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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Pages</th>
<th>Acknowledgements</th>
<th>6–7</th>
<th>Introductions</th>
<th>Dr. John Loike</th>
</tr>
</thead>
</table>

## Section I: CLINICAL ETHICS

<table>
<thead>
<tr>
<th>7-12</th>
<th>Should Oxygen Enhancement Be Used Outside the Emergency Room?</th>
<th>Garrett Ruggieri, Jeremy Thomas</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-21</td>
<td>Reconciling Paternalism and Patient Autonomy.</td>
<td>Skylar Johnson</td>
</tr>
</tbody>
</table>

## Section II: TECHNOLOGICAL INNOVATION

<table>
<thead>
<tr>
<th>22-26</th>
<th>Feel the Pain.</th>
<th>Dylan Marshall</th>
</tr>
</thead>
<tbody>
<tr>
<td>27-32</td>
<td>In Vitro Gametogenesis: Towards a Brave New World of Reproductive Technology</td>
<td>Rachel Koh, John Xie</td>
</tr>
<tr>
<td>33-38</td>
<td>Future Bioethical Implications of Personalized Medicine.</td>
<td>Alyssa Feldstein, Leila Hwang</td>
</tr>
<tr>
<td>39-42</td>
<td>The Segmentation of Parenthood.</td>
<td>Karl Guo, Lauren Hsu</td>
</tr>
<tr>
<td>43–45</td>
<td>Should We Drink From The Fountain of Youth?</td>
<td>Mitchell Feinberg, Kapil Wattamwar</td>
</tr>
</tbody>
</table>

## Section III: HEALTH SYSTEM DILEMMAS

<table>
<thead>
<tr>
<th>46–50</th>
<th>Medical education in need of complete overhaul?</th>
<th>Fernando Barajas</th>
</tr>
</thead>
<tbody>
<tr>
<td>51-52</td>
<td>Life, Liberty, and the Pursuit of Healthcare.</td>
<td>Monica Agarwal</td>
</tr>
<tr>
<td>53-55</td>
<td>The flawed construct of patients as consumers.</td>
<td>Irmina Gawlas</td>
</tr>
<tr>
<td>Page Range</td>
<td>Title</td>
<td>Authors</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>56–59</td>
<td>Hiding Medical Errors.</td>
<td>Austin Barnett, John Xie</td>
</tr>
<tr>
<td></td>
<td><strong>Section IV: PHARMACEUTICAL INDUSTRY</strong></td>
<td></td>
</tr>
<tr>
<td>60–62</td>
<td>A Hard Pill to Swallow.</td>
<td>Andrew Ghazi, Jingkang Chen</td>
</tr>
<tr>
<td>63-69</td>
<td>Dietary Supplements.</td>
<td>Stephanie Cheung, Monica Lopez</td>
</tr>
<tr>
<td>70-73</td>
<td>Is Misinformation a Side Effect of the Pharmaceutical Industry?</td>
<td>Claire Duvallet, Garrett Ruggieri</td>
</tr>
<tr>
<td></td>
<td><strong>Section V: BIOETHICAL DILEMMAS</strong></td>
<td></td>
</tr>
<tr>
<td>74-78</td>
<td>Medical Data Obtained from Nazi Research.</td>
<td>Gregory Judson</td>
</tr>
<tr>
<td>79-84</td>
<td>Identifying Personal Genomes by Surname Inference: Deanonymizing DNA.</td>
<td>Megan Armstrong, Claire Duvallet</td>
</tr>
<tr>
<td>85-89</td>
<td>From Cocaine to Caffeine: Habitual Drug Use and the Prevalence of Addiction.</td>
<td>Megan Armstrong, Christian Carter</td>
</tr>
<tr>
<td>90-93</td>
<td>Discovering Side Effects With Search Queries: Health Trend Innovation or Privacy Invasion?</td>
<td>Andrew Ghazi, Jessica Werlin</td>
</tr>
<tr>
<td>97-99</td>
<td>Sex reassignment therapy and adolescents.</td>
<td>Pin-Joe Ko, Chinenyenwa Mpamaqugo</td>
</tr>
</tbody>
</table>
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Ruth L. Fischbach, PhD, MPE
Professor of Bioethics
Director, Center for Bioethics
Columbia University College of Physicians and Surgeons
This issue of the Columbia Journal of Bioethics contains fascinating opinion pieces on ethical dilemmas emerging from new biotechnologies. We are experiencing a tremendous growth in new scientific discoveries that embraces robotics, genetic engineering, reproductive medicine and sex reassignment. Many of these new technologies also present bioethical challenges that our society must address. These articles offer interesting approaches to resolve these bioethical dilemmas. In addition, there are articles in this Journal that present innovative and controversial opinions on classical bioethical issues such as birth control and the ethical behavior displayed by the pharmaceutical industry.

Once again, a great deal of credit goes to the editor-in-chief and all the copy editors who devoted a great deal of time to ensure the production of this issue of the Journal. Working with these editors and all the students who submitted these articles gave me great satisfaction and hope that the next generation of scientists and health care providers will have the talent, determination, and knowledge to address the future ethical dilemmas that society will face.

John D. Loike, Ph.D.
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In 2006, while Dr. John Kheir was caring for a young girl with severe pneumonia, the girl's lungs filled with blood, causing her oxygen levels to drop. Despite Dr. Kheir’s efforts, the girl died before he could place her on cardiopulmonary bypass. A frustrated Dr. Kheir began investigating alternative ways to deliver oxygen to patients and ultimately discovered that microparticles can be injected directly into the bloodstream to immediately oxygenate the blood (Kheir et al., 2012). Just as Dr. Kheir had hoped for, this astonishing technology could potentially have life-saving effects in emergency medical situations; the loss of one young girl’s life would cause the birth of a technology that could save countless lives in the future. If, however, this technology could be expanded into more lucrative alternative applications, should these alternatives be explored? Even if Dr. Kheir’s technology were used as he initially intended, would it be morally acceptable to also explore less ethical applications if the consequences could be highly profitable?

Dr. Kheir’s research team, at Boston Children’s Hospital, developed a fascinating method of bypassing the lungs to deliver oxygen directly to the bloodstream: lipid microcapsules. Dr. Kheir’s lipidic oxygen-containing microcapsules (LOMs) work the same way as the microcapsules that contain chemotherapy drugs or ultrasound dyes do: micron-size capsules made of a biodegradable membrane are filled with oxygen gas and are injected directly into the bloodstream, where they transfer their contents to oxygen-deprived red blood cells, until they eventually run out of oxygen and dissolve. The red blood cells, now oxygenated, go about their business as normal, as if the lungs had been functioning properly the entire time.

Dr. Kheir’s team has shown that LOMs can be used to continuously elevate blood oxygen levels in test animals from dangerously low levels to nearly complete saturation levels without detrimental effects for up to 30 minutes. This means that someone undergoing hypoxemia – due to a heart attack or a
lung injury that has left them without the ability to breathe for an extended time period – could receive an injection of LOMs to keep their blood oxygen at safe, healthy levels, potentially buying them enough time to rush them to a hospital for advanced respiratory care and support to save their lives. Dr. Kheir suggests that the LOMs could also be used as an emergency treatment to counteract acute carbon monoxide poisoning or to help stabilize newborn babies with congenital heart diseases. They could even be applied externally to skin wounds to help with and hasten the healing process.

The medical potential for LOMs is readily apparent and very profound. If LOMs were to save the life of even just one emergency room patient or newborn child, then its clinical use and applications would be justified. However, LOMs have ramifications and applications beyond those in the hospital. This technology has the potential to be applied elsewhere - perhaps in the military, the private sector, or even the sporting world. By allowing oxygenation and normal body function to occur without the need for respiration for a period of time, they have the potential to blur the line between normal and augmented human ability. So, where should we draw the line? Would it be ethical to take a revolutionary medical technology and use it to give soldiers an extra boost of stamina in battle? And likewise, should use of LOMs be allowed for professional athletes, for whom LOMs could give the winning edge in a competition?

The technology to provide intravenous oxygen delivery to the bloodstream without lungs would have vast potential military applications, but is it ethical to provide soldiers a technology that might end up improving their ability to kill when the technology was originally intended for saving lives in the emergency room? There is no doubt the military is already greatly interested in battlefield applications of this technology; Dr. Kheir’s research is partly funded by an award from the U.S. Department of Defense (Graham, 2012) as a part of the Multidisciplinary University Research Initiative (MURI),
which funds projects they believe will benefit the U.S. military (DOD, 2012). It is possible the military will restrict use of the LOM injections to situations it was intended for, such as aiding the treatment of a soldier undergoing hypoxemic cardiac arrest or hemorrhagic shock. However, it is also possible the military will expand the technology into a performance-enhancing tool, similar to the use of stimulants like Ritalin and Adderall by soldiers (Fiedman, 2012). Because blood oxygen levels are critical for peak athletic performance, the U.S. military started experimenting with “blood doping” in 1992 in an attempt to increase the blood’s oxygen levels for increased soldier aerobic capacity and endurance in hostile environments and to decrease mental fatigue (United Press, 1987; Foundamental Health Solutions, 2012). If Dr. Kheir’s method could quickly oxygenate the blood and if it can achieve the performance boosting effect sought after with blood doping, it is possible that this technology, although originally developed for medical aid, will be used to turn soldiers into more powerful killing machines on the battlefield.

Although this is a speculation – there is no scientific evidence that Kheir’s microparticles would have performance enhancing effects on humans – the ethics of expanding new biotechnologies into unintended and less ethical applications is an important issue, especially when the alternative applications could be extremely profitable. If Dr. Kheir’s LOMs could enhance performance, the athletic and exercise worlds would share the military’s interest. In an attempt to increase blood oxygen levels, athletes are known to use methods such as “blood-doping,” breathing oxygen from concentrators, or high altitude training to increase red blood cell mass (Fundamental Health Solutions). If Dr. Kheir’s LOMs were commercially available and could successfully increase blood oxygen levels, they would be in high demand as an effective and simple alternative to other blood oxygenation methods. A legal and commercial form of the drug could claim a huge stake in the athletic performance enhancing supplement market, an $18 billion industry (Pitzer, 2012).

However, this introduces the possibility that the use of LOMs in the sporting world could be classified as a style of doping. The World Anti-Doping Agency (WADA) defines doping as the “presence of a prohibited substance or its metabolites or markers in an athlete’s sample; or use or attempted use by an
athlete of a prohibited substance or prohibited method” (World Anti-Dope, 2009). Further, in 1984, the NCAA and American College of Sports Medicine ruled that blood-doping is “unethical, unfair, and exposes the athlete to unwarranted and potentially serious health risks,” but it is difficult to distinguish athlete use (Beckman, 2012). Similarly, it would be impossible to unequivocally detect that an athlete is in fact undergoing LOM injection. So, although the idea of performance enhancing LOMs is entirely hypothetical, the risk of the drug becoming a “prohibited substance” would need to be carefully considered before its commercialization.

The issue at hand is deeper than simply whether LOMs should be used for non-medical purposes; it’s whether such medical technologies should be used for less-than-just reasons, such as enhancing a soldier’s efficiency or helping an athlete eke out a victory, if it means being able to make a lot of money out of it. While expanding this technology into more lucrative applications at a small expense of moral justification is not the most ethical solution, it is acceptable under the stipulation that profits will drive the original medical research. Hypothetically, LOMs could be carefully licensed to the military or to private sector businesses based on prospective alternative applications. The profits could catalyze Dr. Kheir’s research and reduce the time it will take to get this drug into emergency rooms where it’s really needed. Additionally, alternative profitable applications would reduce pressure to profit from the emergency room use of the drug. Revenue from the alternate applications could provide a safety net so that the drug would remain inexpensive for medical patients.

In the end, these medical technologies will still be used for what they were originally intended to do - save lives - and even if the technology ends up being used elsewhere, the research driven by their profits would invariably result in developing even more medical technologies - and saving more lives.
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Michael Pitzer, M. Pros of Supplement Use in the HS Athlete. https://

In his 2010 New Yorker piece titled “Letting Go,” Dr. Atul Gawande discusses a case in which a couple decides to aggressively manage the wife’s, Sara, metastatic and terminal lung cancer. Despite numerous rounds of experimental medications and powerful and aggressive chemotherapy treatments, Sara passed away within eight months of her diagnosis. Like Sara, many terminally ill patients focus entirely on the medical battle against their disease, effectively avoiding the difficult but necessary conversations surrounding end of life care. Dr. Andrew Billings and Dr. Eric Krakauer of Harvard Medical School note how conditions surrounding these prolonged medical struggles are often inconsistent with the values and goals of the patients themselves. How does the patient-physician relationship need to evolve in order to reinforce patient autonomy while ensuring the quality of life (and death) the patient desires?

It is important to understand that terminally ill patients have concerns besides prolonging their lives; surveys report that top priorities include avoiding suffering, being with family, and not burdening others (Gawande). However, the questions that are commonly heard in the hospital revolve around medical technicalities, including the use of cardiopulmonary resuscitation, ventilators, and feeding tubes. The role of the physician is to find a balance between the prolongation of life and the preservation of its quality by individual patient standards. To address this problem, all primary care physicians should introduce “Advance Care Planning” to their patients before they fall ill (Billings and Krakauer). In other words, physicians should have a detailed discussion with their patients to find out what is most important to them. Currently, Dr. John Loike of Columbia University posits that most conversations regarding health care decisions boil down...
to the patient asking the physician what the physician would do if he were in the patient’s position. This conversation is inadequate. Since preferences vary widely based on cultural, religious, and personal beliefs, discussions play an essential role in illuminating what patients desire and what they want to avoid.

After the action plan has been made, how should a physician care for a terminally ill patient? Some palliative care specialists argue in favor of hospice care rather than making the often futile effort of treating an incurable illness. However, many oncologists think the opposite; what if this patient is the exception to the statistic and survives? Paleontologist and writer Stephen Jay Gould exemplifies this medical rarity (Gawande). Although he was diagnosed with mesothelioma, a cancer of the protective lining of the cells that coat the internal organs, Gould refused to accept the statistic that the median survival expectancy was eight months. Instead, he opted to attack the cancer in the battle for his life. With a tenacious treatment plan, Gould miraculously made a full recovery and lived for twenty years after his diagnosis. Physicians cannot ignore that a strong will to live can be a powerful force in survival.

What is wrong with treating every patient like he is Stephen Jay Gould? The problem is that a supermajority of patients will not be as fortunate as Gould. It would be ethically and professionally wrong for a physician to treat his patients assuming that they will be the exception. Instead, it is vital that physicians be honest with their patients. Many patients want the advice of their doctor in order to make informed, autonomous decisions about their end of life care. Patient autonomy is disrespected when physicians mislead them, believing that they will be outliers to the statistic. A recent study found that 40% of polled oncologists had deceived their patients by offering them a treatment they knew would not work out of fear of crushing the patient’s hope (Gawande). At the same time, a physician that is too pessimistic about a patient’s potential outcome is just as harmful towards the patient’s autonomy. Both cases highlight why “Advance Care Planning” is so important; while some patients are motivated to pursue aggressive treatment when they are told about the probability of their survival, others may find that hospice is
When most people think of hospice care, they think of a patient attached to a morphine drip, drifting in and out of consciousness, waiting to die. Hospice care is stigmatized because it is assumed to be a way to let people die "naturally." In contrast, the true goal of hospice care is to help people live the fullest possible lives during their illnesses. Hospice care often allows patients to live at home with their loved ones. Patients can manage their own pain and are given emergency packs in order to address a smattering of symptoms including nausea, fever, and anxiety. Choosing hospice care does not mean that a patient has given up his will to live; it means that he does not want to die bedridden and intubated in an Intensive Care Unit. Moreover, it has been demonstrated that individuals in hospice care enjoy their final days more (and live longer) than do individuals in an Intensive Care Unit. Hospice care allows for terminally ill patients to set the terms by which they live each day according to their particular values and goals. To preserve patient autonomy and quality of life, primary care physicians need to have honest conversations with their patients about their illnesses, options, and moral values. Such conversations should be specific to each patient, taking into account the patient’s personality and his views on death and illness. As future physicians, we hope that the implementation of "Advance Care Planning" will remove the stigma that surrounds hospice care and will help our patients make autonomous decisions about their treatment plans.

References:


The current prevailing view of autonomy is that of personal autonomy, or respect for the individual and his or her judgments and values. The concept of respect for autonomy is, therefore, that an individual should make decisions, as long as they do not harm or interfere with the autonomy of others, and that their decisions are to be respected, regardless of whether these decisions seem reasonable to the majority. This type of respect for autonomy is built into our legal system in the form of informed consent. This idea of autonomy and respect for one’s autonomy can be seen as a response to the paternalism prevalent in medicine prior to the first legal cases that resulted in protecting autonomy. Paternalism has its roots in the idea that the physician, with greater knowledge and experience in medicine, consequently has a better idea of what the morally better choice is in a given medical situation. This article will consider the arguments for both paternalism and the modern patient-centric decision model in the context of different ideas of what constitutes autonomy, and then attempt to reconcile the two with the concept of shared decision-making.

Prior to the advent of scientific medicine, where the physician actually has knowledge of medical practices or treatments that could shift the course of certain diseases, the doctor had a minimal or even a deleterious effect on the course of disease in historic times. In these times, the patient decided whether to bring the doctor into the home, and either followed the advice given or disregarded it completely. With the advent of modern medicine, the patient, in choosing to come to the hospital, has chosen to be under the care of the doctor. Prior to the widespread use of insurance, the patient was intrinsically allowed to express their values, based on the medical services and treatment courses that they decided to purchase. Before autonomy was valued in the modern sense, the advent of insurance negated financial considerations in the patient, and current medical practice alone dictated what series of treatments were warranted for a given medical condition. Therefore, once the patient came to the hospital, the patient could choose which
tests and medical treatments should be done. With paternalism, once the patient has chosen to come to the hospital, their medical decisions on treatment courses are made for them.

It could be argued that, under the paternalistic view of modern medicine, the patient is still being autonomous: They decide to place their fate in the hands of doctors who have expertise in a field that they do not. The concept here can be compared to that of choosing a religion. When one decides to believe in a certain religion, the values and moral viewpoints of the religion then theoretically become ingratiated in one’s concept of self, and one’s decisions made are no longer those of the individual, but those of the religion one has chosen to believe in. Though the individual is still making each individual decision under the auspices of religion, their initial choice has led to each later choice being under the influence of the moral ideas of that religion. When one comes to the doctor, one, therefore, has made a choice to believe in the moral compass of modern medicine, and secedes one’s beliefs in favor of what the physician thinks is the best decision, as based on scientific literature and evidence within the field at that time.

However, as it has been pointed out by Iain Brassington, taking on a Kantian interpretation of autonomy, where human reason creates a moral categorical imperative, and autonomy means being free from any inner or outer influence, only decisions made with pure reason are to be respected[1]. Under this concept of autonomy, the person who allows him or herself to be subjected to the views of others are not truly acting autonomously, and therefore, his or her decisions should not be respected. However, this Kantian view can be interpreted in two very different ways. It is used by Iain Brassington to defend a more
conservative view of autonomy, for patients who have impaired decision-making skills, and do not have the ability to make autonomous decisions (Brassington, 2012). However, it can also be interpreted to mean that as physicians, we should attempt to ensure that there are no outside influences, so that the patient is free to make an autonomous, reasoned decision. Therefore, if a person makes a conscious decision to enter into the care of modern medicine, it is the duty of the physician to protect their autonomy, by attempting to remove undue influence, including their own, from the patient’s decision-making. At each juncture of course, the patient can choose not to make an autonomous decision. The argument against this would be that there is only one “right,” decision, as according to Kant, because reason for him is governed by the universality of any given decision, and therefore, if patients are not using their own autonomy and must be protected, then doctors would have to make the decision for the patient regardless.

This, however, is where interpreting Kant becomes difficult. Humans are shaped by their subjective experiences, and though, these experiences are not to be respected in terms of autonomy in the Kantian sense, there is inevitably disagreement about what the universal morals are in each given case. In the end, doctors’ decisions are shaped by their own values, which are difficult to universalize to every case. If we attempt to apply what we think are universal maxims to each individual case, inevitably, the subjective values of others might necessarily be harmed adversely. The idea of respecting autonomy with regards to authority can be seen as a reconciliation of Kantian and liberal views of autonomy in an era where individuals are respected as having subjective moral compasses. The idea of subjective autonomy was included in Aristotelian ideas, where Aristotle, in discussing the meaning of life as happiness, comes to the conclusion that self-sufficiency is an essential ingredient of happiness, and involves a lack of dependence upon external conditions for happiness (Dryden, 2010).

This concept of self-sufficiency has been reflected in many modern philosophers ideas of the individual. In “On the Genealogy of Morals,” Nietzsche presents the idea of the ascetic ideal, where a person can rise above their desires, which have been created through the sensible world, and attain a state of independence, or self-sufficiency (Nietzsche, 1887). In other words, this
person can rise above morals by becoming post-moral, and freeing themselves from sensible desire. This is often incorrectly interpreted to mean that a person can do anything they want, as long as it aligns with whatever moral compass they choose. However, the meaning of his work is more similar to Aristotelian ideas, that a person is truly free and autonomous when they break free of societal influences and act in accordance with individual reason.

If a person murders others to achieve happiness, then they are not truly free of the influence of society, as they need others to achieve their desires, and their happiness is not one of self-sufficiency, but one based on morals, where there must be an opposite of happiness in which the person needs act within society, in order keep on the good side of their subjective moral compass. With this idea, the achievement of individuality and thus, autonomy, is not dependent on a universal reason, but a reason not influenced by desires rooted in societal norms or outside influences. From this view, individuals can have their own values that transgress any sort of universal moral, as long as they are values based on reason and not desires, as reason for the self-sufficient person is free from sensible desire or moral values. As suggested by Hope et al., the doctor’s responsibility is then, to respect an individual’s non-influenced self, the true self, or the one with authority, as this will lead to happiness of the individual.

The problem with this viewpoint is that it can be difficult to determine what the patient’s true values are. The values of the physician are inherently based in the concept that the medical goals are the ones of value, and should take
precedence over other goals. In the modern idea of valuing autonomy over any type of paternalism, the doctor theoretically lets his or her values take a backseat to choices of the individual, and the patient becomes the primary decision maker. Daniel Groll argues that the patient often knows what they want their end to be, but do not know what proper decisions are medically necessary and best means to that end (Groll, 2011). The doctor seeking to meet the patient’s desired goals becomes both someone with expertise in medicine, but also, someone looking out for the patient’s well-being and best interests. It is a value judgment for the patient, not the doctor, to make regarding what their well-being means to them and what their best interests are. It is the duty of the physician to determine what values have authority in the patient in order to protect their autonomy, by helping them make choices that will be reconcilable with those values.

A proposed solution to this is through shared decision-making. This is an emerging concept whereby the physician relates the best-available evidence to a patient regarding their treatment choices. The patient is then guided through deliberation of the possible positives and negatives of each option. The physician and the patient then discuss what the patient hopes to achieve from treatment in order for both the physician and the patient to get a better concrete understanding of what the patient’s end-goals are. The physician then guides the patient through making an informed decision determined to best achieve that goal. The physician acts as a reservoir of knowledge and as an expert in what management option might best fit the patient’s values and goals. Promising preliminary research on shared decision-making shows that it likely will increase both patient and provider satisfaction with encounters and decisions (Bozic and Chiu, 2011).

There are of course situations in which this approach is not possible, as in patients with impaired mental states. The difficult situations will still be those in
which the patient is delusional about what their values actually are, or where they are not able to make a coherent decision with respects to their values, because they are afraid of the means through which those must be achieved. This latter situation is where it could be argued that the current concepts of a liberal respect for autonomy are actually detrimental to the values of the patient that hold authority. Paternalism in this setting would actually protect the autonomy of patients in that their true-self, the one with authority, is respected. It can be argued that these desires of the patient to seek options that do not achieve the goals their authority values, whether through fear or anxiety, are not to be respected as autonomous, because they are influences that do not allow the individual to be self-sufficient. As discussed by Hope et al. in regards to authority, because the physician has the duty to protect the patient’s autonomy, the patient should be protected from these sensible desires; and the goal that is most in-line with what the patient values should be sought, regardless of the means. In this sense, the physician has the duty to act paternalistically to protect the patient’s autonomy in circumstances where desires belie those post-moral goals (Hope et al., 2011).

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Section II: Technological Innovation

Feel the Pain: Examining the Bioethical Issues of New Technologies that Measure Pain Signatures in the Brain
By Dylan Marshall

Whether a patient is suffering from a gallbladder attack or undergoing childbirth, the pain that is addressed is usually self-reported. In an article titled An fMRI-Based Neurologic Signature of Physical Pain, published in The New England Journal of Medicine, the authors discuss that this current way of assessing pain is far from perfect (Wager, Atlas, et al., 2013). A physician asks a patient how much pain he feels on a scale of one to ten, the physician not only trusts that the patient is being honest, but also assumes that the patient can accurately communicate what is being experienced, given that the patient has the capacity to communicate at all. The researchers write that “the capacity to effectively report pain is limited in many vulnerable populations”, this includes “the very old or very young, persons with cognitive impairment, and those who are minimally conscious.” The study chronicled in this article addresses the problem of self-reporting of pain by developing a technique to detect pain using fMRI. This research has the potential to make a significant impact on medicine and clinical care as it can lead to the development of an objective, standardized technique to measure pain in clinical settings.

The brain imaging technology that is used, Functional Magnetic Resonance Imaging (fMRI), “works by detecting the changes in blood oxygenation and flow that occur in response to neural activity – when a brain area is more active it
consumes more oxygen and to meet this increased demand blood flow increases to the active area” (Devlin, Tracey, et al. 2013). This technology is used to identify a ‘neurological signature,’ or consistent pattern of brain stimulation for when individuals experience both physical pain in the form of heat and emotional pain in the form of thoughts about a recent break-up of a romantic relationship. The authors reinforce the validity of the technique within the context of this study by demonstrating that there is minimal brain activity in the areas that are active with pain (the thalamus, the posterior and anterior insulae, the secondary somatosensory cortex, the anterior cingulate cortex, the periaqueductal gray matter, and other regions) immediately before and after pain is experienced, which means that only pain itself can cause a traceable pain signature in the brain. It was also found that the neurologic signature of pain is on a gradient: with a more intense stimulus there is a more intense response in the brain. Finally, they demonstrate how, with an opioid called remifentanil, the pain signatures in the brain were diminished. This altogether allows the visualization of the sensations of pain that words often fail to convey successfully. It is also able to distinguish between emotional and physical pain, and can display the impact of pain medication, making it extremely beneficial to the field of healthcare as a whole.

Though this technique seems to have immediate clinical applications caution must be exercised before it is used, just as with any new technology. In their article, Wagner, Atlas, et al., (2013) describe some of the issues that need to be worked out before this technology can be incorporated into “medical decision-making settings”. They point out that “pain classification may be less accurate in patients than in healthy persons” and that “pain-associated fMRI patterns may differ according to body site”. The researchers offhandedly remark that the “development of multiple pain signatures” will be necessary, and that any “clinical use would require calibration across persons, scanning protocols and research sites”. In other words, while the technology exists, the authors acknowledge that the way it will be used needs to be discussed and standardized before implementation.

The researchers list future technical issues with the technology, but they neglect to mention any bioethical concerns that may arise with the use of this technology beyond the fact that “the [neurologic] signatures [of pain] could
not...rule out the presence of pain with a non-normative neurophysiological basis," This brings up the issue of individualized vs. generalized pain management. When managing pain, should a patient’s own description of the pain being experienced be neglected in favor of the standardized report generated through fMRI? In the same vein, should a physician medicate a patient until the fMRI no longer shows the neurological signature of pain or until the patient himself verbally reports that the pain has subsided?

While addressing this bioethical issue, it must be kept in mind that the physician’s duty is to never do harm (non-maleficence) while working towards accomplishing good on behalf of the patient (beneficence) and respecting the patient’s wishes (autonomy). When it comes to pain, there is often a clash between the aforementioned ethical principals, especially since it is hard to make it tangible. One example is when a patient expresses pain but the physician either refuses or is legally unable to make a prescription of a high strength painkiller (Meier, 2013). When this occurs, patients who are not satisfied with their pain management either request a higher dose of their current medication, a stronger opioid, or a new physician, in an attempt to get a prescription for the drugs they want. In such instances, the use of the fMRI can provide an objective way for a physician to determine which painkiller and at which dose is appropriate for his patient. This technology can be used to limit over-prescription and potential prescription drug addiction and abuse. This also ensures that the prescription given to the patient is neurophysiologically appropriate—it would substantiate claims made by patients deserving stronger prescription drugs if the fMRI shows tonic activity in their pain centers in spite of their current narcotic.

While this technology can in some ways benefit those who are in vegetative or minimally conscious states by bringing to light the pain that they may not be able to
convey, it can also have grave ramifications for them in the case that the fMRI has not been able to appropriately judge their pain. The Hastings Center Guidelines for Decisions on Life Sustaining Treatment and Care Near the End of Life presents a set of ethical guidelines to efficiently manage pain while also respecting the patient’s rights (Hastings Center, 2013). As the above example demonstrates, this technology can help to overcome communication and language barriers that arise whilst providing care. But this does not mean that doctors should simply stop listening to their patients. Using fMRI to detect pain can also reduce the time taken to diagnose painful conditions that have no physiological basis, such as somatoform pain disorders. An unforeseen merit of this technology is the economic benefits that it can lead to. Pain not only lowers productivity of labor but also has significant healthcare costs. It has been found that the nation’s annual economic cost of pain ranges from $560 to $635 billion (Gaskin and Richard, 2012). While the use of fMRI technology for the management of pain can help to make the workforce more productive and lower medical expenditure by making treatment more efficient, the perceived economic benefits of the technology can also have negative impacts on patients. It can be misused by insurance companies to avoid paying for certain pain medications and other forms of therapy that address pain.

Keeping in mind the advantages and the ethical issues, this technology should remain investigational until it can be further validated outside the research context. Additionally, if and when the technology is put to clinical use, it should not be forgotten that the phenomenon of pain is yet to be completely understood on physiological and neurological levels, and that many painful experiences are both physically and emotionally damaging. As a result,
a physician needs to make an effort to understand a patient’s entire experience. No matter what the fMRI says, the physician must strive to uphold the Belmont Principles – autonomy, non-maleficence and beneficence – while providing care.

**References:**


In Vitro Gametogenesis:
Towards a Brave New World of Reproductive Technology

By Rachel Koh John Xie

Advancements in reproductive technology have brought us closer to the world of science fiction. The technique of in vitro fertilization (IVF) already allows for fertilization to occur outside the human body. Now, we may be a step closer to producing human egg cells in vitro. The study “Offspring from Oocytes Derived from in Vitro Primordial Germ Cell–like Cells in Mice” by Katushuiko Hayashi et al. has demonstrated reconstitution of the oocyte production in mice in vitro, from germ cell development to maturation (Hayashi et al., 2012). In this process called in vitro gametogenesis (IVG), embryonic stem cells (ESCs) and induced pluripotent stem cells (iPSCs) were induced into primordial germ cell-like cells (PGCLCs), which were then aggregated with female gonadal somatic cells to reconstitute ovaries in vitro. Upon transplanting the reconstituted ovary into a mouse, PGCLCs underwent oogenesis to form mature oocyte-like cells, which after IVF, contributed normal, fertile mouse pups. The study, however, had several drawbacks. It had lower efficiency of obtaining mouse pups from PGCLC-derived oocyte-like cells than from normal oocytes (3.9% vs. 12.7%), and roughly half of PGCLC-derived zygotes had three pronuclei (3PN) rather than a normal 2PN phenotype. The second complication could have been due to spindle fiber organization during meiosis II of the PGCLC-derived oocytes, which resulted in lower birth rates. Both points require further investigation.

Nevertheless, this study provides a robust, promising and exciting groundwork research for human application in the not-so-distant future. Since previous researchers have demonstrated IVG of sperm-like cells from ESCs and iPSCs from male mice, this study shows that in vitro gamete
development of both sexes is now possible. Since gamete-like cells can be derived from iPSCs, we can bypass the use of ESCs and the ethical concerns associated with it in both research and therapy, which involve the destruction of embryos. Recently, adult human fibroblasts have been successfully reprogrammed into iPSCs, which can be used for IVG research (Takahashi, et al., 2006).

As we get closer to using human IVG as an assisted reproductive technology, both the potential benefits and ethical concerns need to be considered. The impact on recipients of IVG and their families can be evaluated on a psychological and health-related basis. IVG offers new opportunities within medically assisted reproduction, particularly the ability for parents to establish a genetic link with their children. Current technologies can help infertile couples create a child with donor gametes, but this means that the parents and child are not genetically related. With the potential to use one’s somatic cells to create gametes, these parents would be able to pass their genes to their offspring. The establishment of a genetic link benefits both the parents and the child psychologically, as it promotes a positive conscious experience. Parents instinctively value the genetic link, stemming from a desire to extend their family lineage or to simply see certain traits of themselves in their child. We believe that the bond that the genetic link provides is undeniable, as there are countless cases of fathers deciding to care for a child solely based on genetics.

The ability to form a genetic link also resolves one of the fundamental bioethical issues associated with medically assisted reproductive technologies (ART). One of the well-known objections to IVF and other ARTs is that the child will suffer psychological consequences upon learning how it was conceived. This is particularly true in the cases where donor gametes are involved, as the social parents are different from the genetic parents. Should the child be informed of its genetic origins? Although the child has a right to know, the psychological trauma that may result could be more harmful than if the child
were not informed. A more extreme case would be children born from oocytes of aborted fetuses, as it is very difficult to tell a child that he or she has no biological mother. The use of IVG would resolve this ethical dilemma, as the genetic and social parents are the same. There is no risk for any secret to be accidentally revealed, as the parents would have no problem passing a paternity or maternity test. Even if the parents decide to tell the child about the IVG, the psychological harm would be relatively limited, as the child’s personal identity would not be affected. Thus, genetic origin arguments against the use of ART are not applicable in the case of IVG.

Although IVG resolves a traditional ethical issue, it may also introduce a whole new set of ethical dilemmas. IVG opens up the possibility that same-sex parents could produce children from their own genetic material. Since primordial germ cells lack sexual dimorphism, it theoretically means that sperm can be produced from a woman and eggs from a man. Even if this is possible, whether it is ethically permissible to do so is another question entirely. In order to resolve this ethical issue, its impact needs to be evaluated on both the individual and societal levels. On the individual level, proponents will point to the original genetic link argument by saying that homosexual couples also wish to pass on their genes to their children. On the societal level, while the couple is physically fertile, they are “socially infertile” on the basis of being unable to reproduce together. Allowing a child to be created from a homosexual couple would involve a manipulation of genes beyond what is possible in nature. While society has largely accepted DNA manipulation of non-human species (e.g. genetically modified foods), it still has reservations when human genes are being experimented on (e.g. human cloning, human-animal chimeras, etc.). Another ethical consideration involves the child and the psychological trauma that may result when he or she learns that both genetic parents are of the same sex.

In order to make IVG more acceptable to the community as a whole,
we propose that the IVG technique be used only for heterogeneous couples, at least until human gene manipulation becomes more widely used. Although this solution admittedly infringes on the autonomy of homosexual couples, a utilitarian approach is more applicable here based on the effects of IVG on children and social conventions.

Benefits of IVG are not restricted to infertile couples; this technique would offer a healthier, safer alternative to fertile couples that are having trouble conceiving, as well as to cancer patients. Currently, the most commonly used ART is IVF using eggs retrieved from hyperstimulation. Hormonal over-stimulation by means of medication can pose serious potential health risk and side effects, such as ovarian cancer and in extreme cases, Ovarian Hyperstimulation Syndrome, whose symptoms include blood clots, kidney failure and shock (Loike and Fischbach, 2013). Also, during the oocyte retrieval procedure, a thin needle is inserted into the vaginal wall and can lead to increased rate of infection, hemorrhage, and pain. Another ART, oocyte cryopreservation freezes and stores eggs for future fertilization, but yields a very low live-birth rate per oocyte thawed (3-4%), and is thus restricted to terminal cancer patients (Loike and Fischbach, 2013). IVG does not need to harvest oocytes and would produce oocytes in abundance from somatic cells for use in IVF.

IVG also has the potential to significantly reduce the chance of transmitting genetic diseases (e.g. Tay Sachs, Cystic Fibrosis) compared to IVF, as IVG supplies a much larger pool of gametes for Pre-implantation Genetic Diagnosis (PGD). Although genetic screening has human enhancement-related stigma, parents seeking PGD are motivated by the child’s welfare, as Jonathan Glover, a British ethics philosopher, mentioned in Choosing Children: Genes, Disability and Design: “Instead of the subordination of the individual to the social Darwinist struggle for survival, there is compassion for the future child. Instead of coercion by the state, there is respect for parental choice” (Glover, 2006). Also, since gamete selection is limited to the couple’s
genes, a child would be created from the best possible combination of those genes. As long as intentions are pure, IVG and PGD should complement each other as effective tools.

As with current ARTs, late pregnancy using IVG presents some ethical issues related to health risks for both parent and child. Studies have shown that older women who give birth have increased risk of cardiac disease, hypertension, and diabetes, and increased risks to the fetus, including low birth weight, preterm birth and fetal mortality. Furthermore, adult somatic cells from older women may have suffered considerable DNA damage and may be an inadequate source for deriving gametes (Newcomb, et al., 1991). To resolve this ethical issue, one needs to balance the potential adverse effects with the individual's rights.

Despite the health risks involved, a defined age limit would be difficult to impose on the basis of reproductive freedom and sexual equality (i.e. men can reproduce at very late ages). Another problem is the lack of conclusive data needed to justify a hard age cut-off. Therefore, the practice of late childbearing should be discouraged by the government and private clinics, but not outright prohibited.

Overall, we have only begun to scratch the surface of potential applications of IVG. While this technique is useful for infertile couples and genetic testing, perhaps the most intriguing application is in the field of eugenics. The creation of gametes from stem cells or somatic cells would allow for generations of humans to be created on the Petri dish. Once an embryo is formed, its stem cells could be used to create new gametes and fertilization can begin again - up to three generations of human beings could be produced in a year (Sparrow, 2013). One bioethicist, Robert Sparrow, claims that such a quick turn-around would allow scientists to conduct genetic screening and enhancement on humans (Sparrow, 2013). Of course, such a technology also brings new ethical issues to the forefront. In particular, the children...
created from this method would have no biological parents, and they would only grow more distant from their forefathers with repeated generations on the Petri dish. Thus, both safety and ethical considerations need to be addressed before we even begin to think about making Huxley’s *A Brave New World* a reality.

**References**


In this paper, we examine the bioethical implications of personalized medicine, specifically how medications for the treatment of Alzheimer's Disease may be targeted towards a specific individual's genetic composition in the near future. While the scientific potential presented in 'Stem Cells Guide Alzheimer's Drugs' by Kondo, et al. (Nature 2013) is still in its early stages, the historical success of pharmacogenetics gives such scientific possibility lots of potential. There are thus serious bioethical ramifications with which to contend, including: 1) fair access to potential individually-tailored Alzheimer’s drugs; 2) how to sustain and fund medical research and development in areas that affect only a small population subset and; 3) the ethics behind monopolies of genetic test products. We evaluate each of these bioethical quandaries in turn before examining potential solutions that attempt to address these serious issues.

The article ‘Stem cells guide Alzheimer’s Drugs’ by Kondo, et al. published in Nature (28 February 2013), discusses the possibility of devising more intricate categories of Alzheimer’s disease with iPSC cells and targeting effective treatment depending on these newly-defined categories. Alzheimer’s disease is a neurodegenerative disorder that results from the build-up of extracellular amyloid β peptides (plaques) and intracellular tau neurofilaments (tangles). Amyloid plaques are neurotoxic and cause cognitive impairments, leading to the symptoms of Alzheimer’s disease.

Unfortunately, there is very little progress regarding treatment of
Alzheimer’s. Docosahexanoic acid (DHA) was tested in some clinical trials but was ineffective in stopping the progression of Alzheimer’s. The authors of this article experimented on induced pluripotent stem cells from patients with different mutations that led to Alzheimer’s; two patients had familial forms, one with APP-E693Δ mutation, the other with APP-V717L mutation, and two others had sporadic ADs. The researchers confirmed that these mutations led to Endoplasmic Reticulum and oxidative stress, and found differential buildup of extracellular and intracellular amyloid buildup among the patients’ neural cells leading to oxidative stress and DHA responsiveness. The discussion of this paper ended with the hope that this study can galvanize Alzheimer’s pathogenesis and efficacy of drugs depending on different subsets of Alzheimer’s.

Should individualized genetic testing for Alzheimer’s treatment become a reality, the tests and medication would likely be quite expensive. Innovations in genetic testing and personalized medicine are situated squarely within the healthcare debate. Questions of justice and discrimination are inevitably raised when access to healthcare is mediated by financial considerations. For example, current testing for a BRCA1 or BRCA2 mutation by the company Myriad runs from a few hundred to a few thousand dollars (Dowe, 2013). Healthcare insurance often does not cover genetic testing and unless this changes substantially in the future, individuals without the means to pay will be excluded from a potentially life-benefitting tool.

The innovation that the Alzheimer’s research article raises centers around a life-enhancing application, rather than a life-saving application, insofar as a drug’s efficacy can potentially be tailored based on an individual’s genetic markers. When considering questions of discrimination, justice, and distribution, this is an important caveat to take into account. Whether a treatment is life-saving versus life-enhancing is another not-so-subjective evaluation that colors the evaluation of bioethics. Moreover, issues of access disproportionately affect minorities and the poor. Can we really
envision a healthcare landscape in which certain populations are excluded from potentially life-enhancing medical care? Questions of Aristotelian distributive justice regarding optional, non-life saving treatments is complex ethical territory, particularly when funds are limited and priorities must be outlined.

In terms of proposing a potential radical solution to this problem of distributive efficacy, the first priority must be the redesign of the American healthcare system. While healthcare overhaul is a repeated mantra in the political sphere, the real implications of this Alzheimer’s research speak to the urgency of healthcare reform and increasing access to basic health services. The flip side of healthcare reform is that the system cannot possibly financially sustain the myriad healthcare endeavours of millions of currently uninsured Americans. While radical, there needs to be some mechanism by which the government can prioritize medical procedures. We propose that a council or federal agency be formed that can weigh the cost-benefit analyses of different medical interventions (Genetics and Society, 2013). The agency would conduct the same econometric calculations that pharmaceutical companies use to weigh philanthropic medical interventions in developing regions. While it may seem base to reduce medical access to cost-benefit analyses, there must be some mechanism by which we can societally try to redistribute finite resources. At the very least, cost-benefit calculations would reduce the discriminatory manner in which healthcare is accessed in the United States today.

Secondly, a significant bioethical question this paper raises is how to incentivize the research and development of pharmaceutical drugs that are geared to a very specific and tiny subset of people affected by relatively rare diseases. Over 5 million Americans have Alzheimer’s disease which, as a high
proportion, attracts pharmaceutical investment and R&D due to high profit potentials. Highly specific, genetically-targeted drugs would ostensibly shrink the potential-user pool. As personalized medicine gets more specific, at what point does it no longer become economically feasible to develop drugs? Moreover, if we have the technological know-how to create highly targeted drugs, do we have an obligation to manufacture them even if it is not economically sustainable? The bioethical tenet of beneficence would dictate that there is an obligation to provide the best quality of care available and to thus to continue to pursue research in these areas. The problem that most distinctly differentiates this bioethical consideration from the one previously mentioned is that personalized medicine is a medical innovation that could potentially affect millions of people. It is the development of each of these hyper specific treatments that runs aground of practical considerations.

The unfortunate reality is that medical research and care is inherently dependent on funding sources and financial resources. It is unclear how the new ruling of the Supreme Court will affect genetic testing procedures (Dowe, 2013). Since the court ruled that some gene patents and testing technique patents are invalidated, it remains uncertain how market forces will affect the future costs of genetically testing for breast cancer mutations.

We cannot offer a wholly radical solution to this bioethical consideration of incentivizing research in areas that only affect a tiny population subset, due to the constraining logic of economics and finite resources. The government runs a subsidy program for research into rare diseases that affect a small population ("orphan drugs"); it would be impossible to qualify genetic mutations in this category for fear of bankrupting the government. Ultimately, an innovative solution might be crowd-sourced funding. Big name medical causes, such as breast cancer or autism, significantly augment their research budgets vis-à-vis private donations. Similarly, popular funding sources for genetic research should also be encouraged. As genetic testing grows to prominence in such areas as breast cancer prevention, more and more people should understand the ramifications of genetically-informed, personalized medicine which could give rise to an important new source of funding.

The final issue we consider concerns the ethics of private monopolies
over genetic testing tools, which holds particular relevance today given the current controversies about the Supreme Court decision regarding *Myriad Genetics* (Kim and Farrell, 2013). For example, Myriad’s patent on BRCA gene mutation testing has raised questions as to whether it is ethical to force patients to be solely reliant on one company’s test when grave making medical decisions because second opinions from other companies would violate patent protections. A similar ethical issue applies to a situation in which the iPSC technology for subclassifying Alzheimer’s disease became more advanced to allow for genetic testing. The autonomy of the patient is a key tenet of bioethics. Does forcing the patient to be reliant on one company’s test infringe on the autonomous rights of the patient? Such a tricky issue occurs at the intersection of patent law and bioethical standards.

Patents ensure that the development of such vital tests remains a lucrative endeavour and encourages and rewards research and development accordingly. However, patient rights must be equally considered. A potential means of reconciling the needs of pharmaceutical companies and the public would be types of legal loopholes elaborated upon by Mr. Morrison. For example, patent-holding companies would be expected to allow secondary companies to perform the same tests but only in a second opinion capacity, which would eliminate free-riding problems. Should a patient request a second testing of their iPSC cells’ subtype, different centers that are designated by law may have the rights to run another test. These centers can pay a sum of money to the original developer of the technology, and buy the rights to run secondary tests. While the status-quo is unideal, the alternative (patent-elimination in this area) of draining financial incentives and inhibiting critical development of the promising area of personalized medicine proves to be a situation far more detrimental to the patient.

Therefore, we have outlined three primary implications raised by advances in personalized medicine pertaining to Alzheimer’s disease. While access to expensive and sophisticated treatments
remains the most difficult problem to comprehensively “solve,” crowdsourcing remains an innovative 21st century means to begin to address funding deficits. The third ethical question of patient autonomy and legal access to second opinions of genetic testing is bound up in serious legal questions. It is unclear how the Supreme Court’s decision will ultimately prove in future gene patenting cases and in genetic testing for breast cancer (Kim and Farrell, 2013). Ultimately, while each of these bioethical concerns is important in shaping how personalized medicine moves forward, we have faith that the field can advance while balancing the needs of the patient and the constraints of the system.

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The paternally focused, Western definition of parenthood has historically been very strict. If we look at stories from the past, we note a very specific definition of the traditional family where the biological mother and father of a child are defined as the child’s parents. Infidelity and divorce were rarely tolerated, children born out of wedlock were often considered *filius nullius*, meaning a bastard was the child of no one. In plays like Shakespeare’s *King Lear*, for example, an illegitimate child such as Edmund would not be able to inherit anything from his biological parents and would often be depicted as a most unsavory character.

This traditional definition of parenthood makes sense for its ease to enforce in legal matters and for the inherent evolutionary advantages. For legal courts it is much easier to determine who gets legal custody of a child and who has to contribute to the upbringing of the child if there is a tangible linkage between the child and the parents. It was also easy for the court and common people to assume that the biological parents would be most interested in the wellbeing of their child. Beyond legal purposes, keeping track of genetic lineage is useful because not only can it predict the appearance of the child, but also propensities for disease.

However, the traditional definition of parenthood seems to be eroding away in today’s society. In 1998, the California court of appeal ruled in *Buzzanca v. Buzzanca* that “intent” alone was enough for parenthood (Carbone, 2005). The Buzzancas used in vitro fertilization (IVF) and a gestational surrogate to have a child that had no genetic relationship to either parent. When the Buzzancas divorced right before the birth of the child, the court of appeals ruled that the “intent” to raise the child was enough to make John Buzzanca the legal father of the child and liable for child support. Courts no longer seem to adhere to a strictly biological definition of parenthood and judge on a case-to-case basis with the “best interest” of the child in mind.

The erosion of the traditional definition of parenthood can be attributed partially to the technological advancements in DNA sequencing and
IVF. The use of technologies such as IVF makes it possible for non-traditional families to exist, such as two mothers or two fathers in homosexual relationships. These family structures become increasingly relevant as the shifting socio-political tides begin to accept them (for instance the overwhelming opposition to Proposition 8). Once the courts recognized these non-traditional families, it was impossible to use a strict biological linkage to define parenthood. Additionally, advancements in DNA editing and diagnostic technology have begun to erase the need to keep tabs on a genetic heritage. Familial diseases can now be discovered through a lab test without knowing the family’s history. In the near future, it will probably even be possible to tell or design how good looking or smart a child will be just through DNA sequencing. As DNA and IVF technology continues to improve, now is the time to redefine parenthood in the Western world.

When considering the question of parenthood, we must delineate the traits that are ascribed to this role. In the most basic biological sense, parenthood is defined literally as those individuals who combine their genetic material to procreate. In the eyes of the law, the idea of parenthood is strongly associated with guardianship, which brings with it the financial and emotional responsibilities associated with a child’s upbringing. Within a family, the role of a parent is one of protection, education, stability, and support throughout the development of a child. Traditionally, biological parents

He will be quaking in no time

assumed all of these roles. However, with increasingly non-traditional family structures and methods of procreation, segmentation of these roles has become more prevalent. To better understand these relationships, we should reconsider what parenthood means and includes. While we can conceive of this as an ethical issue, its resolution has deep legal ramifications.

Each of these traditional components of parenthood provides a key piece of an individual’s identity: the
genetic contributors give the “raw material,” the legal guardians provide shelter and physical nourishment, and the parental figure in the family provides guidance for intellectual and emotional development. The creation and existence of a human requires the union of all of these components. However, since we are starting to see increasing segmentation of these roles to separate individuals, in order to define parenthood, we should select the factor most important in creating an individual: this must be the amalgam of ideas, thoughts, and experiences that enter one’s development. Are we more interested in the marble that Michelangelo used to create David, or in the sculpture itself? The masterpiece could not exist without the raw material. However, what really distinguishes it is the careful hand that details the sculpture. Similarly, the people who raise, take responsibility for, and educate the child are analogous to Michelangelo. Of course, they would not have the blank canvas upon which to create their masterpiece without the genetic combination from either themselves or the donors, but what really sets that child apart is his or her upbringing. Just as identical twins, with the same genetic material, are individuals, we must realize that the composite of their experiences, thoughts, and treatments constitute whom they are; the nature is always present, forming the framework within which we exist, but it is truly the nurture that defines who we are. For instance, Paula Bernstein and Elyse Schein, both part of a study conducted by Dr. Peter Neubauer, a child psychologist, were twins raised separately who first met in their 30’s. In an NPR interview, they affirm, “we are different people with different life histories,” noting that their identities are shaped by the families who raised them (Neubauer and Neubauer, 1996).

The raison d’être of any species is self-preservation, via one’s offspring. Biologically and within the animal world, this preservation usually means some type of genetic inheritance. However, moving towards the future, employing this identity-centric concept of self and parenthood, we can begin to break down superficial, physical barriers; as more children are raised in families that are nonhomogeneous in looks, we will see a societal shift towards de-emphasis on physical appearance. After all, we remember Socrates for the ideas he promulgated, rather than the way he looked or the children he fathered.
Perhaps we can all begin to pursue more transcendent legacies - based on ideas and identity, rather than on looks. This starts with a well-defined concept of parenthood in modern society: we propose centering this upon those responsible for the upbringing of the individual.

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Is this the land that has the fountain of youth?” asked Juan Ponce de Leon, who in the early 1500s embarked on a voyage to find the magical fountain in the New World. Though de Leon’s question is taught to elementary school children in light humor during history lessons, the answer to his question is more seriously sought after today than ever before.

In May of this year, a paper in the journal Cell by Loffredo et al. (2013) documented a reversal of aging in cardiac tissue by treating an adult mouse with youthful levels of growth differentiation factor 11 (GDF11). This groundbreaking discovery has several positive implications for human life, especially if extrapolated to use for other types of tissue. Yet many see an ethical dilemma: are we using engineering to trespass indisputable boundaries set for us by nature? If we succeed, could this technology give some patients an unfair advantage in life over others? The ramifications of this novel age-reversal therapy need to be objectively assessed in order to guide future research.

This therapy aims to reverse aging of cardiac tissue by modulating cardiac hypertrophy, the thickening of the heart’s walls, particularly in the ventricles. Cardiac hypertrophy is a product of normal systolic function and aging. Using proteomics, GDF11 was found to be a circulating factor that declines with age. The study under consideration employed heterochronic parabiosis of mice, i.e. surgically joining a young and an old mouse to achieve shared circulation. With this shared circulation, the older mouse received GDF11 at blood levels found in young mice. Drug delivery of GDF11 in
old mice reflected the same effects as parabiosis, reversing age-related hypertrophy and suggesting a therapeutic opportunity for cardiac aging (Rand, 1957). There is hope that once this research is successfully conducted on humans, infusions of GDF11 could reverse aging in human tissue.

To tackle the ethical issues linked to the GDF11 discovery, we have to first lay out a foundation for bioethics. Ethics is best defined as a code of values, recommending to all men what choices are right and wrong, good and evil. But why are these choices meaningful for humans? Because we are mortal. For all living beings, a certain course of action will result in life and a certain course in death. It is this life/death alternative that is the basis for all human values. Precisely because we must be alive in order to make any choices, an ethical code must hold life as the primary value. With life as the standard of value, self-destructive actions are thus evil, while values that promote a fulfilled, meaningful, happy life are morally virtuous.

To judge this cardiac technology, we must apply the standard of ethical value: man’s life. Many would argue that GDF11 infusion goes too far by changing our basic biology – transgressing the bounds set for us by nature. Yet based on the research by Dr. Loffredo, this technology has the ability to greatly improve the longevity and the health of countless humans. The latter point makes it profoundly moral. To answer the claim that altering human biology is “not natural,” I reply that neither is any human progress – from farming to running water to electricity to open-heart surgery. The only way humans have moved from cave to civilization is by using the earth’s resources and altering nature for the benefit of mankind’s survival. If a choice exists in granting the moral high-ground either to humans or to animals/plants, we as humans should value our own benefit foremost. This argument for the “natural order” is not very different from arguments presented in the mid-19th century against anesthesia. One midwifery teacher wrote, “the feeling is very strong against use [of anesthesia] merely to avert the ordinary amount of pain which the Almighty has seen fit.” To place the status quo of human suffering in nature above the well-being of humans is a perversion of the whole field of ethics. The concern for overriding nature does not hold weight in the face of a life-improving technology; to set such a boundary for progress would be to directly negate the standard of value, i.e. to enact an anti-life policy. Man must act as a rational being in order to survive, and ex-
To address the availability of anti-aging therapy to patients, we must answer the question of whether the government ought to guarantee such a treatment on the grounds of preventing inequality. But if there is such a principle as a “right to equitable anti-aging,” we must first define a theory of rights. Rights are defined as inalienable freedoms; if an action is a right then when someone prevents this action that person is by definition wrong. Our rights as humans derive from our requirements for life as a man. The rights to life, liberty, property, and pursuit of happiness come from the moral standard of value - for man needs to be free to pursue these in order to survive and flourish. If life is the standard of value, then it is morally right for man to pursue life, to pursue goals in a free society (liberty), to pursue property to sustain his life, and to pursue happiness as the end result of achieving his values. Should promising anti-aging therapy be identified as an additional right, or should this treatment only be available to patients who can afford it?

References


It is common knowledge that medical training in the U.S. is a rigorous and lengthy process. It is a marathon of sorts, as such medical professionals in the U.S. gloat that only the "best and the brightest" can endure the training. Upon completing a bachelor’s degrees, and sometimes additional coursework, U.S. medical students receive preclinical science training approximately for 1-2 years before 1-3 years clinical training during medical school. The focus and evaluation of students vary by rotation. Once students enter the wards, despite changes in focus, they are always subject to a medical hierarchy (that for medical legal purposes precludes them from valuable experiences). Though grueling, the process remains relatively unchanged since the early 20th century and needs to be reviewed for adequacy in producing excellent physicians and health outcomes.

The basis for the medical training in the United States is the Flexner Report published in 1910. It encouraged evidence based medicine and a strong understanding of basic sciences. In other words, the report concluded that sound medicine, as opposed to "quack" practices, could not be a trade; it required significant understanding of the biomedical sciences. Since the report was published, many great innovations have been made including, but not limited to, lab grade pharmaceuticals. Though scientists by training have been involved the process, inquisitive physicians are required to make the innovations and subsequently put them to use. These drugs, while useful tools in doctors' armamentariums, are an enormous responsibility. They must be used judiciously as they can have complex untoward effects not fully appreciated by those without a full understanding of human physiology. For instance, when first confronted with using beta blockers in diabetics, understanding of physiology would allow one to predict that they could be dangerous because they would mask symptoms of hypoglycemia. Furthermore, physician scientists are essential in conducting proper late stage clinical trials.
Similarly, the depth and length of basic science training is commonly de-. fended on the wards by senior faculty. They often justify the length of training by comparing physician assistants to MDs. The most common argument made is that physician assistants are able to follow an algorithm and treat simple conditions; however, unlike residents, they cannot account for unexpected side effects and treat “complex patients.” As all who practice medicine know, expect the unexpected, as patients do not follow the textbooks. That is, the management of patients with comorbidities or with genetic predispositions may fall outside of algorithm, hence requires physicians think, reason, and justify beyond the evidence-based management.

Like the preclinical curriculum, the core rotations in medical school are seen as essential in training adept, well-versed physicians. All core clerkships provide exposure to a unique set of diseases, bedside skills, and etiquette. For example, surgery affords experience with the decompensating patients and management of their acute disease. Medicine on the other hand, allows one to formulate differentials for complex cases and to treatment plans for chronic conditions. Obstetrics and pediatrics each provide exposure to unique subsets of the population. Psychiatry is a rich opportunity to deal with mental illness, which all physicians - regardless of specialties - must deal with respectfully. Finally, broad exposure helps undecided (or indecisive) students determine which field suits their interest and personality. At that point, particular skills learned in medical school can be honed in internship and beyond.

As the Dreyfus model of learning suggests, skill and efficiency are obtained with repetition. The importance of ample patient exposure cannot be underestimated. Nonetheless, senior physicians rapidly focus their assessment and then anticipate lapses in reasoning common to juniors. Thus senior faculty can bridge knowledge gaps or encourage heuristic approaches to hasten juniors’ growth. For example, I initially did not understand why not to order echocardiograms in
some patients with NSTEMI, despite knowing the algorithm. My attending explained that in patients with high pretest risks, a positive result was simply confirmatory, while intervention was still required with a negative result because the posttest risk was still high. More importantly, this test would delay intervention in a patient that statistically would require intervention. Moreover, a senior’s experience and insurance protects juniors from medical malpractice.

While there is a lot of good to be said about the current system, the preclinical curriculum could be shortened without jeopardizing a physician’s understanding of human physiology and approach to medicine. Indeed, while the curriculum at Columbia was abridged beginning in 2009, the class of 2013 had record scores on USMLE step 1 and step 2 CK. Another compelling argument for the futility of some of the knowledge tested in the preclinical curriculum is that many attending physicians do well in practice, despite forgetting a lot of what they have learned in medical school. The reasoning behind this is that the “information is useless in practice.”

Again all the clinical rotations impart important skills; however, the focus may be superfluous. Universally, medical students are asked to attend lectures geared toward those in that field. This information may be considered esoteric by some, yet it is presented by senior physicians who expect medical students to know this. For example, on my Ear, Nose, and Throat elective, we sat through multiple lectures where they discussed nasal packing for posterior bleeds, and then carried on about the merits of each kind of nasal tampon. On my obstetrics rotation, I went to in vitro fertilization (IVF) clinic, where I observed oocytes under a microscope. While these two topics are interesting [to these specialists], they are not useful in practice to an overwhelming majority of physicians.
Though there is a place for hierarchy, due to medical legal aspects of medicine, it has come to impair education and in the long run may jeopardize patient care. According to attending physicians, their residents are less prepared to deal with patients than they were at similar stages in training. This happens, despite the students and residents training under the same curriculum. Regrettably, attending physicians are forced to counsel and perform many procedures in place of their subordinates. They are forced to deprive their subordinates, though for the good of the patient, of valuable experience. Hierarchy also becomes a problem when residents and students alike lie about their abilities or (in)actions, to avoid confrontation with the attending physicians.

During medical school, I have often questioned the utility of the material tested in the preclinical curriculum. Many important topics were covered multiple times in different context. Besides that, the material often taught by PhDs lacked structure and remained unfiltered. That is, the lectures contained more useless factoids than information I utilized on the wards. The sentiment among some of my fellow peers was that they learned by reading on their own rather than from lectures and the syllabi. While the USMLE Step 1 scores increased my year, the NBME shelf exam scores did not, and I feel this is due to the lack of consolidation by studying for Step 1. Step 1 allowed me to focus on important information and integrate information from various blocks in the preclinical curriculum. For these reasons, I feel the curriculum would improve if clinicians reviewed the lectures by PhDs to eliminate redundancies and highlight important subject matter. These changes would not greatly affect physicians as researchers. Provided that physicians learn the importance of lifelong learning and a heuristic approach to medicine, they have the skills needed to conduct research. Once in residency or fellowship, they may learn the minutiae needed to conduct basic science research in their field.

Dr. Ezekiel Emmanuel published a report in 2012, stating that medical education could be shortened by 30%. While some of the proposed cuts are in the premedical and preclinical curriculums, he proposed significant changes in clinical requirements and residency programs. I agree with Dr. Emmanuel, that clinical curriculums can be focused on core clinical skills. Though most medical graduates eventually specialize, particularly those from institutions like Columbia, a shortened curriculum can provide them...
with skills to manage common conditions from each specialty at graduation. What I am suggesting is that course directors teach basic competencies under the premise that most will specialize (in fields other than their own). Under these circumstances, physicians would be able to treat common conditions and have a more holistic approach.

There is certainly a place for hierarchy in medical training. Nonetheless, medical students should not enter these settings until they have achieved core competencies. Learning in a simulation center would safely permit students to get hands on skills. Real life simulations, no different than training astronauts and fighter pilots receive, would allow students to test their clinical reason without killing anyone. Having learned core skills, students could be given more responsibility upon entering the wards.

The current medical education system that has largely been in place since the Flexner report has its merits, yet seems outdated. With a struggling health care system ranked 36 in the World Health Report, it is time for medical education to be reconsidered. A radical approach may be needed, but changes may first address the length and focus of medical school. Medical education should evolve with technology and use simulators to enhance training. Changing the curriculum to a more coherent curriculum, providing competency through simulation, and elevating various experiences may reduce the cost of medical education and improve health outcomes in a rapidly changing health care system.

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"Human suffering - if it exists, it exists. There is lots of human suffering in the world...I don't think about it! My life is my life, and that's my focus." - Yaron Brook, Executive Director of the Ayn Rand Institute.

"Patient dumping", the denial of medical services to a patient for economic reasons, was rampant in the 1980s. Insufficient medical insurance, the lack of admission deposits, or the manifestation of undesirable medical conditions, were grounds for refusal of care. People in need of immediate medical care were routinely and rashly refused treatment. Since its implementation, EMTALA [Emergency Medical Treatment and Active Labor Act (McCarthy, 2013)] has protected against discrimination in emergencies, which are inherently time-sensitive and life-threatening situations. The law mandates that hospitals provide emergency treatment regardless of race, creed, sex, citizenship, or ability to pay. However, with the advent of data-mining technologies, there are new ways to obtain discriminatory information such as credit scores and other financial data. Hospitals now engage in “wallet biopsies” - what essentially amounts to frisking patients’ pockets to ascertain their wealth. They are increasingly refusing treatment or altering pricing schemes based on such patient data. It is not hard to imagine a world where credit scores interfere with appropriate treatment.

Despite the financial discrimination the law works to eliminate, there are some who vehemently oppose EMTALA on the basis of the principle of autonomy. The political mainstream tends to fight for the right to equal access to health insurance, or for the right to access emergency care, but the Ayn Rand Institute fights for a different moral sanction: the right to refuse treatment.

Ayn Rand created objectivism, a philosophy that holds that morality is defined by men’s voluntary desire to live, and so men who choose to live for themselves are moral. Objectivism proclaims it immoral to demand that any person make a personal sacrifice for a greater good, and regards the notion of a right to emergency care as a form of enslaving doctors. This implies that a doctor, a hospital, or an insurance company may turn away a desperate patient if it causes even a small inconvenience, in the name of...
“rational selfishness.”

Even if we adhere to the principles of objectivism, it is clear that EMTALA does not violate the individual rights of doctors. The employment contract of an emergency room doctor is a purely voluntary contract consented to by both parties - with the implicit understanding that the doctor will treat certain patients free of charge. This is not a violation of rights, because the doctor contractually adheres to the hospital’s EMTALA policies. Even the hospital’s administration voluntarily agrees to the law; only by choosing to accept Medicare payments does the hospital become subject to EMTALA (McCarthy, 2013). Therefore, these hospitals are not innocent parties subject to harsh legislative action. Even the most individualistic society is inherently interdependent. Everyone from the richest businessman to the poorest janitor has a function in society. All humans have equal potential to be a productive member of society, including the young, old, poor, and disabled. Our nation’s founders and the writers of the U.S. constitution believed that “all men are created equal.” The founding fathers intended to provide for all men an equal footing. This does not imply that all are born with the same physical characteristics, rather that all men, regardless of the differences caused by natural forces, are entitled to equal opportunities. The reality is that nature is unjust. People do not choose their diseases, disabilities, and to some extent, their financial situation. Similarly, there is no choice in an emergency situation. Because each life has an inherent worth to society, every person deserves an equal opportunity to live. In this regard, EMTALA ensures the right to life.

Requiring a credit score or proof of citizenship at the emergency room door insinuates that humans are commodities of differing value, calling into question the very notions of equality that our nation was built upon. EMTALA is both practical and fundamentally moral, and it should be defended on principle. In a society that champions human life, to refuse care to any person is to negate the immeasurable worth of the individual.

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Capitalism and the free market have become as essential to American democracy as liberty and the pursuit of happiness. As a nation, we have decided that the most efficient and just way for goods and services to be exchanged is the free market, in which rational actors make informed choices in their own self-interest.

Thus far, we have rejected the premise of universal health care, and maintain that individuals are responsible for purchasing their own health insurance and are entitled to decide how they would like to consume health care.

The debate surrounding the Affordable Care Act has exposed the extent to which we value choice; whether it is the right to choose which doctor or hospital to go to, or what kind of care we want at the end of life (insert death panel reference of choice). Similarly, “rationing” of healthcare seems absurdly anti-American; it conjures Cold War-era images of oppressed Eastern Europeans standing in long lines for bread or milk.

Over the past two decades, Western Medicine has been heavily concerned with the informed consent and the autonomy of patients. This is why we do not assume brain dead patients would have wanted their organs donated, and why a woman’s right to make decisions about her own body trumps society’s discomfort with aborting fetuses.

We have come a long way from the historically paternalistic culture of medicine, and the memory of tragic lapses in informed consent and autonomy in cases such as Tuskegee irreparably harm the image of medical research for decades, and rightfully serve as reminders of the importance of protecting the rights of patients.

However, anyone who has encountered a frantic parent with a sick child, or a distraught family faced with end
of-life decisions for an incapacitated loved one, can recognize limitations of a model that assumes patients are rational actors making informed choices in their own self-interest. I believe that as a result of our obsession with the benefits of a free market and overemphasis on individual autonomy over all other values, we have created an unrealistic, flawed construct of the patient as a consumer that is detrimental to the patient-doctor relationship and meaningful attempts at health care reform. Ignoring the knowledge gap between physicians and patients is naïve and dangerous.

To take a simple example, when looking for a surgical oncologist, a patient might look for the surgeon with the lowest operative mortality. Suppose the patient finds out that surgeon A has a 1% mortality rate and surgeon B has a 6% mortality rate. The patient might rationally conclude they should seek treatment with surgeon A. But what if surgeon B’s mortality rate is higher because they have greater technical expertise and accept more complex cases? And surgeon A’s mortality rate is low because they accept only the simple cases to maintain favorable statistics or because they don’t feel comfortable performing more complex operations? Clearly, even a patient seeking to make an informed decision might arrive at a misguided conclusion.

With a few notable exceptions (fertility care, cosmetic surgery), patients wish they did not need the medical services they are consuming. Getting medical treatment is not buying a smartphone. After reading some blogs about their respective features, you can’t walk in to a hospital, try out a few chemotherapy regimens, and decide which one is the most user friendly. Medical decision-making is emotional, and fraught with ethical issues and uncertainty. In some cases, even experienced physicians have difficulty applying facts and reasoning; this is why doctors are not allowed to treat themselves or their family members. Emergencies are even less amenable to the consumer model—patients are logically taken to the nearest hospital equipped to treat their level of emergency, and seen by the first doctor or nurse available who happens to be on shift.

As a society we acknowledge the hard-earned expertise of lawyers, and recognize the legal system as too complex to be reasonably navigated by a lay person. It is a mistake not to acknowledge that, like the financial and legal systems, modern medicine is incredibly complex, and it would be absurd to expect patients to integrate the available information and make informed decisions
on their own; after all, we require physicians to train for over a decade before they can do so without oversight.

A recent podcast from RadioLab NYC exploring end of life issues (RadioLab, 2013) provides yet another illustrative example of the knowledge gap in medicine. Both physicians and non-physicians were informally surveyed about what sort of interventions they would want for themselves if they were brain dead. The non-physicians almost unanimously stated they would want CPR, mechanical ventilation, dialysis, antibiotics, and so on. The physicians, on the other hand, overwhelmingly did NOT want these interventions, and stated they would only want to be given pain medication. Revealingly, when asked how they would want to die, members of BOTH groups gave answers that amounted to “quickly, peacefully, and without pain”; so what patients said they wanted in the abstract was directly contradictory to their perception of specific interventions. The hosts of the podcast and their physician-guest go on to recount how little patients understand about intensive medical therapy – patients were shocked to learn that the success rate of CPR is in the single digits.


Aside from highlighting the pervasive lack of understanding of end of life issues, this report emphasizes the knowledge gap between physicians and patients. Call me a communist, but if the underpinning of a free market is that consumers make informed and rational choices, it seems that the model of patients as consumers rests on a shaky foundation.

References:
Medical mistakes are frightening and cannot be ignored. We’ve all heard it before – a surgical tool left in the body after operation; the wrong limb is amputated; an overdose of medicine is prescribed. It should not come as a surprise that even doctors make mistakes. What may be unexpected is the frequency and severity of these errors. According to a 2010 report released by the U.S. Department of Health and Human Services, medical mistakes contribute to 180,000 patient deaths a year (Levinson, 2012). Only heart disease and cancer are responsible for more deaths in the United States. In a 2011 study, it was estimated that one in three hospital admissions will result in a medical error by hospital personnel, which is ten times more than previously believed (Fleming, 2011). What’s even more disturbing is the lack of disclosure of these incidents to patients. This has contributed to a growing sense of doubt on the part of patients about whether their physicians have their best interests at heart. In a field that is and always has been about placing patients first, there is an urgent need to restore trust in the patient-physician relationship, by promoting transparency on the side of the physician.

From an ethical standpoint, all medical errors should be disclosed to the patient. Physicians have a duty to reveal the truth out of respect for the patient’s informed consent and autonomy. This is especially true when a medical malpractice – defined as a medical error that causes physical or emotional harm to the patient – occurs. In these cases, further
medical treatment or close supervision is often required, and the physician should ensure the patient is willing to permit or cooperate with these measures. However, if the doctor does not reveal the mistake, can the patient really give informed consent? Patients are not truly in charge of their lives if they lack complete medical information to make an informed decision. Even for mistakes that are not deemed malpractice, such as ones that have little marginal impact on the patient’s health or are corrected before harm is done, the physician has a duty to disclose the error. Establishing trust is paramount based on the nature of the patient-physician relationship. The disclosure of a medical mistake allows an open and honest discussion to develop, strengthening the trust of patients in the physician.

Unfortunately, ideal ethical standards do not always translate into reality. A recent study indicates that an overwhelming majority of patients (98%) favor disclosure of medical errors, regardless of significance. However, in a recent nationwide survey of 1,600 physicians, 34% surveyed did not agree that significant medical errors should be reported. Furthermore, 20% indicated that they withheld information about medical mistakes in the past year (Kaplan, 2012). What causes physicians to be hesitant about disclosing mistakes? Common responses from physicians are based on perceived harms to the patient or to themselves.

A doctor may fear that revealing these mistakes will ruin the bond of trust in the doctor-patient relationship. After learning about a mistake, the patient may become so disillusioned in the medical system that he or she is less likely to follow the doctor’s recommendations. While this is a valid concern, invoking this argument already undermines the foundation of trust built between patient and physician. How can doctors ask a patient to trust in their recommendations and treatment plans when they are not reciprocating that trust to reveal when things do not go according to that plan? By trying to preserve the bond of trust by not disclosing mistakes, they tend to jeopardize the bond even further.

Another common motivation to hide a medical mistake is the fear of retaliation by the patient, such as through litigation. As a result, doctors often have a gut reaction to “deny and defend” their actions in order to protect their careers and reputation. Patients often sue out of indignation, not because a mistake was made, but rather from a lack of honesty and reluctance to apologize on the part of the physician (Kaplan, 2012). This suggests that candid disclosure of a mistake
may actually decrease the likelihood of legal liability. After all, we as patients realize that even physicians make mistakes and are more willing to forgive if physicians are upfront about what they did wrong. The University of Michigan Health System has shown that a policy of full disclosure is effective, as their number of existing claims and lawsuits dropped from 262 to 83 in a span of six years. It appeared that by being more open about medical mistakes, malpractice lawsuits decreased as the patient-physician relationship was strengthened.

The temptation to hide medical mistakes will often be great, despite all the ethical arguments. Applying a disclosure policy based on pure ethics will be of little value if we put unrealistic expectations on the doctors themselves. Instead we need to change a popular culture that seeks to punish disclosure rather than encourage it. Rather than overreacting to a medical mistake and rushing to file a lawsuit, we should have more realistic expectations about medical care, including the fact that mistakes will always happen. Instead of saying to our doctor “How could you make this mistake?!” we should say “What will you do to fix it?” After all, trust is a two-way street – if patients can trust doctors to fix a mistake that was made, perhaps doctors will follow suit and be more open about revealing their mistakes.

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Clinical trials have served the important purpose of delivering safe, effective drugs through scientific research for the benefit of public health. The scars from the Thalidomide and Elixir sulfanilamide scandals still serve to remind us of abject results that can arise in the absence of clinical trials. These two drugs caused birth deformities and deaths that could have been avoided had they been subjected to the strict rigor of modern clinical trials. As beneficial as clinical trials are for the greater good of the community, there are also sacrifices that are made because of it. In 2010, two cousins, Thomas McLaughlin and Brandon Ryan, who were both suffering from melanoma ended up with starkly different fates. McLaughlin was enrolled in a clinical trial for a new experimental drug known as Vemurafenib, while Ryan was being given control treatment that has been shown to be ineffective for the past 30 years. McLaughlin’s tumors shrunk considerably after two months whereas his cousin passed away a year later. Such scenarios have led oncologists to question if extending the lives of patients, or overall survival (OS) rate, was still a valid clinical trial endpoint. Instead, by using progression-free survival (PFS) - the length of time after a treatment during which the condition does not get worse - as the primary measurement, the need for a control group may be obviated since there will be no need to compare the relative survival rates. Instead, all patients will be able to receive possibly effective drugs.

Vemurafenib was a highly successful candidate for treatment of melanoma even in Phase I trials, displaying exceptional tumor regression and median PFS though OS rate had not been determined then (Shaw and Nathan, 2013). Given Vemurafenib’s preliminary performance, many physicians felt it was unethical to deny patients access to the drug, especially when existing melanoma treatments are incredibly ineffective. However, marketing a drug without fully characterizing its effects runs the risk that the treatment can prolong PFS without improving OS. For instance, Avastin was recently revoked for use against breast cancer despite its efficacy in tumor regression because it did not help with overall survival.
and also resulted in toxic side effects such as hemorrhage and hypertension (Montimer, et al., 2013).

History has shown us that there is no way to be absolutely sure if a drug that had appeared efficacious in early clinical trials will be proven ineffective in more rigorous tests later. The thorough, systematic approach of controlled clinical trials will allow physicians to administer the best treatment for their patients with confidence, thus avoiding offering unsubstantiated hopes and needlessly taxing an overstretched healthcare system.

There are a few methods to help patients who do not respond well to a control treatment. FDA has an expanded access program which will allow terminally ill patients to use an unapproved drug when no other treatments are available (see www.FDA.gov). Moreover, patients in the control group may be removed to be placed in the trial group in what is known as crossover studies. For instance, it would appear unethical to continue subjecting patients like Ryan to an ineffective treatment. However, out of fear that unexpected side effects could hurt the chances for the drug’s approval and to prevent patients from gaining access to the drug without enrolling in clinical trials, pharmaceutical companies often deny patients the compassionate drug use. Furthermore, pharmaceutical companies want to avoid crossover studies for data clarity since such unplanned crossovers could introduce bias in analyses, which may delay the drug’s approval and release to market.

Often in clinical trials, the lives of patients are ultimately at the mercy of the pharmaceutical companies funding and managing the trials. If left entirely up to market forces, it is highly likely that programs that will benefit patients such as the expanded access program would not
be provided by profit-driven pharmaceutical companies. If healthcare were to be considered a public good, should NIH step up to fund and manage all clinical trials involving terminal illnesses, so that patients’ welfare is not compromised? Importantly, such conflict of interests also extends to the data analysis of clinical trials. In an attempt to make a new drug appear superior to existing treatments, clinical data may be selectively reported by those who stand to profit from the drug’s sales.

By prioritizing economic objectives and viewing clinical trials as transactions, pharmaceutical companies have often failed to respect patients as human beings and treated them as instruments for financial gain. Pharmaceutical giant GlaxoSmithKline will be fined three billion dollars under the False Claims Act for deceptive marketing and reporting of clinical data (Kelton, 2013). This is not an isolated case. Pfizer and Abbott Laboratories have also been fined hefty sums for the same act. While some may argue that a desire to maintain good reputation will encourage companies to be more thorough in trials, the truth is that companies are willing to forgo ethics in a bid to stay ahead of competition. However, legislating for NIH to take over clinical trials will be an enormous uphill task, not to mention the colossal amount of public resources required to pull off such an operation. In a time when various governmental departments are facing budget cuts, such a scenario is highly unlikely.

Short of becoming a nanny state where the NIH manages all clinical trials, the institutional review boards (IRBs), which review and approve clinical studies, could identify life-threatening diseases that lack effective treatments early and take measures to ensure that pharmaceutical companies give the assurance to provide expanded access in such situations. Also, to avoid a court case whenever a compassionate drug use is unjustly denied, the terms of compassionate drug use should be clearly and simply stated out in the informed consent document approved by the IRB before the commencement of clinical trials.
The solution may not be straightforward but the message is clear - clinical trials are here to stay but there must be balance between scientific rigor, economic objectives and patient well-being. Only then can a common understanding among stakeholders be achieved and the hard pill made easier to swallow.

References


According to a Center for Disease Control (CDC) report released by the National Nutrition Monitoring System on dietary supplement use among adults in America, the percentage of the population that uses at least one dietary supplement has risen from 42% in 1988-1994 to 53% in 2003-2006 (Gahche et al., 2011). While there is a growing trend in dietary supplement usage there is also an even faster growing trend in ignorance and misinformation among the general population about the efficacy of such supplements. This disparity comes in part from mixed messages sent from conflicting, difficult—to—understand research results and over-enthusiastic pseudo-experts hoping to profit from equating vitamins and supplements to medicine. The danger in this kind of practice arises when fact becomes mixed with fiction in a medical setting. Claims that supplements prevent cardiovascular disease or stroke are especially dangerous because cardiovascular disease is the leading cause of death worldwide. The CDC reports 597,689 deaths per year due to cardiovascular disease. With such a prevalent disease that takes so many lives, it is important that the correct information regarding prevention is presented.

In a systematic review by Dr. Seung-Kwon Myung of over 2240 articles (Myung, et al., 2013) that study the efficacy of supplementation with vitamins and antioxidants over the past 23 years, it was concluded that there was no evidence that the use of vitamin or antioxidant supplements aided in the prevention of cardiovascular disease or stroke. The review looked at many different vitamins and antioxidants, such as vitamin A, vitamin B6, vitamin D, vitamin E, vitamin C, etc. Myung looked at 7 studies involving vitamin C, a familiar vitamin that has medicinal qualities associated with it. Over all, these 7 studies showed the relative risk for cardiovascular disease to be 0.99 with a 95% confidence interval of 0.94 to 1.04. Having relative risk as 0.99 means that the ratio of the control group to the experimental group in these studies was 0.99, meaning that the added dosage of...
vitamin C did not prevent cardiovascular disease any more than the control treatment. The 95% confidence interval tells us that if these studies were done many times, in 95% of them the relative risk would still fall between 0.94 to 1.04. This demonstrates a very small difference associated with taking vitamin C. The ratio barely changes whether the dose is low (120 – 250 mg/day) or high (500-1000 mg/day). This is significant because the surgeon general recommends a dosage of 75 mg for females and 90 mg for males, but it seems that going beyond this dosage, which many outside sources, such as WebMD, recommend is not beneficial.

Breaking the result down even further, Myung et al., (2013) looked at the role of vitamin C in the prevention of specific outcomes. It was shown that vitamin C supplementation has a relative risk associated with cardiovascular death of 1.03 with a 95% confidence interval of 0.95 to 1.12 and the relative risk associated with stroke is 0.95 with a 95% confidence interval of 0.88 to 1.09. Clearly, these numbers show that consuming more vitamin C has no benefits in preventing cardiovascular disease or stroke. The validity of this paper comes from its thorough meta-analysis of the current research on vitamins and supplements. Only articles that are of high quality (double-blind, randomized, masked, follow-up conducted after 6 months or later) were assessed in the analysis. Other different factors were accounted for as well, including the type of prevention, dosage, study design, duration of treatment, funding source, type of control, number of participants in each trials, and supplements given singly or in combination with other supplements, etc. (Myung et al., 2013)

Individuals who are knowledgeable in the field of science are able to find such scholarly publications and examine the references and conclusions in a critical manner; however, for those who are unfamiliar with the field, it is not difficult to follow the one-sided presentation of “facts” regarding vitamin supplements presented by profit-driven industries. For
instance, there has been a new boom in the market of vitamin and antioxidant supplements due to modern obsession with details regarding health. The problem with this is that people often turn to the Internet as a source of fast, accessible, easy-to-process information. However, there is a lot of scientific (and/or medical) information online that is often biased and unverified. Foremost among such websites is WebMD Health Corporation, which supposedly aids in the translation of information from scientific research, physicians, and health professionals to the public, but more often uses its platform to spread misinformation and push the agenda of their advertising sponsors. Self-proclaimed scholarly sources of scientific and medical knowledge that do not provide objective information yet have the public's ear and trust, infringe on the bioethical principles of nonmaleficence and autonomy. The principle of nonmaleficence requires that one ‘does no harm’. Using pseudo-science and biased medical “facts” to lead people to believe something that would be harmful for personal gains is a clear infraction of the principle of nonmaleficence. Presenting unverifiable and biased medical information along with a parade of health-related business advertisements to sell specific products by playing consumers’ fears is a clear violation of nonmaleficence. Such unethical business practice also goes against respecting consumers’ autonomy. Upholding an individual’s autonomy means being respectful of his/her ideas, opinions, and decisions. In short, autonomy is self-authority. By misleading a trusting audience, organizations such as WebMD put forward misrepresented medical ideas under the guise of legitimacy. This violates the autonomy of their audience members by influencing the choices of those individuals based on possible misinformation that has been supplied and altering the competency of those individuals to make their own decisions. Instead of making informed choices based on objective information, individuals are now coerced into making decision that are based more on their fears, rather than rational choices.

WebMD Health Corporation is a prominent example of this bioethical dilemma because it is "the number one
most trusted consumer brand in the U.S” with “the largest number of visitors of any health information site.” It claims to be a health and medicine-specific information source that offers “credible and in-depth medical news, features, reference material, and online community programs” and puts forth information under the pretense of being a legitimate source of scientific/medical knowledge when it does not adhere to the same standards as the scientific community (WebMD-1, WebMD-2).

Myung’s paper serves as a point of reference when examining the manner in which information about supplements is disassembled to the general public. The article cites a number of legitimate sources, examines each source objectively, and was submitted to a journal that required unbiased peer review. On the other hand, the information that WebMD reported regarding the connection between vitamin C and stroke and cardiovascular disease, was highly one-sided and appeared to follow an underlying agenda. The specific WebMD entry reads: “Although research has been conflicting, one study in the American Journal of Clinical Nutrition found that those with the highest concentrations of vitamin C in their blood were associated with 42% lower stroke risk than those with the lowest concentrations. The reasons for this are not completely clear” (WebMD-3). Here, there is a clear desire to portray only one side of the ‘conflicting’ research, the side that shows an impressive correlation between high levels of vitamin C and decreased risk of stroke, yet there is no mention of the other, contradictory side. Despite the clear biased presentation of information, WebMD uses references to validate the line of reasoning desired. But upon examining the reference list, the cited “sources” are other individuals on their WebMD team, other article entries within the WebMD website, and journals that have poorly identified articles--
references that would not be considered legitimate sources for sound scientific publications.

Another step that is taken to mimic a sense of scientific reputability is having the articles are often written by health professionals, and then reviewed by other health professionals. In the case of vitamin C and stroke entry, the article was written by an MPH, RD, and LD, who is also the director for WebMD. The entry was subsequently reviewed by another MD who was a former member of the WebMD medical team. The authors and reviewers of WebMD entries provide authority and legitimacy to the information presented by WebMD on the premise of being health professionals, yet this is false legitimacy because both the author and the reviewer are working on the same team, thus lacking objectivity. In any legitimate scientific publication, the peer review process is conducted by an unbiased third party. WebMD exhibits its articles as if they have been peer-reviewed, yet they are only reviewed by other WebMD-affiliated people, that creates a clear conflict of interest, because the reviewer is now more prone to not question or contradict what is asserted in the article.

Considering that autonomy of and nonmaleficence towards consumers can achieved only by providing scientific research that is legitimately and objectively translated to the public, there is a necessity to change and improve current practices. This is important especially in the field of vitamin and supplements where FDA regulations do not protect consumers as stringently as with traditional medicine. Preventing WebMD and similar entities from putting forth information to an all-too-trusting public and thereby expounding a specific side of scientific and health-related ideas can be dangerous. We suggest forcibly holding such entities to the standard that they pretend to uphold. If WebMD, or any other related health information organization, proclaims itself to offer "credible and in-depth medical news, features, reference material, and online community programs", then they should be held to the following standards: citing all sources, which must all be legitimate, addressing and bringing upfront any conflicts of interest, as well as undergoing unbiased third-party peer reviews (WebMD-1). By holding self-proclaimed authoritative sources of health and medical information to the standard that they pretend to abide by, we will be able to achieve the objectivity seen in accepted scientific publications, as exemplified by the article we examined.
(Myung et al., 2013).

**References**


Is Misinformation a Side Effect of the Pharmaceutical Industry? Business As Usual

By Claire Duvallet and Garrett Ruggieri

Do you ever feel sad? Does your body hurt sometimes? Do you ever feel tired after a long day at work? Don’t worry; you might be just like millions of other Americans who are duped by pharmaceutical companies into believing that they need the newest drug on the market! Direct-to-user advertisement is not for the uneducated consumer. A tendency to self-diagnose is common in children, young adults, adults, and seniors, so talk to your doctor if you think you might know better than them. Potential side effects include misinformation, blatant conflicts of interest, and a false sense of awareness and understanding. Ask your doctor about the commercial you’ve seen and ask whether it is appropriate to be put on the newest magical drug.

The pharmaceutical industry, a 235.4 billion dollar business, spends almost twice as much on ads and marketing as it does on research and development. For example, the company Allergan (responsible for Botox) developed Lumigan as a topical treatment for glaucoma and ocular hypertension, but when clinical trials revealed that a side effect of Lumigan is increased eyelash growth, Allergan made the swift and ingenious move to begin marketing a second identical drug, but under a different name—Latisse. Through the magic of marketing, Allergan put a completely new drug to market for a miniscule fraction of the cost of developing an entirely new drug, and convinced healthy people to treat a minor complaint with long-term use of an already available drug.

To anyone who’s watched television in the U.S., the Latisse ad is familiar: actress Claire Danes glamorously
presents Latisse like it’s an ordinary, harmless cosmetic product. The ad uses a cleverly misleading tactic that is ubiquitous among pharmaceutical advertisements; the viewer is distracted from the drug’s serious side effects by the promise of an enticingly simple solution.

The U.S. is one of only two countries that still allow these misleading drug advertisements to air and, yet, there is virtually no regulation. The FDA does not oversee the advertising of over-the-counter drugs and has no involvement in the creation of prescription ads. Federal law does not even allow the FDA to require that drug companies submit ads for approval before the ads are used. According to the FDA website, “[they] see many ads at about the same time the public sees them.” So what happens when a pharmaceutical company produces and airs an advertisement that violates the law? The FDA simply sends a letter asking the drug company to alter or take down the ad. Not only are advertisements for prescription drugs virtually unregulated by the FDA, but the penalty for airing an illegal advertisement seems to be no more than a strongly worded letter.

Direct-to-user pharmaceutical ads are aired freely and unregulated, exposing the public to manipulation by a health care-about-profits business that easily presents claims based on shaky platforms of misleading statistics. Like any powerful tool, statistical analysis can be harnessed for good as easily as it can be used for evil. A pristinely worded null hypothesis or a specific exclusion of key outliers is all it takes to make the data say exactly what companies want it to say while still convincing consumers that the numbers speak for themselves: consumers easily buy into Wellbutrin’s “low risk of sexual side effects” while ignoring its other “low” risk of seizures and without considering what “low” actually means—a 0.1% chance? 5%? Companies have complete freedom in choosing confidence thresholds, and negative results from drug trials are easily omitted from groundbreaking publications or cocooned as “trade
secrets” and thus kept from the public’s eye. In a clinical trial for treatment of stress urinary incontinence by duloxetine, a commonly prescribed anti-depressant, the FDA investigation of multiple suicides in patients with no previous depression was reported as a trade secret until an investigative journalist forced the company to reveal the suicides. Experimental trials are frequently funded by the pharmaceutical companies themselves, resulting in flagrant conflicts of interest that bias the results to be in favor of the companies. The information presented by pharmaceutical companies in advertisements is easily transformed into misleading, manipulating, or incomplete claims that maximize profit at the price of the public’s health. And sometimes, the information is totally omitted: one 30-second commercial for Prozac simply shows a woman opening a window and immediately shows, “talk to your doctor today, or visit Prozac.com” with no other information presented.

Considering that the human body is an incredibly complex network of organs, tissues and cells interacting in ways that science has yet to fully illuminate, important healthcare decisions cannot possibly be boiled down to 30-second sound bites. In fact, many companies don’t even fully know about their drug’s functionality and side effects: Latisse comes with the risk of changing your eye color, which is “likely permanent” and eyelid skin darkening may occur, which “may be reversible”—all for the sake of thicker eyelashes. Packaging potential toxins as essential therapeutics through the use of fluffy, lofty commercials is
misleading and dangerous. The vast majority of Americans are not educated enough to make an informed decision on their preferred method of treatment without extensive external consultation. However, it has been shown that drugs which are advertised directly to users are prescribed nine times more than drugs that aren’t, meaning that consumers are clearly influenced heavily by the advertisements. Only doctors and physicians are equipped with the knowledge to make competent medical decisions, and while it is important that consumers be well-informed, it is more important that they are not misinformed. Commercials that urge people to “ask their doctors” about the latest and sleekest drugs lead people to demand expensive treatments that are potentially inappropriate or even dangerous, empowering them with a false sense of awareness more lethal than even the basest of ignorance.

The hurried barrage of side effects breathlessly zoomed through at the end of commercials is commonplace. On the other hand, a commercial for Cymbalta spends over a minute of its minute-and-a-half-long commercial running through potential side effects ranging from possible “life-threatening” conditions to dangerous interactions with common medications like NSAIDs and aspirin, and still expects that consumers will ask their doctors about the drug. Yet the decisions involved in committing to pharmaceutical products involve the most important of your assets: your body, your health, and your life. Your health is not a commodity that can be bought and sold like the newest brand of dog food, and therefore should not be marketed likewise. What is at stake here is not the model of your next car or the brand of your morning cereal—what is at stake is your health and ultimately your life. With this in mind, it is ludicrous that we in America give pharmaceutical companies free reign to manipulate us through their powerful marketing schemes and allow them proceed with business as usual in this most unusual of businesses.
Section IV. Bioethical Dilemmas

Medical Data Obtained from Nazi Research

By Gregory Judson

Main issue:
“Is it ethical to use medical data obtained from Nazi research?”

Position 1: It is ethical to use data gained from Nazi research.

The Nazi party was directly involved in some of the worst atrocities ever committed in the history of the human race. Through a systematic campaign of genocide they sought to exterminate Jews, gypsies, homosexuals, and political dissidents. While outright murder of these groups was the ultimate goal for the Nazi party, physicians often sought to gain scientific insight through the use of human experimentation prior to the inevitable demise of these prisoners. Drs. Mengele, Rascher, and Eppinger, among others, performed experiments that caused incalculable amounts of pain and suffering to concentration camp prisoners. While many of these “experiments” were little more than racially motivated pseudo-scientific forms of torture that sought to prove the racial superiority of the Aryans over “undesirable” populations, some of the data from research performed at Nazi concentration camps could be directly extrapolated to practical use.

During World War II, the Luftwaffe was very interested in understanding how long downed pilots stranded in the North Sea could survive before hypothermia was certain to cause death, as well as the ideal methods for re-warming these pilots once they were rescued. Dr. Sigmund Rascher undertook a series of experiments on prisoners at the Dachau concentration camp that recreated the conditions experienced by pilots in the North Sea. Prisoners were stripped naked and immersed in ice water for hours at a time. Their “body temperature, heart rate, muscle response, and urine output” recorded with typical Nazi meticulousness. (Cohen, 2010) The majority of prisoners involved in these studies died outright, however it was found that some survived through the use of novel rewarming techniques that involved immersing them in warm fluids following prolonged exposure to cold.
Previous medical dogma at that time was that hypothermia patients should be rewarmed with blankets and warm air. Dr. Rascher, through inhumane, unethical, and abhorrent means, disproved this thinking, at least within the Nazi medical community.

The work of Dr. Rascher came to the fore in the US through the work of Dr. Robert Pozos at the University of Minnesota. Dr. Pozos worked in the emergency room in Duluth, Minnesota, and had established a research lab examining the ideal methods for re-warming hypothermic patients. Medical practice in the US still had not definitively determined whether the “active” method, the use of warm fluid baths, or the passive one, the use of warming blankets and the patient’s own body heat, was the best means of reducing complications in the re-warming period. Animal models had provided some headway into answering this question, but animal physiology differed so much from humans’ in the way it exchanges heat, that it had little practical use to physicians.

While Dr. Pozos had retrospective data from his own emergency room, prospective studies with finely controlled parameters were needed to definitively determine the ideal re-warming technique. While prospective trials involving inducing hypothermia to the point of near-death were clearly highly unethical, Dr. Pozos’ dilemma was whether it was ethical to use information already procured at Dachau.

Dr. Pozos decided that it was in the greater good of humanity to use this data to save those suffering from hypothermia. He attempted to publish his results using data from Dr. Rascher in the New England Journal of Medicine and was rejected by the editorial board on ethical grounds (New York Times, 1988).

The decision by the New England Journal not to publish the data from hypothermia research was shortsighted and may in fact harm patients suffering from hypothermia even today. While no rational person can condone the actions of the Nazi doctors, some good may come
out of the suffering of concentration camp prisoners through the use of this data. Would it not be a greater crime to let innocent people die because we have an incomplete understanding of hypothermia that could be ameliorated by using Nazi data? Would not the possible increased loss of life today caused by this incomplete understanding further propagate the immense suffering caused by the Nazi regime? Is it not righteous to use research that caused human suffering to now protect against suffering? It seems that the best way to honor the memory of holocaust survivors is by using this data to save lives today. This would be the ultimate condemnation of the Nazi regime, and it would be a shame to ignore practical, life-saving information in order to not validate the scientific contributions of evil men.

Position 2: It is un-ethical to use data gained from Nazi research.

To call the work of the Nazi physicians involved in human experimentation “research” is disingenuous and works to validate a regime involved in pseudo-scientific sadism. The very validity and scientific practice of the Nazi work in human experimentation must be called into question solely due to its highly unethical and unscientific nature. Supporters of the use of Nazi data today claim that it would be a greater evil not to use information obtained by nefarious means if it has the potential to save lives. This conclusion is based on the assumption that Nazi research was scientifically rigorous. The reality is far from the truth. In an article published in the New England Journal, Dr. Robert Berger discusses the major methodological flaws in the Nazi human experiments, specifically those looking at hypothermia (Berger, 1990). In the hypothermia experiments, baseline characteristics of the study participants were not recorded, subgroup analyses were not performed, and no reliable information about the type of external heat sources involved in rewarming prisoners is mentioned beyond a note from an assistant stating that one of the prisoners was immersed in boiling water. In fact, the main finding of the hypothermia “research” of Dr. Rascher, that warm liquids are the best means of rewarming hypothermic patients, is not supported by any examination of survivals. The ultimate goal of the Nazi physicians was to prove the racial inferiority of those who were not Aryan. Thus, the main outcome of interest to researchers today, the overall survival rates among those rewarmed actively vs. passively, was not rigorously tested. All that is available are brief notes and case.
reports about individual prisoners who may have survived slightly longer (before being ultimately executed) than those rewarmed using different techniques.

Furthermore, the link between ethical research practices and “good science” which produces accurate and reproducible results is a strong one. A good research study begins with a solid hypothesis. When the hypothesis is tainted by the biases of the researcher, or when outside influence makes the results of a study a forgone conclusion, valid study design is impossible. Phrenology, the study of human skull sizes, was conducted by anthropologists and evolutionary biologists at some of the most prestigious universities in the world and provided empirical data showing that the skull size of the Caucasian male was significantly larger than women’s and that of people of other races. By extrapolation, these researchers concluded that skull size correlated with brain size and human intelligence. Without commenting on the faulty link between skull size and human intelligence, the work of the phrenologists had major methodological flaws. The phrenologists purposefully chose the largest Caucasian skulls they could find and excluded skulls from other races if they were found to be too large. This skew in the sample was the result of the phrenologists’ a priori belief that Caucasian men were the most intelligent race and led directly to the publication of poor quality scientific data.

Since the very foundation of good science must be called into question when the people performing the studies are immoral and their studies unethical, it is unacceptable to give Nazi physicians the most important validation of their work – publication in scientific journals (Moe, 1984). What message would it send to a future Dr. Mengele? That unethical and evil experimentation can be part of the scientific community as long as there may be some future justification for the use of this data? This scenario is ethically.

Final opinion

Any moral person should be abhorred by the thought of using data that was obtained by causing extreme human suffering. In order for any data gleaned in such a manner to be considered for use, it must pass a very large hurdle: will it save
lives today? If the answer is ‘yes’, then I believe that the ethical choice is to use the data, only if it passes strict scientific standards. I propose that all data published from the Nazis come with a disclaimer that makes it very clear that the use of this information is only justified because of its potential to ease suffering today. I also recommend that the convention for citation of scientific work be changed in the case of the Nazi physicians, so that there is no mention of their names in the scientific literature. While admittedly imperfect, the above may provide a partial solution to the contested and disconcerting problem of giving Nazi doctors scientific esteem for their works.

References:


In their paper "Identifying Personal Genomes by Surname Inference," Gymrek et al. (2013) successfully showed that it is possible to identify male individuals and their patrilineal relatives by anonymous genome data combined with publicly available tools that offer genealogy services. Although the results do contain significant limitations, the ethical implications of identifying individuals' DNA via publicly available information present serious bioethical issues. If a scientist finds new markers for a disease in a previously donated anonymous genome, is he or she obligated to re-identify and inform the donor? What should policy concerning anonymity and re-identification be for future genetic donations? And finally, can re-identified DNA be used to aid in criminal investigations?

In this paper, the authors first attempted to recover the surnames of 911 anonymous individuals from the genetic genealogy database YBase by looking at the shortest time to most recent common ancestor (TM RCA) via an input haplotype from the Y-chromosomes of the individuals (Y-STR haplotypes). They ran the inputs through parsed YSearch and SMGF records, which are two databases that contain Y-STR genotyping results along with identifying information. Then, using a user-inputted threshold, the authors' algorithm attached the surname of the record corresponding to the TM RCA to the inputted haplotype. It also labeled results with too low of a confidence level as unknown. The authors screened multiple thresholds to optimize the return of correct surname results and screened the false returns to yield a 12% rate for recovering surnames of U.S. Caucasian males.

They then simulated a situation in which the target’s birth year and state of residency were available in addition to the surname, and attempted to identify unique individuals. They chose these additional
identifiers because they are not protected by the United States Health Insurance Portability and Accountability Act, and so could reasonably be assumed to be available through public search engines. This addition to the algorithm narrowed the median list of identified individuals to 12 males, which was readily investigated manually.

The success of their algorithm was confirmed when they tested it against real databases. First, they extracted Y-STR haplotypes from three identified genomes in the National Center for Biotechnology Information archives. In Craig Venter’s genome, the algorithm returned a clear match for “Venter,” and once combined with state and birthdate data, retrieved two matching records, of which one was Craig Venter himself. Additionally, the authors chose 10 genomes from a collection of male genomes of Utah Residents with Northern and Western European ancestry. In five of the cases, the authors were able to identify the individuals and their entire families.

In conclusion, the authors state that “data release, even of a few markers, from one person, can spread through deep genealogical ties and lead to the identification of another person who might have no acquaintance with the person who released his genetic data.” They state that their method’s strength and robustness lie in the fact that they only used publicly available records to infer identities from genomes. Such a technique, they claim, will make it much easier to expand the types of genomes they can identify, to include even female genomes.

While the authors make strong points that are supported by their data, there are a few inherent limitations to their approach. First, the databases they use to infer surnames for Y-STR genotypes are limited to Caucasians, since they belong to genealogic services that are available mostly to upper- and middle-class U.S. Caucasians. Second, since the authors looked at the haplotypes from the Y-chromosomes, their results were limited only to males. Third, their surname identification algorithm will fail if no person in the target person’s lineage has submitted their genomic data to a database like YSearch. Fourth, the algorithm only returns a surname, which leaves additional manual work to recover an individual. Fi-
nally, their success rate is currently quite low: they claim to project a success rate of 12% with a 5% false return rate.

Despite these limitations, the new technology the authors propose warrants serious bioethical consideration. Considering that genomes are continuously being added to gene databases by “genealogy enthusiasts,” and that genomic sequencing is getting cheaper and faster by the year, it is not unlikely that in the very near future these limitations will be resolved and re-identifying technologies will see high public demand. It is not unreasonable to presume that in a few years’ time, the algorithm these authors propose will be more robust, accurate, and inclusive, so that almost anyone in the United States could be identified from anonymous DNA. As such, one must consider the bioethical implications involved in re-identifying anonymous genomic data.

The first of three major ethical considerations that arise is whether scientists have an obligation to re-identify individuals who previously participated in genomic studies and who are determined to have fatal or inheritable diseases. At the time the genetic material was donated and shared between scientists, it was purely anonymous. Any additional information discovered about the donated genes that was unrelated to the study could not be returned to the donor because there was no way to identify the individual to whom the genes belonged. However, with this new re-identifying technology, complicating questions arise: does the researcher have an obligation to tell the donor that his or her genes indicate a predisposition to a disease? What if there is no treatment for that disease? If a treatment does exist, but it is not affordable for the family, what action is to be taken then?

By discovering information about donated genes, researchers can gain significant information about a person’s health. As such, they should be kept to the same standard to which doctors are kept in the Hippocratic Oath – to keep patients from harm and injustice. However, how to
adhere to this standard is ambiguous in this case, as it is unclear what kind of good or harm a researcher would cause by informing a gene donor of his or her disease status. For example, informing donors of an inheritable disease may mean that they will choose not to have their own children to prevent from passing the gene on to the next generation. Moreover, in the case in which there exists no treatment or cure for the donors’ diseases, would informing them in fact cause emotional and psychological harm that could have otherwise been avoided?

In this paper, no definite answers to these questions are presented. However, there is a socially established ethical principle of “autonomy” in medical decision-making decisions about one’s health should be in the hands of the person whose health is in question. To leave all medical decision-making up to the doctor would put decisions in the hands of someone who is familiar with only the physical aspects of a person, not the emotional, social and spiritual aspects that also contribute to decision-making about health. In order to give patients authority and choice in their health, doctors are expected to provide as much information as possible so that patients can make autonomous decisions. Due to the increasingly common occurrence of gene testing, researchers, not just doctors, have additional information that would enable patients to make fully autonomous decisions. Therefore, to do the least harm to the people who have already made their genetic information available, researchers should re-identify genetic material from donors when more information about the donors’ health is discovered in the course of research. This way, donors will be able to make decisions about their health in light all the information that is available.

The second ethical consideration involves dealing with re-identifying future genetic donations. To avoid any uncertainty in future re-identifications, one of two things should occur. First, the donors must unambiguously state whether they would like to know the results of testing on their genes, and what kind of information they would like returned to them. The participants whose genomes were used by the researchers discussed in Gymrek et al’s paper had been informed at the time of their donation that their privacy might be breached. However, they were not told what would happen with their information once this happened. In future studies, such a situation should be avoided by preemptively addressing the possibility of re-identification. Another option would be to amend the Privacy Act to protect genetic material as “personal identifying infor-
mation”, since with this re-identifying technology genomes now could be just that. If the information were protected this way, re-identifying a donor without their consent would be illegal and punishable by law. In both cases, the donor’s consent must be attached to the genetic material itself so that researchers always know in what contexts the genetic material may be used. If either of these conditions is met, the issue of when to re-identify future genetic donors and when to protect their privacy will be resolved.

The third ethical consideration enters the world of crime investigation. There have been recent reported cases of DNA testing used to absolve innocent people of crimes they were falsely convicted of committing. On the front end of criminal investigations, using re-identification technology to identify DNA from crime scene evidence could enhance the ability of law enforcers to establish suspects more quickly and accurately. Once improved, the technology presented in this paper will be able to take genetic material from a crime scene and match it up to its owner, regardless of the consent issues discussed above. Re-identified DNA could be used to reveal potential suspects with criminal backgrounds, similarly to what is done today with fingerprints from crime scenes. If it were not for the precedent of fingerprinting, DNA re-identification would seem incredibly invasive to a person’s privacy. However, fingerprinting, as well as the more recent uses of DNA re-identification, has proven effective in extending protection and justice to society. DNA re-identification will thus be useful and ethical new tool for law enforcement.

Although the re-identifying technol-
ogy presented in Gymrek et al.'s paper is not yet perfected or able to pose significant bioethical dilemmas, it is reasonable to expect that such deanonymizing algorithms will soon be reliable. Thus, it is important to consider when and how scientists should re-identify anonymous genetic donors from previous and future research studies. One must also address the ethics of using this new technology in criminal investigation. In both cases, people’s lives could be drastically changed as a result of the findings of the algorithm. Because the usefulness of genetic data seems to have widespread recognition in society, the number of people that might be affected by this new technology is increasing. We propose that scientists be ethically bound to re-identify any previous genetic donors who are discovered to have fatal or inheritable diseases. However, researchers should be required to obtain informed and explicit consent to be re-identified from all future donors. Finally, because law enforcement has historically capitalized on emerging technologies to aid in its criminal investigations, it is not unethical for them to also adopt this DNA re-identification technology. The technology presented in this paper has much potential social impact, but will not be without bioethical implications that must be considered through its development.

References
Walking into the library on a college campus, you'll certainly see three items patterned across the tables: computers, books, and coffee. What you may sense is a drive and purpose to succeed as students try to comprehend the material before them so that they may reach the point where they believe themselves successful. This desire for success drives most college students to take a full course load while participating in time-consuming activities and internships, which often leaves little time for rest. The healthy thing would be for those students to take times of rest to maintain their physical, emotional and spiritual health, but the pressures to perform and the knowledge that they're on a path to success tend to be far more alluring then personal health. While many groups exist on campuses to support students' health, it is much more likely that students find support from a cup of coffee, an energy drink, or a mug of tea that allows them to eke out one last assignment late at night.

While college students are not by any means the only group of people hooked on their progress to success rather than their health, they are a significant population with a history of using substances to enable their performance. At this point in history, the authors of this paper would like to ask, is the lifestyle supported by caffeine consumption worth the deleterious effects on a person's health? Addiction to caffeine seems to be only a symptom of the root addiction to pursuing success. Here we examine the potential ethical dilemmas of consuming caffeine as a college student, and how it encourages our addiction to success.

Caffeine is consumed in coffee, tea, energy drinks, and various other forms to help people be more alert in class, complete late-night assignments, send out a few more emails for their clubs, and sometimes to stay awake for days at a time. Studies such as the November 2002 article by Lieberman, et al., have confirmed caffeine's ability to help in these areas, showing that while caffeine doesn't help with memory or active learning, it significantly improves one's ability to remain alert especially during periods of sleep deprivation. Sleep deprivation is particularly difficult to struggle against while in situations of low arousal, such as long seated
hours in the library or in lecture. This is where caffeine is particularly useful, as it has proven to stimulate the central nervous system in a manner similar to that of adrenaline. Additionally, caffeine boosts performance in long, repetitive tasks or in tasks requiring vigilance. An adrenaline-like boost and stamina for repetitive tasks make caffeine an attractive tool for the driven college student.

With so many apparent advantages to be gained from caffeine use, it’s natural to wonder if the relevant ethical issues revolve around ease of access. But with caffeine being available at low cost in so many forms, accessibility doesn’t create any significant unfair advantage between students within a college campus. Most substances that increase one’s ability to perform are heavily regulated in order to avoid danger, keep a level playing field or sometimes both. But in this case, the playing field is level since caffeine is so readily available.

However, caffeine has not always been the substance of choice for the high achieving. In the late 19th century, cocaine was the wonder drug that allowed people to reduce pain and increase enjoyment in their lives. Prominent thinkers and leaders encouraged cocaine use similar to the way that common stimulants, such as caffeinated beverages, are encouraged for use today. Now, both its association with dangerous cartels and the problems of excessive use have changed public perception of the drug. Drugs, such as Ritalin and Adderall, promise similar end results as cocaine did in the past – reduce the pain of being unable to focus, and thereby increase quality of life. They enhance focus and allow extended periods of repetitive and low-arousal behavior without compromising alertness or sacrificing performance. While only the students that have been
prescribed these drugs should have access to them, increasing numbers of students are finding illegitimate ways of obtaining such drugs at a reasonable cost. The effects are similar to those of coffee but are exaggerated, and with dangerous side effects. Compared to cocaine and the other stimulants that college students have used to achieve their goals, caffeine looks entirely benevolent.

However, while caffeine's side effects are not so extreme as the Attention Deficit Disorder (ADD) drugs, they are significant enough to prevent some people from drinking coffee. Adverse side effects, including upset stomach, headaches, addiction, depression, heart problems, and anxiety can all stem from being a regular coffee drinker. But that doesn't seem to stop most people. Even the possibility of becoming addicted, something which is normally heavily stigmatized, doesn't sway the millions of coffee drinkers from getting their daily fix even if it means facing withdrawal. The social stigma is characterized by stereotypes and assumptions that users are indulgent, or bad people in the first place for choosing to use a drug that was going to lead to eventual addiction. But for some reason, the negative associations normally attached to addiction, such as with alcohol and nicotine, do not exist in the case of caffeine.

This may be because in caffeine addictions, the symptoms don't look so different from "normal" life. There are already countless people with anxiety, depression, headaches, and stomach problems that can't be blamed on caffeine. It seems that the effects of constant caffeine use don't appear to deviate too far from what's already socially accepted! If that's the case, why is this way of life, which seems so unhealthy, so common? Perhaps the addiction is not to caffeine itself, but what it allows us to accomplish. Whether caffeine is the symptom, or the addiction itself, the fact of the matter is that on a daily basis, millions of American college students regularly take this behavior-altering drug. Many school children were raised with the D.A.R.E. (Drug Abuse Resistance Education) campaign that essentially communicated that drugs were bad when not taken by prescription. Is it still true that recreational drug use is inherently bad, or is it specifically the effects of the drug in question that must be avoided?

Judging by the way drugs are used culturally, the latter is likely the truer. In the case of caffeine, the end effect is increased productivity, sociability, and alertness, all of which support working towards the completion of students' goals. And it supports this without exceedingly obvious physical or mental consequences. But per-
haps this social norm is something that should be questioned. A student living up to this standard, and one may even say, caught in the addiction of success, gains the rewards of their success, but at what cost? For many, the cost is being addicted to the lifestyle that caffeine enables. Students can stay up later, but for their health, sleep may be more important. They can take more classes and do more things, but for their emotional sanity, they may need to do less and spend more time with family and friends. Students can graduate in four years or less, but might not have been able to without the help of this commonly used stimulant.

From this examination, it seems that caffeine itself may not be the problem, but the way of life that’s promoted by society and enabled by caffeine. In the realm of legal drugs, we should always keep in mind that, whatever benefits they bring, they also come with sacrifices and compromises. Most drugs can be expected to induce a measure of dependency, and caffeine is no exception. Indeed, it has a double effect, causing both a physical addiction to the substance itself, and what a person can do more easily by incorporating it into their life. The intention of this paper is not to make a villain out of caffeine or any other drug but rather to highlight the success addictions of which caffeine dependence is only a symptom. Caffeine is not the problem, but addiction itself is, as it creates an unhealthy weight on certain aspects of life, likely causing other fundamental aspects, necessary to a balanced and healthy life, to suffer due to neglect. It may be true that unbalanced, unhealthy people have led the most incredible advances society has seen. But regardless of what they may
accomplish, students should still be aware of the life they’re choosing so they may pursue success with fair regard to their health. To create awareness, more information should be provided on the full effects of caffeine, or any other drug, so that the idea of informed use can be promoted. In this way, students could be educated and encouraged to pursue both successful and healthy lives.
Discovering Side Effects With Search Queries: Health Trend Innovation or Privacy Invasion?

By Andrew Ghazi Jessica Werlin

The World Wide Web contains at least 15 billion web pages, and is accessed by nearly 3 million individuals in North America alone. The information the internet contains is absolutely staggering, but perhaps more enlightening than its content is what information users enter to navigate the web: search queries. Keywords entered into Google, Yahoo!, Bing, and other search engines speak volumes about the interests of internet users. The significance of this data has not been lost on academics, particularly in the medical community. New computational techniques that extract valuable trends and information from this data promise to revolutionize pharmacovigilance. But this work comes at a potential cost: users’ privacy when surfing the web.

This past January, Dr. Ryen White and his colleagues at Microsoft published a paper in the Journal of the American Medical Informatics Association outlining new web search data mining techniques (2013). The paper describes a novel approach to discovering side effects that may go undetected by the FDA’s Adverse Event Reporting System (AERS) for significant periods of time. Though their innovative work has profound implications for pharmacovigilance, it involved researchers’ direct access to stored search queries - running the risk of compromising searchers’ privacy should the system be abused.

White’s particular project pursued web searches for pravastatin and paroxetine, two commonly taken drugs whose interaction is known to cause hyperglycemia. The researchers identified users who searched the names of either of these drugs, hyperglycemia, or symptoms related to the affliction. The study then examined searches collected from millions of users who met the research criteria over a 12-month period before the link between the drug interaction and hyperglycemia was noticed by the FDA. Intriguingly, the paper also found that searches for hyperglycemia were significantly more likely to be conducted by users who also searched for both drugs as opposed to just one or the other. The queries conducted by Internet users successfully predict the high incidence of hyperglycemia in patients on both drugs as opposed to just paroxetine.
or pravastatin.

As demonstrated by the above example, the analysis of search engine queries has the potential to predict side effects from drugs and drug-drug interactions that otherwise may not come to light. “We anticipate more sophisticated log-based detection of adverse events associated with medications,” writes White et al., “and that these will contribute to the faster identification of drug safety information...The prolific use of web search to pursue information can be likened to a large-scale distributed network of sensors for identifying the potential side effects of drugs.” For the thousands of deaths and hospitalizations that occur each year due to adverse side effects and reactions that often go undetected in clinical trials, this kind of work is a crucial advancement.

Despite the anticipated benefits of this type of data collection and analysis, the practice of storing and tracing search queries inherently flirts with violation of users’ right to privacy. “Search queries may reveal quite sensitive information about the querier,” explains Ron A. Dolin, lawyer, computer engineer, and former Google employee (Dolin, 2013). “A spouse looking up STDs” or “a student seeking free copyrighted music” are two examples he provides of potentially incriminating searches a user might conduct. It is no difficult stretch of the mind to imagine abuse of a search query database to stalk an individual.

Microsoft adheres to a privacy policy, and White, as an employee in Microsoft’s research division, held to it during this study. The search queries were taken from users who had “consented” to the installation of a browser plugin, and
queries were linked together by the plugin identification number as opposed to Internet Protocol (IP) address, registered user, or location. Nevertheless, as the New York Times demonstrated when AOL leaked search data in 2006, a user’s identity can often be easily extrapolated just from his or her set of queries alone. Dolin agrees: “Corresponding identifying information can often be sufficient to figure out who the querier is, which can create a trail of sensitive information.” Furthermore, it is unlikely that users were aware of the full ramifications of their consent – where this information would go and who would have access to it. The very act of aggregating search-query information risks users’ privacy.

There is no hard and fast rule that exists regarding the handling of potentially sensitive information users submit. Moreover, complete dissociation of queries can actually even undermine the research work. If each query in the database used for this study had been fully de-personalized, each one isolated from the next, these trends across a user’s searches would not have been found. How can this data that successfully opens doors to critical new health research be accessed without running the risk of abuse?

Good solutions to the problem of search query data mining will strike a balance between protecting the privacy of users and allowing exploratory analysis by researchers in the medical community. One such way to resolve this issue is to allow only specific query-based access to search history data. That is, instead of giving researchers unrestricted access to an array containing a list of all the search terms generated by individual users, the data could be provided in an encrypted or otherwise obscured form that only outputs the data relevant to a specific input query from the researchers. For example, researchers could ask “Give me all of the (anonymized) users that searched for ‘dry mouth’” or “Did user 58918096 ever search for ‘migraines’?”

The types of specific queries that the database responds to could be used as a metaphorical dial with which to tune the degree of access the researchers have. For instance, should the dataset respond to “Give me all of the search terms from user 22562872 (who is known to have searched for ‘dry mouth’)?” More sensitive datasets, such as email search history or Google search history could decline queries like these, while less risky datasets such as search data from WebMD – where users are unlikely to search about sensitive non-health related terms – could provide the data that particular query asks for. The proposed purpose
for the requested access could help the data providers -- who have interests in both protecting the privacy of their users and aiding the researchers -- decide what types of queries the researchers are allowed to ask.

This method of data access would allow researchers to perform exploratory analyses, but would still prevent access to irrelevant and potentially sensitive search data. Researchers that have evidence-based hypotheses on what to look for will still be able to create sophisticated statistical models that give rise to valuable public health predictions, while users that searched for their financial information or copyrighted illegal music downloads should feel comfortable in their privacy. While this method would in theory still allow access to the entire dataset, researchers would need to query over all possible terms to extract enough data to identify an individual person, which would take an impossibly large amount of time.

Since web search histories act as a sample far beyond the size of even the largest medical experiments, data mining on search history has an enormous potential for public good. Beyond use as a continuation of clinical trials once a new drug has been released, such information has the potential to reveal much more about health trends and develop other new areas of medical science, like prompt and targeted response to large-scale disease outbreaks. Query-based access to public search data strikes an effective balance between the protecting of user privacy and allowing the medical community to perform hugely beneficial public health research.

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In “The IKEA Effect: When Labor Leads to Love”, a study published in Harvard Business School (2011), Michael I. Norton, Daniel Mochon, and Dan Ariely show that the IKEA “do-it-yourself” model leads consumers to value their amateurish labor as the work of experts. The phenomenon coincides with Adam Smith’s theory that the real value of products lies in the amount of work invested in their creation. This argument may be true for inanimate goods, but is it also true for the creation of living “products”? We claim that when creating life, it is not the labor that leads to love, but the process of creating something “in your own image”—well, genetic image.

In 2010, Dr. J. Craig Venter, a leading synthetic biologist, published a breakthrough paper that uses an IKEA-like model to design artificial life. Venter’s team assembled the genome of the bacterium Mycoplasma genitalium using entirely synthetic means. By combining several synthetically created DNA pieces, researchers reconstructed the bacterial chromosome with its 582,970 base pairs. After necessary chemical additions to the “naked” DNA, the synthetic genome was transplanted into a different, DNA-depleted bacterial cell. Under the exclusive direction of this synthetic DNA, the new bacterium was both viable and able to reproduce. This discovery takes us one step closer to a biological version of the do-it-yourself model. The IKEA plywood and screws are replaced by long strings of the DNA alphabet, and the furniture by living organisms.

While Venter and his colleagues expect their novel technology to bring about synthetic microorganisms that will solve many of the world’s problems ranging from oil shortage to healthcare, use of their methodology for the creation of a human genome seems imminent. Will scientists render sexual reproduction and birth obsolete? As Andrew Hessel, the co-chair of Bioinformatics and Biotechnology at the Singularity University, said in a 2011 interview, “We’re going to make synthetic human genomes and edit them, and we’re going to end up with IVF technologies that can boot them. It will make cloning look organic, and the ways we have babies today quaint.”
Although futuristic, Hessel’s vision raises a pressing bioethical question. In a world where anyone can go online, choose his favorite eye color, height, IQ and EQ, and receive a baby via FedEx, what will remain of both the biological and social concepts of parenthood? Can we allow for a society in which parenthood has become anachronistic?

When biological parents reproduce, each parent makes up half of the child’s genome, and the unique combination determines almost every characteristic of the newborn. The genetic contribution of the parents denotes their biological and social responsibilities. With a nod to evolution, parents are hardwired to protect their children, the carriers and perpetuators of their own genetic cargo. This system ensures the continuation of the individual, and had been referred to by Richard Dawkins, the famous evolutionary biologist, as the ‘selfish gene.’ This ‘gene’ is the evolutionary force that sees that one’s own genome continues—the factor that propels parents to safeguard their children at all costs. If Hessel’s dream materializes, and synthetic biology replaces “biology”, what will come of this essential mechanism? Will it stand the bioethical test of non-maleficence at the social level? Undoubtedly, synthetic biologists intend no harm, but they can reassure us that without parents who are biologically tethered to their offspring, the ‘selfish gene’ will not be replaced by a gene encoding selfishness?

The notion of parenthood, however, goes beyond the intrinsic need to protect one’s biological heritage. In most countries in the world, parents act as the legal guardians of their children until they turn eighteen, and even then, the “genetic leash” never disappears. They are held accountable for nurturing and protecting their kids; they are entrusted with the most important mission: ensuring that future generations reach adulthood while providing them with the tools to become good and productive members of society. If a child’s genetic makeup comes from a
computer instead of from two people, where does the legal and ethical accountability lie? Furthermore, without a genetic origin and pedigree children will not be treated and perceived in the same way. Unsatisfied parents will be more likely to relinquish their parental commitment, resulting in “synthetic” children without legal guardians. Does it not stand in violation of key bioethical guidelines such as justice and beneficence? Namely, is it ethical to bring a pretty, healthy, and smart, yet genetically rootless and parentless baby to a world in which only the strong survive?

As scientists, we are avid proponents of scientific progress and discovery, including synthetic biology. As members of society, however, we are concerned of uncalculated endeavors. Thus, we believe that two key regulations should be implemented before we allow synthetic biology to extend its reaches to humans. From a legal standpoint, bringing to life a baby by synthetic means should be treated no differently than by sexual reproduction. This will settle possible guardianship disputes, and shift the parental responsibility from synthetic biologists to future parents. Biologically, the use of completely new DNA sequences must be banned. Scientists should base their synthetic genomes on two existing ones, while only being allowed to edit out harmful mutations. This regulation will make synthetic biology a useful medical tool, and simultaneously minimize its evolutionary risks.
Did you know an overwhelming 40% of transgender people in the US have attempted suicide – 25 times the rate of the general population; and more than 50% of transgender youth will attempt suicide before they are twenty (Weiss, 2011)? To begin tackling this problem we must go to the center of the issue.

“Transgender” is a broad term applied to people and behaviors that do not conform to culturally conventional gender roles. Gender is considered a binary relationship, with men and women differing physically and psychologically, which result in separate niches and cultural roles. But these distinctions also cause a number of people to experience “gender dysphoria,” the discontent associated with their sex and/or the gender roles associated with that sex. Often people with heightened cases of gender dysphoria are diagnosed with gender identity disorder (GID).

For example, children that are exposed to “traditional” gender roles from a young age can perceive culturally defined expectations associated with their biologically assigned sex, and may come to develop gender dysphoria. These children feel that they are in the wrong body and seek out an immediate solution in order to align their biology with their psyche. If their gender dysphoria is not properly addressed, some desperate children resort to self-mutilation. However, there are safer alternatives such as sex reassignment therapy, which include hormone supplements, and hormone suppressors and the more drastic sex change surgery. Since modern medical practice conventionally allows patient autonomy, people diagnosed with GID can potentially realign their biological genders with their identities, and ideally alleviate the personal suffering associated with GID.

Given the significant role of gender in society and also the risks associated with gender related therapies, a lot of controversy surrounds children experiencing gender dysphoria and the medical decisions that they make. Though patients are entitled to make their own choices, sex reassignment therapy have irreversible effects, including infertility and permanent surgical reconstruction. Thus from a bioethical standpoint, the concern that

Sex reassignment therapy and adolescents: when waiting isn’t an option

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arises is whether children have the foresight and experience to exercise an autonomous decision that could potentially affect the rest of their lives. Because some cases of gender dysphoria turn out to be a “phase” that the individual grows out of, physicians are reluctant to induce lasting changes in the patient. However, it seems unfair to require individuals to suffer through gender dysphoria when waiting may cause psychological stress on these individuals. The issue with waiting until people are eighteen to begin hormone therapy is that at that age, patients have progressed through most of puberty, and will therefore have suffered through increased gender dysphoria. Throughout this period, adolescents may be at a higher risk of attempting drastic changes, including either genital mutilation or suicide. Many of these children have an intense fear of puberty, and the thought of being trapped in the wrong body for longer is so abhorrent that they would rather take their own lives.

A possible guideline for treatment of people with GID advises physicians that masculinizing/feminizing hormone therapy not be administered until the individual is at least eighteen-years-old, the logic being that at this point the individual can be considered an autonomous adult and make serious decisions concerning sex reassignment. For example, it is difficult for a fourteen-year-old to decide whether sex reassignment is more important than fertility and thus, waiting as long as possible before making irreversible changes is better. So a solution that physicians have found to the timing problem is the use of hormone suppressants to suppress the release of hormones that trigger puberty, essentially delaying puberty and giving the adolescent more time to make an informed decision. Studies have shown that delaying the onset of puberty for a few years has no overall detrimental effects on the individual and thus can effectively pause the child’s development (Yeon 2013 and Healthy Children. Org). However, while it has been shown that children on puberty suppression drugs can reverse the effects and restart puberty if they are taken off the drugs, there is still the question of combining this technique with sex reassignment therapy.

While hormone therapy and gender realignment offer relief for GID patients, a larger scale conversation needs to be engaged about gender roles and normativity. Many supporters of sex realignment therapy believe that children should not have to assign to a specific gender, because gender is merely a social construct. While recent changes have been made allowing transgender children
to use the bathroom of their choice there are still many discussions over the rights of transgender children such as whether they should be allowed to play on sports teams of the sex they wish to identify with. Even larger hurdles await them as they age such as marriage and having children. Along with the growing debate over same sex marriage equality comes the often-ignored question on where transgenders fit into the discussion. There are many ramifications to come from this debate on whether a person should be allowed the opportunity to marry someone of their own biological gender or the gender that they choose to be transformed into.

While current hormone treatment guidelines work well in terms of avoiding permanent changes until a person is conceivably old enough to decide on a sex, biological respite from GID is still only a short-term solution. Society must take the time to deconstruct gender norms and re-examine the binary relationship of gender identity so that no individuals need even experience gender dysphoria.

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