serving a sparsely populated multi-state region, John Erpenbach has logged tens of thousands of driving miles during his 35-year career. Therefore, when the opportunity arose in 2015 to join Avera eCARE's Behavioral Health team located in a Sioux Falls facility just 15 minutes from his home, Erpenbach jumped at the chance. Along with psychiatrists, psychiatric social workers, nurses, and counselors, Erpenbach provides psychiatric assessment, medication management, and treatment recommendations for patients in hospitals, long-term care facilities, and community settings throughout the country. As well as saving wear-and-tear on his vehicle and decreasing nonproductive driving time, telehealth technology has eliminated weather and transportation-related appointment cancellations. More importantly, working with eCARE Behavioral Health has allowed Erpenbach to continue caring for three dozen developmentally disabled adults who live in community 75 miles from Sioux Falls.

"It was the first time I had ever seen the whites of his eyes," said Erpenbach, of Richard (not his real name), a patient whom he has been treating for the better part of two decades. "Richard is severely autistic and when we used to meet in person, he would look down at the floor during the entire appointment. However, since our first telehealth meeting, Richard has consistently made eye contact with me. Communicating through the video camera has provided a level of comfort he didn't experience when we were in the same room." Erpenbach has noted a similar dynamic with several other of his severely autistic patients.

In addition to creating a safe space for persons with autism, tele-behavioral health has enabled greater anonymity and confidentiality for persons seeking mental health and addiction treatment. Rather than being seen entering mental health or addiction treatment clinics—which identify the conditions for which they are being treated—persons may avail themselves of telehealth services at locations where a wide variety of healthcare services is provided.[14] Addiction researchers have suggested that the availability of telehealth—and even the use of avatars in a virtual space—has positively impacted client engagement in the recovery process.[15]

Supporting Aging in Place: "Doc in the Box"

During the early years of telehealth, questions arose about whether technology could mediate personal presence sufficiently to establish and maintain a therapeutic provider-patient relationship. Healthcare has always been a high-touch endeavor, and through the centuries it has also become an increasingly high-tech one. Despite advances in technology, the relationship between patient and care provider remains central. "The Church's moral teaching on healthcare nurtures a truly *interpersonal* professional-patient relationship [italics added]."[16] And, although close physical proximity between a provider and patient may facilitate interpersonal interaction, a therapeutic relationship and effective communication are possible even in the absence of such proximity.

Personal "presence is frequently treated as consisting of spatial or physical presence, and social presence. The former is 'the sense of being in a virtual place,'...ways in which our

perceptions and actions create a sense of space;' the latter is 'the sense of being together with another.'"[17] Researchers agree that personal presence falls along a continuum. The degree to which personal presence is experienced depends upon the degree of physical presence combined with the degree of social presence.[18] Physical presence may be engendered by being bodily in the same room as another person, as well as through the mediation of technologies such as interactive online forums and videoconferencing. Social presence implies interaction between persons. Activities such as in-person dialogue, phone conversations, and "interaction with a virtual or remotely located communication partner"[19] ostensibly facilitate a sense of social presence.

Also, the degree to which persons *intend to be and are present* to one another is directly proportional to their experiences of personal presence. In other words, the more a person is paying attention to, emotionally engaged with and responsive toward another person, the greater the degree of personal presence being mediated. The fact that persons are not within close physical proximity of one another does not preclude a significant experience of personal presence. Technologies like videoconferencing—by which both verbal and "non-verbal communicative clues, such as gaze, direction or posture" are conveyed—have the potential to mediate a high degree of personal presence.[20] Conversely, persons who are in close physical proximity but who are ignoring one another may experience a very low degree of personal presence.

In order to facilitate personal presence and therapeutic communication on the part of eCARE staff, Avera enlisted the expertise of a former television news reporter who assisted in developing a training video about on-camera presentation that is used for new employee orientation. Topics covered include facial expressions, tone of voice, body language and empathetic communication techniques. Staff are also trained in the use of two-way video cameras with an emphasis on safeguarding patients' dignity and privacy. The consistently high eCARE satisfaction ratings from both patients and providers attest to the effectiveness of telehealth to facilitate therapeutic interactions.

Because today's senior citizens did not grow up with virtual technology, presumably they might have more difficulty adjusting to telehealth than younger generations. "In my experience, seniors have been very adaptable to telehealth," said Michele Snyders, LCSW, who serves in Avera's eCARE Senior program. The program provides the expertise of board-certified geriatricians and geriatric-trained nurse practitioners, pharmacists, nurses and social workers to long term care facilities in a multi-state region. Residents of these facilities have affectionately dubbed the telehealth technology "doc in the box" because the eCARE clinicians appear on a large flat screen monitor mounted to a wheeled cart. The mobility of the cart enables telehealth encounters to occur in the privacy and comfort of the resident's room, as well as in other locations throughout the facility. "One time I had pneumonia and the staff was able to wheel the equipment right in my room so I could see the provider," said a resident. "I can see how this impacts quality because of the access to knowledge and how quickly they can come up with the medication needed. It makes healing faster because you don't have to wait to get into the doctor's office."

Another Voice for Difficult News: "I lost my words."

Telehealth provides an extra set—or more—of eyes on the patient, as well as the expertise of board-certified and experienced clinicians who can remotely monitor vital signs and lab values, screen for high-risk conditions, research diagnoses, evaluate and recommend pharmaceutical interventions, and assist with communication and patient transfers. The geographic distance that often exists between telehealth clinicians and the patients they support undoubtedly allows for greater objectivity on the part of these clinicians. Indeed, patients are less likely to have personal relationships with telehealth clinicians located in another town or state, than they are with healthcare providers who work locally. Within smaller communities, it is not uncommon for providers to care for their own neighbors, friends and even family members.

The relative objectivity of telehealth clinicians may enable them to break bad news to the patient more readily than providers who live in the patient's community. Studies have suggested that the length of the provider-patient relationship is a variable affecting the accuracy of mortality predictions; the longer the relationship, the more likely that the provider's prediction will be overly optimistic.[21] Avera eCARE clinicians have experienced this situation in emergency department and ICU cases. On more than one occasion, the eCARE clinicians have diplomatically broached the subject of mortality when the local provider seemed reluctant to do so. After one such case, the local provider later called the eCARE clinicians to express gratitude for their candor. The local provider explained that she had a longstanding relationship with the patient and his family which made it very difficult to raise the issue of mortality. "I lost my words," she said.

eCARE Senior Care is another telehealth program in which discussions about mortality frequently occur. Avera utilizes admission reviews to identify long term care residents who are at higher risk of hospital readmission and/or death. Once identified, a resident is closely monitored and managed according to established protocols. In order to foster appropriate treatment, the medical record is reviewed to ensure that advance directives are documented, and that they accurately reflect the resident's current condition and wishes. Also, eCARE clinicians provide continuing education and support to facility staff who assist residents and their healthcare surrogates with advance care planning.

Managing High Risk and Chronic Conditions: "It was like having a big sister looking over my shoulder."

With the shift to population health management, telehealth enables ongoing monitoring, support and treatment of high-risk and chronic conditions in patients' homes, workplaces, and other community-based settings. One such condition is gestational diabetes mellitus, which affects 7 percent of pregnant women nationally and increases the risk of serious perinatal complications including premature delivery, large for gestational age infants, respiratory distress syndrome, brain injury, fetal demise and serious maternal complications. Infants who do survive are at increased risk of chronic disease later in life, as are women who have had gestational diabetes. Like Type 2 diabetes, the condition disproportionately affects women of color.[22] Fortunately, with early identification and tight blood glucose control, many of these risk factors can be mitigated and even eliminated.[23]

To effectively manage gestational diabetes, evidence-based protocols suggest that a certified diabetes educator (CDE) and/or

registered dietitian work concurrently with the patient's obstetrician or primary care provider to monitor blood glucose on a regular basis, provide nutritional counseling, and recommend medication if dietary modifications are not sufficiently effective. However, many women don't have ready access to specialty healthcare providers due to geographic isolation, lack of financial resources, transportation issues, and a shortage of qualified healthcare professionals. In collaboration with the Health Resources & Services Administration (HRSA), Avera eCARE launched the eGDM Program in November 2016 aimed at managing gestational diabetes mellitus through telehealth technology.

Women newly diagnosed with gestational diabetes are connected within one business day to a coordinated team of eGDM Program specialists (maternal-fetal medicine nurse practitioner, CDE who is typically a registered nurse, and a registered dietitian) via a smartphone, tablet or computer. Patients who don't have such devices are provided with cell phones funded from the HRSA grant. The grant also funds glucometers and test strips which the patient is trained to use for blood glucose monitoring four times per day. Results are uploaded via Bluetooth to a cloud platform checked daily by eGDM clinicians who immediately contact the patient in the event of three elevated readings. "It was like having a big sister looking over my shoulder," said one patient. "I was very motivated to eat healthy because my blood sugars were being reported to the team every day."

When diet alone isn't sufficient to control blood glucose, the patient is scheduled for an appointment with the MFM nurse practitioner. Insulin is often the first choice when medication is indicated, and insulin education is provided via Avera's virtual platform. In addition, patients meet virtually with the eGDM clinicians on a weekly or biweekly basis for a 10-15-minute appointment. These virtual appointments can occur at times and locations—such as home or workplace—that are convenient to the patient and don't require travel or time off from work. Patients also have access to brief (1-3 minute) educational videos about diet, exercise, breastfeeding, and healthy habits that can be viewed at the patient's convenience.

Such ongoing monitoring and timely intervention facilitate the tight blood glucose control necessary to minimize and avoid serious complications. Results from the eGDM Program's first year of operation indicate significantly lower rates of maternal and neonatal complications as compared to historical baseline data, and very favorable patient satisfaction ratings. Efforts are currently underway to expand the use of this technology to other aspects of obstetric care.

Fostering a Culture of Encounter: Influencing the Healing Profession

In light of current and impending healthcare professional shortages, an aging population, and evolving reimbursement paradigms, telehealth is able to deliver high quality care that is often more affordable and accessible than traditional in-person delivery models. Also, as has been demonstrated by Avera eCARE, opportunities to practice virtually may increase the productivity of healthcare professionals who previously commuted long distances between practice sites, extend the careers of those nearing retirement age, and encourage more clinicians to consider treating marginalized populations, such as inmates.

Because many of the hospitals, clinics and prisons supported by Avera's telehealth

programs are secular, collaborations with these entities have created opportunities for Avera "to witness to [its] religious and ethical commitments and so influence the healing profession."[24] Staff at local hospitals have commented about the compassion and support experienced from eCARE clinicians, and have asked clinicians to pray with and for them during particularly challenging cases. After such cases, Avera has arranged for counselors to provide critical incident debriefings to local staff, as well as chaplains who provide spiritual and emotional support.

Throughout his papacy, Francis has called the Church to foster "a culture of encounter" that reflects "Jesus' encounter with his people; the encounter of Jesus who serves, who helps, who is the servant, who lowers himself, who is compassionate with all those in need"[25]. Virtual technology has enabled Catholic healthcare organizations to foster such a culture by extending the healing ministry of Jesus in new ways across geographic, socioeconomic and cultural boundaries. In many circumstances, virtual technology may be the only means whereby persons can encounter Catholic healthcare and, perhaps, any form of accessible healthcare. Finally, collaborations in which Catholic ministries provide telehealth support to secular entities "can help implement the Church's social teaching, ...realign the local delivery system in order to provide a continuum of health care to the community; [] witness to responsible stewardship of limited health care resources; and [] can be opportunities to provide to poor and vulnerable persons a more equitable access to basic care."[26]

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FEATURE ARTICLE

A Status Report on Stem Cell Research and its Implications for Catholic Health Care

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Introduction

The Catholic health care system has led the field of medicine by recognizing the need to treat patients in a holistic way, recognizing their dignity as children of God. Catholic health care acknowledges the spiritual needs of patients, and values people over technology and the financial bottom line. The church has also been the voice of truth and medical ethics in a world which increasingly values a person based on their abilities instead of their innate worth. These values animated our founders and the Catholic identity that they nourished over centuries. Their legacy, however, faces real challenges from secular attitudes, financial challenge and some scientific advances.

Declining reimbursement from Medicare, Medicaid and insurance companies are placing hospitals and physician practices at risk (1). At the same time, the reimbursement system is moving away from fee-for service model to a value-based system (2). Patients are increasingly becoming more consumer oriented (3).

Hospitals and physician practices have seen significant income losses because of incremental underpayments and uncompensated services along with increased cost from regulatory compliance (4). To maintain their economic viability, hospitals have acquired medical practices in which physicians are now employees. This new business alignment has changed the traditional physician's autonomy. According to a survey by the American Medical Association in 2016, forty-seven percent of medical practices are now hospital owned (5). The consolidation between hospitals and physician practices, along with increased consumer expectations, now create greater demands from hospitals to meet the consumer's demand for high quality medical technology.

- Consistent with advances in medical technology, biotechnology has dramatically evolved over the past several decades and has been greatly influenced by secularism. Morally illicit cells and tissues are now ubiquitous in medical research and pharmaceutical drug development. Moreover, it is anticipated that the introduction of biotechnologies like stem cell technology, gene therapy, biologics, methods in small molecule drug development and vaccine

manufacturing will increasingly require using human tissues and cells that have been obtained in ways that are inconsistent with the Catholic Church's moral teaching. Let me begin with an overview of stem cell research.

Definition and Types of Stem Cells

Stem cells have the ability for self-renewal and differentiation into specialized cells. Stem cells are categorized by the tissue source by which they are derived and are found in a variety of tissues such as bone marrow, fat, placenta, umbilical cord and umbilical cord blood. Essentially every organ has resident stem cells. Stem cells are also characterized by their ability to differentiate into a range of specialized cells among the three germ cell layers (endoderm, mesoderm and ectoderm germ layers). For example, a *pluripotent* stem cell can differentiate into a specialized cell from each germ layer.

In contrast, a *multipotent* stem cell can differentiate into specialized cells from two germ layers. Adult stem cells are derived from tissues from the moment of birth or later in life. Adult stem cells naturally found in postnatal tissues or in older individuals are called human somatic stem cells. In contrast, embryonic stem cells are derived from early-staged embryos and fetal stem cells are derived from fetal tissues. Embryonic stem cells and fetal stem cells typically display pluripotent stem cell characteristics and growth capabilities but they are ethically problematic because their creation requires the destruction of human embryos and aborted fetuses.

The Era of Bone Marrow and Cord Blood Transplantation

The most well-known adult stem cell therapy is bone marrow transplantation (BMT) for hematological disorders (6). Bone marrow transplants contain hematopoietic stem cells, which represent a very small fraction of the total cell fraction in bone marrow (less than 1 percent). The first BMT was performed in the late 1950s, and over 20,000 bone marrow transplantations are now performed per year in the United States (7).

BMT requires a HLA match between donors and recipients but the probability of finding a suitable match is so low that it requires a national bone marrow transplant registry to find a matched donor. However, the BMT registry is not sufficient to find a match for some individuals, particularly for minorities (8, 9). As a result, cord blood has been used as an alternative stem cell source. The first cord blood transplantation was performed in 1988 and over 30,000 cord blood transplants have been performed (10). Cord blood is an attractive alternative for hematopoietic stem cell transplantation because it requires less stringent HLA-matching (11). However, cord blood transplants are slower than bone marrow transplants in repopulating resident bone marrow cells (11). Successful cord blood transplantation requires enough hematopoietic stem cells, which are defined by the expression of CD34+ cell surface expression (11). Cord blood transplantation often fails because CD34+ cell represent approximately one percent of the cell fraction in cord blood.

Bone marrow and cord blood transplantation have additional shortcomings. First, BMT carries a risk of graft versus host disease (GVHD), which has a 20 percent mortality (7). GVHD is typically treated with corticosteroids (12). However, fifty percent of GVHD cases are steroid resistant. Third, cord blood and BMT are generally restricted to blood disorders, which represent a very small percentage of chronic diseases. Thus, the shortcoming of bone marrow and cord

blood transplantation has led to the pursuit of stem cells that have greater growth and differentiation capabilities to treat a wider range of chronic diseases than hematopoietic stem cells.

Ex Vivo Cell Expansion and Cell Differentiation of Human Somatic Stem Cells

A major shortcoming of hematopoietic stem cells in cord blood is the small number of CD34+ cells. The typical systemic stem cell dose administered through an intravenous route is 1-2 million cells per kilogram of body weight, which represents 70-140 million cells for an average 70-kilogram male (13), which exceeds the number of CD34+ cells in cord blood. Efforts have attempted to purify and *ex vivo* expand CD34+ cells to increase the stem cell dose of hematopoietic stem cells (14). However, to date, *ex vivo* expansion of cord blood-derived CD34+ cells has not been successful in leading to a viable therapy.

Further, cord blood-derived CD34+ cells have limited differentiation capability beyond converting into hematopoietic cells (15). Cord blood-derived CD34+ cells cannot differentiate into connective tissue, retinal cells, brain cells, cardiac myocytes, hepatocytes and other types of specialized cells. Thus, CD34+ cells can only treat a very narrow number of chronic diseases.

Alternative human somatic stem cells have been explored. The most common human somatic stem cell is a mesenchymal stem cell (MSC). It is derived from bone marrow, adipose tissue, umbilical cord tissue, umbilical cord blood and from placenta (16). MSCs are multipotent stem cells that can differentiate into bone, cartilage and adipose tissue, which makes them popular to treat connective tissue disorders. Also, MSCs exhibit a paracrine activity in which they secrete a variety of peptides and proteins that have trophic effects that mediate cell protection and cell repair (17).

The MSC is the most common stem cell tested in clinical trials and has shown clinical efficacy in anecdotal cases (18). Additionally, MSCs have been studied in over 100 anecdotal clinical reports and controlled clinical trials (13, 19-26). Clinical trials have documented MSC safety, but have not demonstrated clear efficacy for the treatment of chronic lung disease (27), neurological diseases (28), inflammatory bowel disease (29) and graft versus host disease (30). There are several reasons for the lack of efficacy with MSC. First, there has been a lack of quality controls in cell manufacturing with *ex vivo* cell expansion. Cell potency is not routinely measured and monitored during the *ex vivo* cell expansion process. Calf serum is typically used in the *ex vivo* cell expansion processes, which prevents implementing consistent and quality controls in cell manufacturing. Second, the wrong MSC is selected, and the clinical trial design is often flawed. Autologous bone marrow-derived MSC (BM-MSC) or adipose-derived-MSC (Ad-MSC) are commonly used in clinical trials. There is evidence that patients with chronic diseases have fewer potent stem cells and likely suffer from the same insults that are causing the disease in the first place (31). Third, stem cells intravenously administered are sequestered in the lung and rarely reach vital organs like the brain (32). Fourth, MSCs are not homing to the site of disease (33). Last, important paracrine factor(s) (peptides or proteins secreted from stem cells that mediate tissue regeneration) are absent from MSC that is necessary to provide cell protection or stimulate cell replacement for a specific disease.

Thus, before MSC-based cell therapies can be fully realized, several technical challenges must be solved. First, better manufacturing

processes are required and quality controls must be integrated into the workflow. Second, we need better methods to measure cell potency. Third, the clinical trial design needs improvement and better stem cells are required. Finally, we need noninvasive and more direct methods to deliver stem cells to vital organs like the brain to treat conditions like neurodegenerative disorders. Last, MSC requires genetic modification to improve their paracrine function and homing capabilities.

Historic Shortcomings of Adult Stem Cells Ushered in Embryonic Stem Cell Biotechnology

The shortcomings of bone marrow and cord blood transplantation, along with the disappointments of *ex vivo* cord blood-derived CD34+ cell expansion and differentiation, created an opportunity for the secular scientific community to pursue research with embryonic stem cells. Embryonic stem cells emerged for a number of reasons. First, the practice of *in vitro* fertilization matured, and it became a standard practice among fertility clinics to create an excess of fertilized eggs. Second, methods that led to creating mouse embryonic stem cells improved, which ultimately were applied to create human embryonic stem cells in 1998 by Dr. James Thomson (34). Third, secular scientists and organizations (led by the National Institutes of Health) directed lobbying efforts and funded embryonic stem cell research. This research effort has resulted in several academic institutions and government labs that now conduct research with established embryonic stem cell lines. Finally, biotechnology companies acquired the technical expertise to utilize embryonic stem cells in drug testing and cell therapy development. Embryonic stem cells have yet to receive FDA approval for any therapeutic indication so it may be too early to forecast its future as a cell therapy.

Embryonic stem cells pose other challenges. Embryonic stem cells carry a tumor risk when injected into experimental mice (34). Embryonic stem cells must be differentiated into specialized cells and then purified from undifferentiated embryonic stem cells to avoid the neoplastic risk. Yet, manufacturing processes have not yet perfected the ability to eliminate these undifferentiated cells. Also, embryonic stem cells are immunologically distinct from potential recipients. Thus, immunosuppressant drugs must be co-administered to avoid stem cell rejection (35), and the use of immunosuppressant agents increases the risk of infections.

Even if embryonic stem cells have not directly led to a regenerative medicine therapy to date, they have been routinely used in the pharmaceutical industry to screen conventional drugs to evaluate drug safety. These industry practices are frequently protected from public disclosure, which makes it difficult to know which drugs ultimately received FDA approval in the past or which will be approved in the future.

Induced Pluripotent Stem Cell

Induced pluripotent stem cells (iPSCs) were first reported in 2006 as a noncontroversial alternative source of pluripotent stem cells to embryonic stem cells (36). A critical advantage of iPSC is the immunological compatibility that exists with autologous cell therapy. Takahashi *et al.* were the first to report the dedifferentiation of somatic fibroblasts into pluripotent stem cells by retroviral gene delivery of *Oct3/4, Sox2, Klf4* and *c-Myc* (37). Yu *et al.* also reported creating cultured iPSC from fetal and neonatal fibroblasts by viral gene delivery of *Oct4, Sox2, Nanog and Lin28* (38). Both groups

demonstrated that pluripotent stem cells had similar characteristics to those reported in human embryonic stem cells, including teratoma formation. Nakagawa *et al.* further observed that deletion of *c-Myc* from the reprogramming scheme still created pluripotent colonies but eliminated teratoma formation (39). Taken together, these data indicate that the oncogenes, *c-Myc* and *Lin28*, are the chief determinants of the neoplastic risk associated with current iPSC reprogramming methods. Cellular Engineering Technologies and the John Paul II Medical Research Institute previously reported the first-in-kind, virus-free and oncogene-free iPSC reprogramming methods (40). This report demonstrates a potentially safer iPSC reprogramming method for clinical therapies with lower neoplastic risk. Taken together, these data demonstrate that iPSC represents an alternative cell therapy to embryonic stem cell technology. At present iPSC-based cell therapies are currently in early staged clinical trials (41).

Biologic Production

Illicitly obtained cells are ubiquitous in biologic production. Mammalian cells are required to produce human proteins as diagnostics and therapeutics. According to market reports, the global biologic market totaled $200 billion in 2013 and is expected to reach $386 billion in 2019 (42). Biologics can be broken down into three product types: monoclonal antibodies, therapeutic proteins, and vaccines. Unlike biologics, small molecules are typically orally available, prescribed by physicians, dispensed by community pharmacists, and self-administered at home. Biologics are generally administered in a hospital setting.

Half of all human proteins require posttranslational modification by glycosylation -i.e., decorating sugar molecules onto polypeptides. For this reason, mammalian cells are required to produce synthetic proteins. Chinese Hamster Ovary (CHO) cells are used in 50 percent of all proteins currently being manufactured (43). In contrast, human cells are currently used in 20 percent of all human protein manufacturing (43). The most common human cell lines that are used in bioprocessing are derived from aborted fetal tissues such as HEK293 and PERC6. CHO cells are deficient in two respects. First, CHO cells do not provide a fully human glycosylated protein in which the biological activity and pharmacokinetics departs from native human proteins. Since CHO cells produce an animal-human chimeric protein, there is a risk for hypersensitivity reactions, infectious contamination and drug resistance. Taken together, there is an increased likelihood that human protein manufacturing will ultimately shift to the greater use of human cells to produce fully human proteins. This shift will likely occur as current CHO-specific biologics come off patent because of new legislation that encourages biosimilar biologics.

Europe and the United States have paved a pathway for the development of biosimilar biologics, which is comparable to the notion of generic pharmaceuticals of small molecules. The European Union has its biosimilar approval pathway, while the FDA passed the Biologics Price Competition and Innovation Act (BPCIA) in 2010. The Act codified into law the regulatory pathway for biosimilar approval, and formally opened the door for biosimilar product approval in the U.S, and it allows the possibility of producing biosimilar proteins using alternative expression systems and novel manufacturing technologies. Thus, it is

conceivable that human cell lines will increasingly be used for protein manufacturing to create fully human biologics. These changes will increase the demand for using established and new cell lines from aborted fetal tissue to produce biologics in the future.

HEK293 cells have been used by the pharmaceutical industry to manufacture biologics that include Xigris (manufactured by Elli Lilly) for the treatment of sepsis; Aprolix (manufactured by Biogen Ided) for the treatment of Hemophilia B; Eloctate (manufactured by Biogen Idec) for the treatment of Hemophilia A; Pulmozyme (manufactured by Genentech) for the treatment of cystic fibrosis; and G-CSF (manufactured by Octapharma) for the treatment of neutropenia. (Xigris was withdrawn from the market in 2011 due to lack of efficacy, not due to any manufacturing deficiencies or from consumer pressure from religious groups.)

Gene Therapy

Gene therapy involves the therapeutic delivery of nucleic acid and subsequent translation of that genetic material into a key protein that is critical in a disease process. Gene therapy has typically been restricted to genetic diseases but also has a potential role for treating non-genetic diseases. Genes are large molecules of nucleic acid, which cannot by themselves cross the cell membrane. Genes require a vehicle that delivers gene into cells and ultimately make their way to the cell nucleus to produce message ribonucleic acid (mRNA), which then travels to the cytoplasm where protein is ultimately synthesized. A variety of delivery vehicles have been used to transport nucleic acid which includes viruses, lipid molecules and electrolytes (44). Gene therapy is dependent, in part, on how efficiently the delivery vehicle can transport nucleic acid into the cell nucleus to produce mRNA. The most efficient delivery vehicles of nucleic acid are viruses, which have evolved elaborate mechanism to infect mammalian cells.

However, there are clinical and ethical issues associated with viral-based gene delivery (45). First, viral-based gene delivery evokes an inflammatory reaction. There have been reports of patient deaths associated with viral-based gene delivery (46). Second, immunological reactions can neutralize viral vectors, which make them less efficient if repeatedly administered (45, 47). Third, an intermediate human cell is required to package the gene product of interest with the necessary viral elements to product a fully assembled viral particle. The HEK293 cell line that was derived from aborted fetal tissue is commonly used for producing viral-based gene therapies. For example, the FDA recently approved Voretigene neparvovec (manufactured by Spark Therapeutics), a gene therapy for the treatment of a genetic enzyme deficiency of RPE65 located in the retina, which is associated with blindness. Voretigene neparvovec is an adeno-associated virus produced from HEK293 cells. Additionally, gene therapy is very expensive since it represents a personalized manufactured therapeutic product. The cost of Voretigene neparvovec is anticipated to cost $1 million (48). With the recent developments of gene editing technology through CRISPR, further advances in gene therapy are anticipated (49).

What Implications Do These New Technologies Have on the Catholic Health Care?

The secularization of the biotechnology field and the ubiquitous use of illicitly obtained cells will pose serious challenges for Catholic

hospitals and pro-life health care providers because these products will be administered under a hospital setting. Biologics and gene therapies are already utilizing human cell lines obtained in ways that conflict with Catholic teaching. Embryonic stem cells are already utilized in the drug discovery process, which can result in FDA-approved drugs. Embryonic stem cells could potentially result in life-saving regenerative medicines someday. If these products become more prevalent, the situation could pose serious ethical challenges for Catholic hospitals that will have to decide whether they will or will not allow these products to be administered in their facilities. If Catholic hospitals decide to ban potentially life-saving products that were produced from morally illicit cells, they could suffer financially because they are viewed as providing substandard care, leading patients to choose secular hospitals that they see as more competent. Alternatively, if Catholic hospitals choose to use such products, they risk cooperating with the illicit means used to produce them.

Catholic health care workers and pro-life medical religious providers are also at economic risk. One out of 6 patients are treated in a Catholic hospital, which means that 80 percent of patients are treated in non-Catholic hospitals. Approximately 50 percent of physicians are now hospital employees (50), which places doctors under greater control from hospital management. If pro-life health care providers (physicians and nurses) refuse in conscience to participate in the administration of these products, their employment could be placed at risk. This has already been documented with abortion (50-54).

Further, scientists and technical staff in the pharmaceutical industry and in academia are also at employment risk and promotion if they refuse to conduct research and manufacture products that utilize embryonic stem cells or aborted fetal cells.

Catholic patients and pro-life patients may have no acceptable treatments except from those derived from morally-illicit cells. Patients will have to decide to choose life-saving products or suffer from disease.

The high cost of these specialty drugs is another ethical issue. The high costs of these specialty drugs will prevent patients from getting access to life-saving drugs, which will result in a two-tier system where only the rich will be able to afford them. The cost of these specialty drugs is not sustainable, which will place a strain on our nation's healthcare cost (55). Insurance companies could reject patient access to these drugs, and instead, encourage physician-assisted suicide (56). High prices also raise questions about allocation of health care resources overall. Should this much of our total spending go to treatment of rare diseases?

What Policies Should Catholics Adopt to Address the Moral Challenges in Biotechnology?

Over the past 70 years, secularism has greatly influenced the field of biotechnology to the extent that many technologies now conflict with the tenets of the Catholic Church. Secular academic institutions have historically placed a high priority on medical research to build their universities through federal funding from the National Institutes of Health. In contrast, Catholic universities have focused on a liberal arts education and the vocation of health care. According to the National Institute's research database, no Catholic university is in the top 100 of NIH-funded institutions (57). These trends led to an imbalance of alternative biotechnologies that are consistent with the teachings of the Catholic Church.

Whenever an immoral new biotechnology is developed, the Catholic Church responded by protests. However, such protests rarely changed secular policies in academia and government and certainly never altered the course of the biotechnology industry. Historically Catholics have influenced health care primarily by founding hospitals for needy populations. These were generally not research hospitals. The Pope Paul VI Institute was founded by Dr. Tom Hilgers in 1985, which developed alternatives to contraceptives and *in vitro* fertilization. More recent non-profit organizations like the John Paul II Medical Research Institute and the Sound Choice Pharmaceutical Institute were founded to develop alternative treatments to embryonic stem cells, morally-tainted biologics and vaccines. Early-staged pro-life biotechnology companies such as Cellular Engineering Technologies and AVM Biotechnology are developing pro-life-based regenerative medicines. However, pro-life biotechnology remains a very under-developed sector compared to the established secular biopharmaceutical industry.

Even though according to the Michigan Right to Life, over 300 organizations support embryonic stem cell research (58), I believe many aspects of this research contribute to a culture of death. These changes will have a negative impact on health care but disproportionately impact the Catholic health care system and pro-life health care providers. Advances in embryonic stem cells, human biologics and gene therapy that utilize illicitly obtained human cells will result in both moral and economic challenges on our Catholic health care system from a moral perspective as well as an economic one.

In 2005, the Pontifical Academy of Life issued ethical guidelines on the use of vaccines derived from aborted fetal tissue by concluding degrees of cooperation of evil exist that allowed patients and doctors to use such treatments if a morally-acceptable alternative vaccine did not exist (59). Yet, the document also stated that "doctors and patients should take recourse, if necessary, to the use of conscientious objection" in refusing to use the abortion-derived vaccine." The document further concluded that Catholics have "a moral duty to continue to fight and to employ every lawful means in order to make life difficult for the pharmaceutical industries, which act unscrupulously and unethically." These challenges will require Catholics to adapt and take a greater active role in the future of biotechnology to preserve the viability of the Catholic health care system; protect Catholic and pro-life patients; and protect religious health care providers and scientists from the threats of secular biotechnology.

I propose several steps that might enable us to have greater influence on the development on these technologies.

1. Catholics need to exercise greater due diligence in investigating which private medical research organizations support research that support embryonic stem cells and aborted fetal tissue.
2. Catholic health networks and foundations need to be educated in biotechnology and become more actively involved in advancing pro-life biotechnology.
3. Catholic media organizations need to use their media platforms to communicate and educate Catholic audiences on the biotechnology issues that confront them.
4. Catholic universities need to increase their emphasis in

biomedical research and participate in research consortiums to advance pro-life biotechnology.

5. Catholic financial institutions need to invest and financially capitalize a biopharmaceutical industry that is consistent with Catholic teaching.
6. The United States Conference of Catholic Bishops needs to update the next edition of the *Ethical and Religious Directives for Catholic Health Care Services* and provide guidelines on biotechnology and its implication on Catholic health care.

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"Be fertile...": On Catholic Health Care's Distinctive Social Responsibility to Treat Infertility

A response to an article by Sr. Patricia Talone, RSM, published in a previous issue of HCEUSA.

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Introduction

In her recent article, "First, Do No Harm: Ethical Questions about Ova Donation and Surrogacy" in *Health Care Ethics USA*, Sr. Patricia Talone, RSM, Ph.D., speaks powerfully to areas of vulnerability arising from infertility.[1] She highlights how current circumstances place young women—especially those with economic disadvantages—in compromised positions, for instance, donating gametes and even their bodies despite not having pertinent information about the potential risks and harm. She also does well to shine light on the dehumanization and commodification that such practices reinforce. Sr. Talone is clear: while Catholic healthcare does not offer such interventions, it still maintains certain obligations on the issue, as a matter of respect for human life. These include pragmatically minimizing the commodification of human beings, especially women and children, and advocating for public policies and regulation that protects women and children against extortion.

I concur with Sr. Talone. Catholic health care can and should do what it can to help protect these vulnerable populations of women and children. For instance, working with our local Catholic conferences to address state level public policy is one excellent opportunity to bring this voice to bear.[2] At the same time, I would add to her proposal: Catholic healthcare can and should take a leadership role in *addressing infertility* itself—the root cause of these problematic behaviors. This should be done consistent with our Catholic moral tradition. Our Christian anthropology and moral tradition require us be *distinctively focused on and recognized for* our infertility treatment. But why has this not been the case?

A Recognized Public Health Concern

In June 2014, the Centers for Disease Control (CDC) published a *National Public Health Action Plan for the Detection, Prevention, and Management of Infertility* which outlines infertility as a public health concern. This *Action Plan* was developed in light of nationally representative data from the CDC which showed "that 6%, or an estimated 1.5 million U.S. couples, were infertile, meaning they were unable to conceive after 12 months of trying. Additionally, 12% of reproductive-aged women had impaired fecundity, meaning they had experienced difficulty conceiving or carrying a pregnancy to term during their lifetime."[3] According to one analysis, a $3-4

billion industry that in large part centers on interventions such as IVF has developed to meet these needs.[4] Yet, the need continues to grow.

To better address this need, the CDC *Action Plan* outlines three priorities:

1. Promoting healthy behaviors that can help maintain and preserve fertility.
2. Promoting prevention, early detection, and treatment of medical conditions that can threaten fertility.
3. Reducing exposures to environmental, occupational, infectious, and iatrogenic agents that can threaten fertility.

These priorities are very broad but the message is clear: the secular world recognizes infertility as a *social* ill—a "crisis" even—just as much as it is an individual matter. However, in my experience, when discussion of infertility, and associated with matters pertaining to sexual activity like contraception, it usually takes place in terms of "act analysis" of individuals: determining whether a specific action is licit or illicit under the principles of the Catholic moral tradition.

While Catholic healthcare should find nothing objectionable about these CDC priorities in themselves, there would, of course, be a divergence regarding some of the methods proposed for remediation. The *Ethical and Religious Directives for Catholic Health Care Services (ERDs)* outline these.[5] There is a distinctly Catholic approach to addressing the issue of infertility but it is usually understood in terms of proscribed individual actions to the neglect of social considerations. Why does our tradition (appear to) focus predominately on infertility in this way?

Theological Foundations

Sexuality is an intrinsically social reality. It is an inherent dimension of human life and is defined, primarily, through its relationship to the other sex,[6] that is, sex is defined best by the *telos* towards which it is *per se* ordered: unitive procreation. Thus, the sexes, male and female, are always defined—and only fully intelligible—through their relationship with each other. The creation stories in scripture attest to the fundamental and pivotal the nature of this interdependent relationship—in the relationship of Adam and Eve, creation reaches its culmination, for together they are to exercise dominion over it. The fall led first to a broken relationship with the Creator, then to fracture is the relationship between man and woman. Whereas in truth each is "bone of my bone, flesh of my flesh (Gen 2:23)," their relationship is now characterized by self-assertion and dominating the other, instead of the harmony of original justice. This fractured relationship then spills out into the whole of human society.

It should therefore be no surprise that, in the redemption that Jesus won through his life, passion, death and resurrection, marriage is raised to the level of a sacrament.[7] Here, God the creator and redeemer accepts the free invitation of the man and women to be a primary actor in the relationship precisely so that through his grace he is able to nurture a relationship of total self-gift, which moves it beyond original justice into Divine charity.[8] *Gaudium et Spes* summarizes with these words: "The Lord, wishing to bestow special gifts of grace and divine love on [marriage], has restored, perfected and elevated it."[9]

It is only within this context that the logic of the Church's teaching regarding fertility becomes fully and manifestly evident. Here, I am speaking first of the Church's anthropological teachings and, secondarily the moral teachings which establishes that fertility is a gift given to an individual with a social purpose. Indeed, through this gift society comes into being. In short, the connections between the individual and the social whole are inborn and ineradicable precisely because of humanity's social nature. The Church summarizes this connectivity in its statement: the family is "*the first and vital cell of society*. [It] is a divine institution that stands at the foundation of life of the human person as the prototype of every social order."[10]

Reality-based Moral Guidance

With its established potency, the reproductive faculty lays out a track, what Karol Wojtyla calls a "vector of aspiration," that leads to human flourishing.[11] Hence, we recognize the inclination and desire to find a spouse and have children as powerfully natural and dispositive.[12] Given this innate desire and drive, infertility then is a source of great suffering for many married couples. The Catholic Church is deeply committed to help those who suffer in this way. It seeks to help in a manner that respects the dignity of all involved, including the nascent human being.[13]

Consequently, the Church distinguishes different kinds of interventions that are used to overcome infertility:[14] those interventions that assist marital intercourse (e.g. corrective surgeries for endometriosis, hormonal medications to manage progesterone) and interventions that replace marital intercourse, which depersonalize and commodify human beings, treating them as raw material that can be stored, discarded, or destroyed.[15]

In other words, only interventions that address the reproductive health and function of the spouses, thereby *assisting* the husband and wife in marital intercourse, are consistent with their personal dignity, and the exclusivity and fidelity of their marriage. In contrast, interventions that *substitute* for sexual intercourse between a husband and wife, perhaps including third parties, would be not consistent with the moral identity of a Catholic health ministry.

Our understanding of human dignity holds that it is an injustice to violate the exclusivity and fidelity of marriage or to treat a human being as a mere object or a commodity. This is true for individual relationships as well as social relationships. As Sr. Talone suggests, practices like surrogacy and IVF represent an injustice on both the individual and social level. The surrogacy contracts that she describes clearly illustrate human commodification and the exploitation of vulnerable individuals. The social dimensions of this harmful practice are so clear that several countries recently banned the practice of surrogacy precisely for its exploitative nature.[16] Given this, I argue that matters of sexuality provide one of the clearest examples for how the Church's moral teaching is indeed a 'seamless garment'—a social-life issue.

A Distinctive Calling

If reproductive matters are so clearly both individual and social, then what might explain a perception that the Church's teaching is exclusively focused on individual acts? One possibility might be perception and reaction to documents like *Humanae Vitae*.[17] In this document, Pope Paul VI sets forth, from a

natural law perspective, the Church's teaching on pursuing or avoiding pregnancy. This approach lends itself very easily to act analysis, i.e. making distinctions to apply moral principles amid varying concrete circumstances. Further, some felt that the teaching was too invasive into their personal, private lives. While the natural law approach is at the heart of our moral method, it can be seen as too "act centered," to the neglect of its social dimension. I believe that an exclusive focus on its 'act analysis' implications misses the bigger picture: *Humanae Vitae* is, fundamentally, Catholic Social Teaching (CST).

Most summaries of CST resources do not include *Humanae Vitae* among them.[18] But I argue that they should. Indeed, documents that are unquestionably part of the CST canon, such as *Gaudium et Spes*, recount the same teaching.[19] As mentioned, the subject matter itself is inherently and pivotally social. Further, Paul VI calls out the social ramifications that will result from the widespread adoption of contraceptive practices. In this regard paragraph 17 is particularly notable, as it speaks to the general tenor and character of relations between the sexes as well as the population control efforts of state governments that arise from the adoption of contraceptive practices.[20] These claims are not just 'far-sighted'. They are simply spelling out the social dimensions of the teaching regarding fertility and what Pope John Paul II describes as a "contraceptive mentality,"[21] which rends sex and procreation asunder, evacuating sex of meaning and reducing human beings—especially children—down to mere objects. This mentality, which does not recognize the inherent meaning and value of sexuality and fertility or the value of human beings, is a seedbed for further socially corrosive and harmful thought patterns, such as those that Pope Francis has denounced as a "throwaway culture" (in which human life, among other things, is not valued) and "ideology of gender" (which rejects the givenness and meaning of biological sex).[22] Given manifest development of these socio-cultural ills, along with the concerns that Sr. Talone mentions, it is time for the Church and Catholic healthcare in particular to recognize *Humanae Vitae* (HV) for the value it poses as an element of CST and energetically promote it and the practices it inspires as such.

In my experience, one consequence of an overly narrow interpretive lens of HV has been that Catholic healthcare has generally been passive when it comes to infertility. For instance, Richard Fehring notes, "The Catholic Church and in particular the popes from Pius XI through Benedict XIV and Francis have called upon and pleaded with Catholic health care providers and Catholic institutions of higher education to provide NFP [Natural Family Planning] services, education, and research in this area of family planning."[23] But, given its appropriate emphasis as an element of CST, HV calls the Church and its health care ministry further. We should adopt a dynamic, active, missionary approach.

For Catholic healthcare, I suggest this specifically entails developing robust mechanisms and service lines for treating infertility in accord with Church teaching. As Fehring highlights, "Many morally sound standardized and evidence-based treatments exist for women's health problems. They include medical and surgical treatment of endometriosis, medical and lifestyle treatment of PCOS [polycystic ovarian syndrome], medical and surgical treat of infertility that does not involve in vitro fertilization, and surgical and medical

treatments for dysfunctional uterine bleeding..."[24] Moreover, these options can be less costly and more effective than practices like IVF (which are often several thousands of dollars, requiring multiple rounds and not necessarily covered by insurance). Do only the wealthy deserve the ability pursue having children? Catholic teaching clearly says no. We have the answers to address the root cause of these significant social ills; all that is needed a collective, institutional will to help these practices and services advance and grow.

We are called to go out and encounter the suffering that arises from infertility of individual couples as well as the dehumanizing practices that have developed to treat infertility. The anthropology at the heart of the Church's teaching on sexuality and fertility provide a roadmap for the Church to go out to the margins, to the suffering, and help them heal and be restored, to first heal their wounds, as Pope Francis has said. This is not simply a calling to provide a "Catholic alternative" to people who want to pursue (or avoid) pregnancy. This is galvanizing our internal resources to minister to the deepest generative aspirations of human beings. This can in turn heal elements of the social order that tend towards exploitation and dehumanizing practices.

Conclusion

Because of it our social understanding of the person, fertility can be seen in its fullness as a social-life issue. Catholic healthcare therefore has a unique obligation on a social level. This means we cannot just not be passive, receiving the culture where practices like IVF dominate. Rather our commitment to social justice imposes an obligation address social conditions that contribute to or reinforce practices that dehumanize, objectify or commodify people, especially those are socio-economically vulnerable. Sr. Talone calls for fighting these practices at the level of public policy. I agree, and add that our approach must be multipronged. There are many ways that Catholic healthcare institutions can act towards this goal on a social level. I have argued that the best way to address the social injustices Sr. Talone identifies is through developing robust infertility services in line with Church teaching.

This should be a task of the whole Church. Today, this would include collaborating with the medical and scientific professionals that are advancing techniques and services for infertility that are consistent with Church teaching. It would also include helping lead public health initiatives that address factors that lead to infertility, e.g. sexually transmitted infections. By becoming a dynamic leader in infertility services, the Church can, in some small way, begin to heal the wounds of the culture as she is called by Christ to do.

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[1] Sr Patricia Talone, "First, Do No Harm: Ethical Questions About Ova Donation and Surrogacy," *Health Care Ethics USA* 25, no. 4 (2017): 1-7.

[2] Brigid Ayer, "Bill to Expand Ivf across State Lines Advances in House," *The Criterion* (2018), https://www.archindy.org/CRITERION/local/2018/02-16/icc.html. (accessed March 23, 2018)

[3] Lee Warner, Denise J. Jamieson, and Wanda D. Barfield, "CDC Releases a National Public Health Action Plan for the Detection, Prevention, and Management of Infertility," *Journal Of Women's Health (2002)* 24, no. 7 (2015), http://dx.doi.org/10.1089/jwh.2015.5355.

[4] Amelia Josephson, "The Economics of Infertility," accessed. https://smartasset.com/personal-finance/the-economics-of-fertility. (Accessed 3/1/2018)

[5] For instance, Catholic healthcare does not treat infertility with those methods proscribed by directives 38-42. United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (2009), Cf. No. 38-42.

[6] Elliott Louis Bedford and Jason T. Eberl, "Actual Human Persons Are Sexed, Unified Beings," *Ethics & Medics* 42, no. 10 (2017): 1-4. As Karol Wojtyla clarifies, "The natural direction of the sexual urge is towards a *human being* of the other sex and not merely towards 'the other sex' as such. It just because it is directed towards a particular human being that the sexual urge can provide the framework within which, and the basis on which, the possibility of love arises." Karol Wojtyla, *Love and Responsibility* (Boston: Pauline Books & Media, 2013), 49. In other words, the highest end of our sexual nature is complimentary love that is a holistic expression of the person.
[7] *Catechism of the Catholic Church* (Collegeville, MN: The Liturgical Press, 2008), No. 1601.
[8] Ibid., No. 1661.
[9] Second Vatican Council, *Gaudium Et Spes* (1973), no. 49.
[10] *Compendium of the Social Doctrine of the Church* (Washington D.C.: United States Conference of Catholic Bishops, 2007), No. 211.
[11] "The sexual urge...is a natural drive born in all human beings, *a vector of aspiration* along which their whole existence develops and perfects itself from within." Wojtyla, 46. (emphasis in the original).
[12] "Sexual inclination is something that humans share in common with all living beings, but it exists in humans in a more perfect way. It comes to fulfillment in marriage, which unites a man and a woman for life. It is not solely biological, even though this component is a characteristic feature of it. It engages the entire personality through the bonds of affection. We commonly distinguish two ends of marriage: first there is generation – the gift of life and education of children, who ensure the growth and continuance of the human species and is cultural heritage. Second, there is the love and mutual support of the couple. The two finalities naturally aid each other. One cannot be fulfilled without the other, for the law of love is gift and fecundity." Servais Pinckaers, *Morality : The Catholic View* (South Bend, Ind.: St. Augustine's Press, 2001), 103-4.
[13] *Catechism of the Catholic Church*, Nos. 2374-79.
[14] Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae: On Certain Bioethical Questions* (2008), No. 12.
[15] See Pope Francis on 'throwaway culture. Francis X. Rocca, "Pope Says 'Throwaway Culture' Harms Environment and Human Life," accessed. http://www.catholicnews.com/services/englishnews/2013/pope-says-throwaway-culture-harms-environment-and-human-life.cfm. (accessed 2/20/2017). This devaluation of human life in assisted reproductive technologies is recounted by Paul Conner, "Ivf: Mayhem and Murder--Well Disguised," *Nova et Vetera* 14, no. 2 (2016).
[16] "As Demand for Surrogacy Soars, More Countries Are Trying to Ban It," accessed. https://www.economist.com/news/international/21721926-many-feminists-and-religious-leaders-regard-it-exploitation-demand-surrogacy. (accessed 3/1/2018)
[17] Pope Paul VI, *Humanae Vitae: On the Regulation of Birth* (Glen Rock, N.J.: Paulist Press, 1968).
[18] See, David J. O'Brien and Thomas A. Shannon, *Catholic Social Thought: The Documentary Heritage* (Maryknoll, N.Y.: Orbis Books, 2010).
[19] See Council, nos. 49-51. It is noteworthy that in 1965 *Gaudium et Spes* no 51 articulates the same teaching on regulating birth (e.g. citing *Casti Connubi*) that *Humanae Vitae* would later reaffirm in 1968. However, historically, the reception of the two documents has been very different: GS was lauded as the great piece of social teaching that it is, while HV was received with great controversy.
[20] Paul VI, No. 17.
[21] Pope John Paul II, *Familiaris Consortio* (1981), No. 6.
[22] Pope Francis, *Ladauto Si* (2015), No. 56.
[23] Richard Fehring, "Fertlity Care Services," in *Catholic Witness in Health Care: Practicing Medicine in Truth and Love*, ed. John M. Travaline and Louise A. Mitchell (2017), 202.
[24] Ibid., 191.

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Ethics and Aging

Increased Longevity Creates Opportunities for Catholic Health Care

David Sulmasy's book *The Rebirth of the Clinic*[1] was an eye-opener for me. It helped me see how the scientific revolution and the Enlightenment shaped our understanding of medicine and healing as primarily scientific undertakings. The original clinic, Sulmasy argues, conceived medicine, dying and death in quantitative and analytical terms. It gave rise to the "clinical gaze" which rendered the patient an object of observation rather than a subject in need of caring. My impression from reading Sulmasy was that this trend led to the emergence of modern medicine in the late 18th and early 19th centuries.

Sulmasy is correct that the modern disciplines of medicine and medical education took shape after 1850. However, another book, *Growing Old in Christ*,[2] helped me see that roots of this view of medicine, aging and death went back much further. The essays in this book describe aging in the biblical, patristic, medieval and modern periods. They show that the tension between scientific and religious views of sickness began long before the birth of the clinic.

The earliest example is the great literary work *Piers Plowman*, which was written between 1360 and 1380. The author, William Langland, sees the traditional view of aging and death as a spiritual experience rooted in the death and resurrection of Christ and in Christian community, as jeopardized by economic changes. As a result, says David Aers, "human life and the traditional virtues are transformed to sustained communities in which markets, market values, and individual profit are paramount goods and the church is assimilated to the practices and values of this world."[3] Old age, he says, began to be viewed through a "secularized medical tradition" which valued medical remedies that can drive away death."[4] [I am sorry to say that at least in Langland's view, the mendicant friars, who have been described as an adaptation to the market economy of the Middle Ages, played a significant role in promoting this view].

This emerging view is reflected in the work of Franciscan Roger Bacon (d. 1290), who was a brilliant polymath, an empiricist and a very early proponent of what we would now call the scientific method. It is hard to imagine his precocious work *De Retardiatione Accidentum Senectutis coming* from a time when so few life-saving interventions were available. It was based on the conviction that old age and even death could be delayed. Even then, this created fears that "medicyns for the body" threatened to replace known spiritual remedies.[5] It would be a long time till Bacon's views blossomed into the clinic that Sulmasy describes, but they contained the seeds of our present attitudes to death and dying.

Modern market theory and capitalist economics were developing at the same time, and they too had their effect. David Shuman notes three things that changed our attitudes about death: a) the

biomedicalization of death; b) the hegemony exerted by our capitalist economy; and c) the gradual erosion of our communities including ecclesial communities that sustained the more traditional view of aging and death. These factors created an analytical and economic approach to life in which the elderly were seen as quantities factored into an equation.[6] This tendency to see health care in strictly economic terms persists to this day as we see the most contentious arguments about health care reform revolve around "how much will it cost?" and "who will pay for it?"

Another influence may have been Protestant Evangelicalism, which has its roots in the early Enlightenment period. One writer says a new view emerged from the dominant Protestant culture that was shaped by "perfectionism in physical and spiritual matters and belief in the power of the individual will, [which led them to] dichotomize and rationalize experience in order to control it.[7]

Happily, contemporary movements toward hospice and palliative care have begun to reverse some of our stunted thinking about aging and death. However, even these two important movements risk compromise unless we in Catholic health take care to imbue them with spirituality and an ethical framework that is grounded in our Resurrection destiny and Eucharistic hope. Such a grounding will balance out the excessively technical and economic paradigms that have shaped medicine thus far. Let me cite several things that I think must inform our ethics of aging.

1.) Create space for theology. D. Stephen Long is correct when he says that theology has ceded its rightful place to economics in such a way that it views economics as a "Technical science like auto mechanics, gall bladder surgery or housing construction...because these are neutral, technical disciplines we need not relate theology to them, nor should they encroach on theological language."[8] It is true, as we often say, that there is no "such thing as a Catholic appendectomy", but this does not mean that sound technique is the end of the story. These techniques, indeed all of the aspects of Catholic health care, must be shaped by our understanding of the person as essentially spiritual and the care that we deliver as having a transcendent dimension.[9] This is particularly true when we are dealing with aging and death, which are stubbornly mysterious and not fully comprehensible to us in this life. Death is not just a biological or clinical event.

2.) Find ways to restore aging to community. Sickness and death are very solitary experiences – no one can feel exactly what we feel. Still, no one should die alone. Each of us has to find the meaning of death, but we can't do it alone. We need the help of others. Ethicist Daniel Callahan says, "We cannot find the meaning in death entirely on our own, even if this seems to be the demand placed on us. We need the help of others, of a community whose meaning we can share, making it our own with the same strength as if we discovered it ourselves..."[10] This is a huge challenge if what John Milbank says is true: Our capitalist system "in its most innate tendency precludes community. This is because...it makes the prime purpose of society as a whole and also of individuals to be one of accumulation of abstract wealth or of power-to-do things in general, and rigorously subordinates any

desire to do anything concrete in particular, including the formation of social relationships."[11]

This means strengthening the bonds of friendship for the elderly, many of whom complain about loneliness and isolation. Hauerwas and Yordy go so far as to say that "we must be taught to die through friendship."[12] This learning starts with retirement, which usually signals a time when we leave the world of economically-productive work. It is important to remember that we may be leaving a job, but not our vocation, and our vocation includes eventual death. But what is the vocation of an older person who may no longer have income-producing work (and so does not fit into the economic equation), but who still has a call to the Christian life? What pulls the elderly retired person into the future, and to the completion of her vocation if there are no promotions, or raises, or successful deals to complete? This is especially pertinent if the market has shaped us to see ourselves as "producers and consumers" which undercuts "the ways of life of those tradition-bearing communities with substantive commitments to particular accounts of the human goods."[13]

3.) Acknowledge the uniqueness of aging and dying. Aging may be a universal experience, but we do not all age and die in the same way.[14] This is simply a variation on the fundamental Catholic theological principle "grace perfects nature." Grace does not come in one size only, it is custom-made for each of us so that it matches our personalities, dispositions, intellects and vocations. Were it otherwise, all the saints would look alike. In fact, the saints were all holy, but they achieved that holiness in a myriad of ways each of which was completed by a particular form of grace. So too, as we age, grace perfects us in different ways. Part of clinical and pastoral care must involve discovering the specific ways in which the grace of aging and dying is given to this specific person.

4.) Cultivate the virtues of aging. Health care ethics, perhaps like health care in general, has tended toward the episodic. Mostly we deal with "ethical questions" which often revolve around crisis situations. This is markedly true with end-of-life care, where we focus on "doing" rather than "being." Charles Pinches suggests in his essay that we need to help the elderly develop the virtues appropriate to aging. He names simplicity, delight, empathy, courage [note that he says there is no private courage, which takes us back to the importance of community], truthful remembrance and hope as starters, but there are many more that we could name and cultivate. These virtues are necessary for those of us who are aging, but they are also necessary to the young, who may learn from our example.[15] Cultivating and sharing these virtues may be the most distinctive aspect of our vocations as we age.

Conclusion

The rapid rise of longevity and the hegemony of scientific and market paradigms of medicine create a unique opportunity to see aging as more than an economic, social or clinical problem to be fixed. As we deal with the real ethical challenges that aging brings, we must see them through the lens of a graced period of life that is, as much as youth and middle age, a gift from God.

C.B.

[1] *The Rebirth of the Clinic: An Introduction to Spirituality in Health Care*. Washington: Georgetown, 2006.
[2] Stanley Hauerwas, Carole Bailey Stoneking, Keith Meador and David Cloutier, eds. Grand Rapids: Eerdmans (2003).
[3] "The Christian Practice of Growing Old in the Middle Ages," *Growing Old in Christ*, 38-62, at 55
[4] Aers, 56.
[5] Aers, 56.
[6] "The Last Gift: The Elderly, the Church and the Gift of a Good Death," in *Growing Old*, 151-169, at 153-54.
[7] Carole Bailey Stoneking, "Modernity: The Social Construction of Aging," in *Growing Old*, 63-90 at 71; see also 78 on connection with "liberal capitalist values"; and excessive dependence on the Word, which led to diminishment of symbol and ritual, which prior to the Reformation had helped provide meaning for aging and death.
[8] "The Language of Death: Theology and Economics in Conflict", in *Growing Old*, 129-150, at 139.
[9] Another dimension of this is to understand Catholic health care as sacramental. See Clarke Cochran, "Renewing the Sacramental," *Health Progress* (November-December 2003) 12-15.
[10] *The Troubled Dream of Life: In Search of a Peaceful Death* (New York: Simon and Schuster, Touchstone, 1993) 223.
[11] Joel Shuman quoting John Milbank in "The Last Gift" in Growing *Old*, 158.
[12] Stanley Hauerwas and Laura Yordy, "Captured in Time: Friendship and Aging," in *Growing Old*, 169-185, at 183.
[13] Shuman, "The Last Gift," in *Growing Old*, 159.
[14] Patricia Beattie Jung, "Differences Among the Elderly: Who is on the Road to Bremen?" in *Growing Old*, 112-129, at 112.
[15] See Pinches, "The Virtues of Aging," *Growing Old*, p. 212. He says the virtuous elderly can "teach us in this to live, and delight in what is now present."

Advance Directives & Dementia

On March 30, 2018, Kaiser Health News published an article titled "'Aggressive' New Advanced Directive Would Let Dementia Patients Refuse Food."

Such a headline quickly made the rounds through the CHA offices, and many members forwarded the article for our attention. At first glance, one might view this title as regarding artificial nutrition and hydration using tube feeding - a topic discussed many times in this quarterly.[1] However, the article details a different and more troubling option. In filling out this directive, a patient can agree with the statement, "My instructions are that I do NOT want to be fed by hand even if I appear to cooperate in being fed by opening my mouth." The group proposing this new advanced directive is End of Life Choices New York, which claims that the directive "aims to provide patients a way to hasten death in late-stage dementia, if they choose." "Hasten death" is the key phrase in the ethical assessment of this document. The *Ethical and Religious Directives* specifically prohibit actions whose intent is to hasten death.[2] I do not want, however, to focus my entire conversation on why this document is illicit and contradictory to Catholic moral teaching.

Instead, I believe we are once again witnessing a continued push within our culture for the elimination of the dying process. Looking at the motivation behind this document, we only need to listen to the words of its author who argues that patients with dementia "do not want their dying prolonged." Society has in some ways accepted death as the

ultimate outcome. Yet, the days, weeks, or months at the end of life have become an obstacle to be overcome. Death is no longer the fear. *Dying* is the object to be avoided at all costs.

The new effort in New York stems from the same underlying norms and beliefs held within our broader society concerning this stage of life. We see echoes of it in the physician assisted suicide debates where control over dying is framed as a personal choice. In some ways, this document falsely upholds this hegemonic view of autonomy within the medical field. In others, it merely reaffirms what we have witnessed in the past decade regarding care at end of life; society and the family should not bear any burden from the patient. Pope Emeritus Benedict XVI named this very problem in a 2007 address to the International Congress of the Pontifical Council for Health Pastoral Care. He identified that "today's efficiency mentality often tends to marginalize our suffering brothers and sisters, as if they were only a 'weight' and a 'problem' for society."[3] Such marginalization forgets the inherent dignity of the person and places the comfort of others above the one suffering.

Many of you know the Church's historic *ars moriendi* tradition. One other exemplar of a "good death" is St. Therese of Lisieux. St. Therese's final years were plagued by illness, that many now believe to be tuberculosis. She connected her final days with the image of a spiritual journey: "Yes, I'm like a tired and harassed traveler, who reaches the end of his journey and falls over. Yes, but I'll be falling into God's arms!"[4] This imagery of a journey continues in our tradition and was a favorite of Benedict XVI who proclaimed that death "is a passage toward the embrace of the Heavenly Father, full of tenderness and mercy."[5] How then do we help society share this beautiful imagery? Are we too late to overcome this rising sentiment towards a "hastened" death?

I wish to echo Fr. Charlie's concluding point in his article, while substituting one key word: we now have the unique opportunity to see *dying* as more than an economic, social, or clinical problem to be fixed. This renewed focus by society on dying ought to spur Catholic health care's efforts in increasing palliative medicine and hospice care. Access to these services gives patients more authentic autonomy and provides greater dignity and comfort during their last days. This effort of expansion is advocated by major health systems, the United States Conference of Catholic Bishops[6], and the Pontifical Academy of Life. The latter two groups are championing for collaboration between different ministries of the Church to approach this challenge across the globe.[7] The challenge that faces our efforts is great, but not insurmountable. The reframing of this stage as a truly important step in our life and in the life of those whom we love will take even more exemplars to show the way. It will attack what is at the root of the problem, not fear of death, but rather fear of dying. The Catholic Church's rich tradition of providing comfort and care for the dying provides a compelling path forward for a new vision of human dignity and death.

N.B.H.

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[1] An overview of this ethical concern was published in 2016 in an HCEUSA article by Fr. Myles Sheehan S.J. titled "Feeding Tubes in Advanced Dementia and Ischemic Stroke."

[2] *Ethical and Religious Directives*, #61.
[3] Pope Benedict XVI, "Address of His Holiness Benedict XVI to Participants in the 22nd International Congress of the Pontifical Council for Health Pastoral Care." Nov. 17, 2007
[4] *The Way of the Cross with the Carmelite Saints*, (ICS Publications:2013).
[5] Pope Benedict XVI, "Address of His Holiness Benedict XVI to Participants in the 22nd International Congress of the Pontifical Council for Health Pastoral Care." Nov. 17, 2007
[6] Secretariat of Pro-Life Activities, "Physician-Assisted Suicide: Threat to Improved Palliative Care," April 3, 2017. http://www.usccb.org/issues-and-action/human-life-and-dignity/assisted-suicide/to-live-each-day/upload/suicide_palliative_care-2.pdf
[7]http://www.academyforlife.va/content/pav/en/projects/pallife/pallife-project.html

Aida Herenda (J.D. anticipated 2019) of Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, Associate Director, supervised.

Rethinking Perspective of HIV Exposure Lessons from California's New Legislation

California is departing from precedent with the enactment of SB 239, a statute reducing criminal charges for those living with HIV. The statute replaces felony charges with misdemeanor charges, while reserving penalties for the intentional transmission of HIV; repeals felony charges for solicitation by those with a positive HIV status; and decriminalizes the donation of blood or tissue by those living with HIV. California distinguishes itself from the rest of the country, where currently 34 states have HIV-specific criminal statutes and 23 have general statutes which criminalize HIV exposure. While retribution and deterrence are arguments for the criminalization of HIV exposure, evidence indicates that penalties are unevenly imposed on the basis of race and sex and that the presence of HIV-specific statutes does not make an impact on disclosures of HIV positive status. By treating transmission of HIV similarly to the transmission of other serious communicable diseases, California makes a positive impact on public health by reducing the stigma around HIV and encouraging people to get tested and learn their status. Y. Tony Yang and Kristen Underhill, *New England Journal of Medicine*, March 29, 2018 http://www.nejm.org/doi/pdf/10.1056/NEJMp1716981

Trump Administration Proposes Rule to Loosen Curbs On Short-Term Health Plans

The Trump Administration has released a proposed rule that would allow insurers to once again sell short-term health insurance plans. Short-term health insurance plans are cheaper than ACA-compliant Marketplace plans, but most of these plans exclude coverage for maternity care, preventive care, mental health services, and substance abuse treatment. However, short-term plans could provide more choices to the market and broaden provider networks in rural areas. Anywhere from 100,000 to 200,000 "healthy people" are estimated to switch from ACA-compliant plans to a short-term plan. A shift of this size will cause premiums to increase, which in turn will cause federal subsidies for ACA Marketplace plans to rise, costing the government anywhere from $96$168 million. Julie Appleby, *Kaiser Health News*, Feb. 20, 2018 https://khn.org/news/trump-administration-unveils-proposed-rule-to-loosen-restrictions-on-short-term-health-plans/

CMS Cites University of Maryland Hospital for EMTALA Violations

Following widespread outrage from a video showing the mishandling of a mentally ill patient, the University of Maryland Medical Center has been cited by the Centers for Medicare and Medicaid Services (CMS) for violating the Emergency Medical Treatment and Labor Act (EMTALA). EMTALA requires emergency departments to screen patients for emergency medical conditions and provide stabilizing treatment, regardless of a patient's ability to pay. The video which prompted the investigation by CMS, featured

two security guards from the hospital abandoning a mentally ill patient, clad in nothing but socks and a gown, at a bus station in freezing temperatures. CMS' investigative report indicates that hospital security guards were responsible for deciding who could enter the hospital's locked ED waiting room, but the security guards involved with the incident were unaware of EMTALA requirements. CMS has accepted the hospital's corrective plan for addressing the deficiencies identified by an internal root cause analysis, an independent analysis by outside experts, and an audit by the Joint Commission. Harris Meyer, *Modern Healthcare*, March 20, 2018 http://www.modernhealthcare.com/article/20180320/NEWS/180329990/cms-cites-university-of-maryland-hospital-for-emtala-violations

Trump Clears Path for States to Require Employment for Medicaid

The Trump Administration has moved to allow states to impose work requirements to Medicaid programs for able-bodied and working-age Americans. Although the administration believes the requirements will strengthen the program and improve health outcomes by encouraging Americans to seek jobs, others fear that the number of uninsured Americans may increase. Medicaid is the largest provider of health insurance for Americans, with about 72 million covered by the program in 2017. New state systems will be necessary to determine who is subject to these work requirements and whether beneficiaries have fulfilled them, increasing the risk that those with the most barriers to work and individuals who fail to submit adequate documentation will lose their benefits. Roughly ten states have proposed adding work or community engagement requirements to their programs. Centers for Medicare and Medicaid Services Administrator Seema Verma announced that the federal government will begin approving state plans for work requirements soon. Zachary Tracer, Justin Zink, John Tozzi, *BNA*, Jan. 11, 2018 https://www.bloomberg.com/news/articles/2018-01-11/trump-clears-path-for-states-to-require-employment-for-medicaid

SCOTUS Nixes CareFirst Plea to Decide Data Breach Harm Standard

The United States Supreme Court has decided not to respond to a request for review by CareFirst Inc., to answer how much harm a data breach victim must suffer to bring claims in federal court. Data breaches were at an all time high in 2017, and a split among federal appeals courts has left plaintiffs, attorneys, and companies awaiting an answer. Whereas, the Third and Fourth Circuits have ruled that mere fear of identity theft is too speculative of a harm to have standing in federal court, the Sixth, Seventh, Ninth, and DC Circuits have found that substantial fear of identify theft does constitute a sufficient harm to bring claims in federal court. The Supreme Court's refusal to review this question signals support for the Court's previous holding in *Spokeo, Inc. v. Robins*, noting plaintiffs must allege imminent or actual harm rather than speculative harm to have standing in federal court. Daniel R. Stoller, *BNA*, Feb. 20, 2018 https://www.bna.com/scotus-nixes-carefirst-n57982088996/

CMS to Form Interagency Group to Review Stark Law

The Centers for Medicare and Medicaid Services (CMS), the Department of Health and Human Services' Office of Inspector General, the Department of Health and Human Services' general counsel, and the Justice Department will convene in an effort

to deduce how to lessen the impact of the Stark Law on new value-based care models. The Stark Law prohibits physicians from referring patients to entities that provide designated health services with whom they have a financial relationship, unless a specific exception applies. One of the central tenets of value-based care is paying providers more when they meet certain quality metrics, but the Stark Law prohibits this as well, as such agreements are not susceptible to a fair-market value assessment. Although agencies are in favor of modernizing the application of the Stark Law, CMS Administrator Seema Verma has indicated that Congress will need to step in to truly effectuate a transformation of the Stark Law. Virgil Dickson, *Modern Healthcare*, Jan. 17, 2018 http://www.modernhealthcare.com/article/20180117/NEWS/180119915

Cigna to Buy Express Scripts in $52 Billion Health Care Deal

As a wave of consolidations sweep through the health care industry, health insurance giant Cigna has announced its plan to purchase Express Scripts, the nation's largest pharmacy benefit manager. However, as the final major independent pharmacy benefit manager left for smaller insurers, the Federal Trade Commission and Department of Justice may not approve the acquisition. Vertical integration is happening across the health care industry, with just recently CVS Health and health insurer Aetna announcing a merger. This increase in vertical integration may be traced to rising health care costs for employers and consumers, unfavorable scrutiny of pharmacy benefit managers in recent years, and concerns about Amazon, JPMorgan Chase, and Berkshire Hathaway entering the health care industry. Antitrust experts are unsure how such mergers are going to impact the health care market, but they predict the Justice Department will be on high alert for any anticompetitive effects.

Katie Thomas, Reed Abelson, and Chad Bray, *New York Times*, March 8, 2018 https://www.nytimes.com/2018/03/08/business/dealbook/cigna-express-scripts.html

Can This Judge Solve the Opioid Crisis?

Judge Dan Aaron Polster of the Northern District of Ohio is tasked with resolving more than 400 federal lawsuits surrounding the national opioid tragedy involving opioid manufacturers, distributors, and the pharmacy chains selling them. Judge Polster, who has experience mediating settlements in multidistrict litigation, ordered lawyers in the first hearing for the current case to prepare for settlement discussions immediately, indicating a refusal to spend years dragging out the case with traditional litigation. Touched by a personal experience related to the opioid crisis, Judge Polster has shown concern for the number of lives at stake each day that a resolution is delayed. Judge Polster's approach to handling the opioid lawsuits is already having an impact on the national crisis, with Purdue Pharma, the makers of OxyContin, announcing that they would no longer market OxyContin to prescribers. Jan Hoffman, *New York Times*, March 5, 2018 https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html

Nakesha Williams Died Homeless on a Manhattan Street. Should She Have Been Forced Into Treatment?

Nakesha Williams had a bright future ahead of her as a successful graduate of Williams College, but after developing serious mental issues and turning down aid from friends and outreach workers, she passed away at the age of 46, homeless on the streets of New York.

Sam Tsembris, founder of a nonprofit that helps homeless people secure housing, describes the ethical and legal issues associated with involuntary commitment programs for homeless people with mental illness. Ultimately, involuntary confinement requires someone to be an immediate danger to themselves or others, a factor Ms. Williams did not meet. Furthermore, although Ms. Williams was mentally ill, she was clear in her conversations with others about her preference to remain homeless instead of entering programs where she did not feel safe. In order for Ms. Williams to have been involuntarily committed, a petition would have been required in the mental health court of a hospital, stating that Ms. Williams was noncompliant with treatment and a danger to herself. However, the careful balance of , rights to make their own choices and keeping them healthy can be difficult and requires a "radical acceptance" of their point of view. Benedict Carey, *New York Times*, March 6, 2018
https://www.nytimes.com/2018/03/06/health/nakesha-williams-involuntary-commitment.html

What Happens When Amazon Takes on Health Care?

In head-turning news, Amazon, Berkshire Hathaway, and JPMorgan Chase, announced their plan to enter the health care sector as a new joint enterprise to exclusively serve the health care needs of the 1.2 million individuals employed by the three companies. The growing cost of health care seems to have been the key factor behind the unification of these three industry giants. If the enterprise is as effective as it is anticipated to be, reduced heath care costs will not just benefit the three companies but also make a meaningful impact on the lives of their employees, with improved access to care and less of their paycheck spent on health care. Karl Vick, *Time Magazine*, Feb. 1, 2018
http://time.com/5128377/amazon-and-friends-takes-on-a-new-industry-health-care/

Christopher Ostertag, 2nd year Ph.D. student in the joint Theology and Health Care Ethics program at Saint Louis University, contributed the following items to this Of Note column.

Blind Boy Might Be Able to See Again After New Breakthrough Gene Therapy Surgery

Nine-year-old Creed Pettit was the first person to receive Luxturna, possibly the first true gene therapy in existence. Creed has a rare genetic retinal disease called Leber congenital amaurosis, which causes blindness in adulthood. In December 2017, the FDA approved Luxturna.

This gene therapy utilizes a virus for delivering the corrected gene, which is injected under the retina of the patient. For Creed, the virus carried a corrected copy of RPE-65, which is responsible for making a protein essential to the health of the retina. Creed will receive gene therapy in his right eye first, then the left the following week. Dr. Bryon Lam, Creed's physician, expects improved vision, but not perfect vision.

Luxturna is not a gene editing therapy, but rather injected corrected copies of the gene into the retina. However, Dr. Lam does not know what long-term effects of the therapy will be. For gene therapy in both eyes, Luxturna costs $850,000, but Pettit's insurance will cover the therapy. Now, we just have to wait and see what the future holds for Creed. Kate Sheridan, *Newsweek*, March 21, 2018
http://www.newsweek.com/9-year-old-gets-new-breakthrough-gene-therapy-blindness-853908

Opioid Epidemic So Dangerous, Says CDC, It's Finally Killing as Many Americans As Guns

According to the CDC, over 42,000 people died from opioid abuse in 2016. This figure is five times higher than in 1999. Because of this alarming increase in incidence, we have an opioid epidemic. While it is truly a tragedy and measures must be taken to fight opioid addiction, the number of fatalities from opioid abuse in 2016 highlights another problem: gun violence.

In 2016, over 38,000 people were killed in gun-related incidents. 2016 is the first year that deaths from opioid abuse surpassed those from gun violence—yet we don't speak about the epidemic of gun violence because the statistics have been stable over many years. However, the number of deaths from firearms has been increasing some the last several years.

Since the deaths associated with firearms are well-documented, the CDC ought to spend more on research related to firearms and public safety. But the 1996 Dickey Amendment prohibits the CDC from studying gun violence in its relation to public safety for the promotion of gun control. The statistics of the opioid epidemic should highlight the persistent epidemic of gun violence, causing us to examine our underlying ideological commitments. Ethan Siegel, *Forbes*, March 20, 2018 https://www.forbes.com/sites/startswithabang/2018/03/20/opioid-epidemic-so-dangerous-says-cdc-its-finally-killing-as-many-americans-as-guns/#5f70cf306c21

Mississippi Imposes 15-Week Abortion Ban; Nation's Toughest

Mississippi now has the most restrictive abortion laws in the United States, banning most abortions after 15 weeks gestation. Republican Gov. Phil Bryant signed House Bill 1510 in a closed ceremony attended by supporters of the bill. This bill was immediately challenged by the Jackson Women's Health Organization, who argue that this bill is unconstitutional.

Under this new bill, abortion after 15 weeks gestation is only permitted if the fetus has health problems that are incompatible with life outside the womb or if the mother's health is in serious danger. Pregnancies resultant from rape and incest are not exempted.

In an email about the bill, Lt. Gov. Tate Reeves hoped to make Mississippi "the safest place in America for an unborn child." Jeff Amy and Sarah Mearhoff, *The Washington Post*, March 19, 2018 https://www.washingtonpost.com/national/health-science/mississippi-imposing-nations-toughest-15-week-abortion-ban/2018/03/19/48eea592-2b5d-11e8-8dc9-3b51e028b845_story.html?utm_term=.67decf03fc62

Jacob Harrison, Ph.D. student, Albert Gnaegi Center for Health Care Ethics, Saint Louis University, contributed the following items to this Of Note column.

U.S. Immigration Policy Threatens Shake-Up in Home Health Business

Currently in the United States there are around three million people who provide homecare to the elderly and a quarter of these homecare providers are immigrants. The consideration by Congress and the White House to change the immigration policy has some within the homecare industry concerned that there will not be

enough people to care for the nation's growing elderly population.

Robyn Stone, senior vice president for research at Leading Age, which represents the nonprofit side of long-term care, argues, "If we shift in our policy [on] immigration, the pipeline for this workforce could be substantially affected." Furthermore, according to the article, the nation's rapidly aging population has made personal care assistants and home health aids the fastest growing low-skilled occupation in the United States.

Others, such as Steven Camerota, director of research at the Center for Immigration Studies, which advocates for restrictions on immigration, do not believe tighter immigration policies will hurt the home health business. He points to the many unemployed U.S. citizens that could fill these jobs.

The extent to which a change in immigration policy will impact the home health business remains to be seen but for those like Zoila Guttierrez, policy changes could have a personal impact. Guttierrez came to Albuquerque in 2004 without documentation, while her youngest is a citizen and her two older children are both registered under DACA. For her, being in a class to prepare her to be a state-certified home health aide is more than just an increase in her paycheck, it is a job where she finds meaning in caring for the elderly. Ina Jaffe, *National Public Radio*, March 5, 2018 https://www.npr.org/sections/health-shots/2018/03/05/587691189/immigrants-who-staff-home-health-care-in-the-u-s-worry-about-deportation

You've Detailed Your Last Wishes, but Doctors May Not See Them

Dr. Daniela Lamas, through her work in the I.C.U., has felt firsthand the frustration of trying to search through electronic records for notes and scanned documents. Dr. Lamas has spent the last year researching advanced health care planning and electronic health records by interviewing clinicians who have first-hand experience of trying to retrieve these documents and talking with companies that are behind some of the most widely-used electronic records.

In the absence of nationwide standards, Dr. Lamas says, there is significant variability among hospitals as to the accessibility of end-of-life documentation. Even in hospitals such as her own where there is an "Advance Care Planning" tab, difficulties remain in accessing these documents. Dr. Lamas explains, "Habits are hard to break, and without a clear set of incentives, training and ongoing education, doctors (myself included) continue to record information about end-of-life conversations in progress notes, where they are not readily available, particularly when they are urgently needed." These difficulties become especially problematic when patients receive treatments that they have previously expressed they do not want, but the documentation of the advance wishes are lost or missed because of a difficulty locating the document.

Through her research, Dr. Lamas often heard that creating standards of sharing or "interoperability" across all electronic records would make a meaningful difference in ensuring that a patient's end-of-life wishes are not missed by the physicians. She says that maybe patients should be able to access their health records through a patient-facing interface that allows them to send in their own directives and possibly update related notes. But currently, health care is playing catch-up, which is putting patients at risk for receiving care that goes against their wishes.

Daniela Lamas, M.D., *The New York Times,* March 27, 2018, https://www.nytimes.com/2018/03/27/well/live/advance-directive-end-of-life-wishes-electronic-health-record.html?rref=collection%2Fsectioncollection%2Fhealth&action=click&contentCollection=health&region=stream&module=stream_unit&version=latest&contentPlacement=6&pgtype=sectionfront

HHS Takes Major Actions to Protect Conscience Rights and Life

On Jan. 19, 2018, the U.S. Department of Health and Human Services (HHS) announced two actions being taken to protect life and the conscience rights of Americans. The HHS' Centers for Medicare & Medicaid Services (CMS) issued new guidance to state Medicaid directors that rescinds a 2016 guidance that restricted states' ability to take certain actions against family-planning providers that offer abortion services.

Secondly, HHS' Office for Civil Rights (OCR) announced a "new proposed rule to enforce 25 existing statutory conscience protections for Americans involved in HHS-funded programs, which protect people from being coerced into participating in activities that violate their consciences, such as abortion, sterilization, or assisted suicide." OCR Director Roger Severino says that the new proposed rule will provide the new Conscience and Religious Freedom Division with enforcement tools for these conscience laws. HHS Press Office, January 19, 2018, *U.S. Department of Health & Human Services,* https://www.hhs.gov/about/news/2018/01/19/hhs-takes-major-actions-protect-conscience-rights-and-life.html

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