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## Bioethics: Preparing for the Unknown- Abstracts

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Abstracts are listed alphabetically by last name of first author or panelist

**Bioethics: Preparing for the Unknown**  
**Abstracts**  
**March 17-18, 2016**

**The Center for the Study of Ethics in Society**  
**Western Michigan University**



CME credit provided by Western Michigan University Homer Stryker M.D. School of Medicine

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### Synthetic Biology and Ethics: A Biosecurity Argument

Marko Ahteensuu

Division of Philosophy, Royal Institute of Technology, University of Turku (Sweden)

Synthetic biology—i.e. an engineering-based modelling and building approach to biology—holds promise for a number of practical applications in fields such as medicine, energy production, material technology, and bioremediation. At the same time, synthetic biology raises a welter of ethical issues. It has become customary to group them into two categories: *Intrinsic concerns* embody the idea that (specific) research on and/or practical applications of synthetic biology are morally questionable because of some feature of (the use of) the technology in itself, irrespective of its consequences. Questions of this type include, for example, the following. Does constructing new forms of life cross moral boundaries of playing god, unnaturalness or human hubris? According to *extrinsic concerns*, (specific) research on and/or practical applications of synthetic biology are morally questionable because of their (known and possible) consequences. Following questions belong to this group: Does “creating” new kinds of organisms and species change the way we perceive nature and ourselves? Does the use of synthetic biology result in unjust distributions in society? Besides these, intrinsic concerns also involve worries about possible harmful consequences to human health, animals and the environment. Here it has become standard to talk about the management of two kinds of risks. On the one hand, *biosafety* refers to principles, practices and specific actions taken to prevent possible unintended and unexpected consequences. Laboratory facility requirements and protection measures in relation to four classes (risk groups) of pathogenic microorganisms provide an example. On the other hand, *biosecurity* refers to principles, practices and specific actions taken to prevent intentional misuse of synthetic biology. This forms a continuum ranging from mere “bionuisance” to bioterrorism and to biological war.

I begin with pointing out that ethical questions that are highly similar to those of synthetic biology have been extensively discussed before in the context of gene ethics and the ethics of new technologies. It is in fact a matter of disagreement whether there is anything new, ethically speaking, in synthetic biology. I will argue, however, that at least biosecurity considerations pertaining to synthetic biology are to some extent new. I will highlight differences in response to “synbiosecurity” in the United States (US) and the European Union (EU), and discuss possible reasons for why in the US biosecurity concerns related to synthetic biology have received more attention in media and by regulators than in the EU. This is followed by an analysis of *a biosecurity argument*, the core of which is explicated below. It turns out that the *general* argument—as it is often stated in the literature and discussions—needs to be qualified, and that many improvements to biosecurity have already been implemented, mainly as self-governance of research and industry. Furthermore, I suggest a *new specific strand* of the argument: as synthetic biology falls under gene technology regulation in the EU, the divergence in biosecurity considerations (when compared to those of gene technology) provides a reason to review and possibly make refinements to the legislation as well as administrative and supervisory practices in the EU.

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### **Ethical Issues and Medical Error: Preparing for the Unknown**

Shirley Bach

Western Michigan University, Center for the Study of Ethics in Society  
Homer Stryker M.D. School of Medicine

The publication in 1999 of the Institute of Medicine report, "To Err is Human: Building a Safer Health System" was a most significant event which galvanized both the medical profession and the public to deal constructively with medical error. It stimulated public discussion as well as institutional and professional reflection, with regard to our dedication to prevent medical errors and to deal constructively and ethically when medical errors do occur. Only a short time earlier, there were significant disclosures in the press of wrong site surgeries and fatal medication errors in clinical practice and research, and these disclosures added to the dedication to address the magnitude of the problem.

As professionals, we asked how we ought to respond to the current increased concern in enhancing patient safety and reducing medical error? In addition, we addressed the ethical basis for this response on a personal, institutional, and professional society level.

Since we have a professional duty to benefit patients and reduce harm whenever possible, we have, at the very least, a moral obligation to incorporate the techniques already in existence in order to reduce errors. In addition, it was felt that we should consider our obligation to go beyond what is already known and support research in new methodologies aimed at enhancing patient safety.

When errors do occur, we must develop an ethically defensible approach to dealing with them. Respect for patients finds expression in telling the truth, in being honest with patients. Trust in the healthcare system, and certainly trust in our physicians, is founded on the expectation of honesty and the belief that the physician is working in the patient's best interest. There is also an expectation that when patients are injured, we owe them or their families a prompt and full disclosure. Patients want an honest explanation and, if appropriate, an apology. Furthermore many patients have said that it is important that others not be harmed in the same way and therefore they should be informed that the factors involved in the injury will be investigated in order to reduce the likelihood of a similar injury to future patients.

The Roman god, Janus, looks forward and backwards also. If we have made significant recent progress in reducing harm to patients, medical professionals are now looking at where the need appears greatest in the future. One area which warrants increased attention is the need to address the magnitude of patient harm from diagnostic error. This particular concern looms large when considering the extraordinary possibilities of increased genomic research and decisions that must be made as personalized medicine becomes more of a reality. Another area of ethical concern is the necessity to address the importance for timely and appropriate apology, as well as the offer of appropriate compensation, if patients have been harmed.

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**The Voice is As Mighty as the Pen: Integrating Conversations into Advance Care Planning Policies**

Kunal Bailoor  
University of Michigan Medical School

Advance care planning allows patients to reflect upon and articulate their preferences with regard to their medical treatment, lifestyle, and surrogate decision makers in order to anticipate and mitigate their potential loss of decision making capacity. Ideally, advance care planning is a dynamic process in which patients analyze their preferences regarding medical interventions, goals of care, and quality of life and communicate these preferences to their healthcare providers. Written advance directives are often emphasized in this regard. These written statements of preferences may take many forms, including designation of a surrogate decision maker, living wills containing written statements of preference, Do Not Resuscitate (DNR) orders, and health care proxies. While these contain important information, there are several barriers to consider: veracity and accuracy of surrogate decision-makers making choices consistent with the substituted judgment standard, state to state variability in regulations, literacy issues, lack of access to legal resources, and cultural inadequacies. These barriers can often prevent vulnerable patient populations from making use of these written statements of preference. In addition, patient preferences are dynamic with time and health status. Given these issues, it is vital to increase our use of patient and healthcare provider conversations as an advance care planning tool, and to increase integration of such discourse into advance care planning policy as adjuncts and complements to written advance directives. We refer specifically to clinician-patient conversations that are subsequently documented in the patient's progress notes, which we refer to as "documented interactions." This paper reviews current national and state laws with regards to written advance directives and dissects how documentation of these verbal interactions can help patients faced with legal barriers. We discuss specific changes made our institution as a potential model to illustrate challenges related to implementation. Finally, we explore the ethical issues surrounding the increased usage and recognition of clinician-patient conversations in advanced care planning including whether written orders and documented conversations should be considered equivalently; whether documented interactions can be used for pediatric patients; and the potential issues with bias inherent to medical documentation.

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**Bioethics Training for Front Line Medical Providers and Staff: Legal and Ethical Issues**

Emily Bergquist, Master of Science in Administration Program, Central Michigan University, and Daniel LoBello, Western Michigan University Cooley Law School

Emily Elder, Master of Science in Administration Program, Central Michigan University, and Christopher Marker, Western Michigan University Cooley Law School

Kineta Sadler, Master of Science in Administration Program, Central Michigan University, and Holliann Willekes, Western Michigan University Cooley Law School

Chair: Julie Janeway, Western Michigan University Cooley Law School

**Panel summary:** Each law student will be paired with a front line medical provider or staff member. The moderator will introduce the topic and structure of the presentation. Each front line individual will briefly discuss bioethics issues she has encountered personally, and situations that are encountered commonly by providers and staff other than nurses or physicians. Examples of issues include conflicting morals and values among care teams, intersection of personal morality and technology among front line providers, allocation of quality healthcare resources to those considered undeserving or unworthy, patient autonomy and listening to and respecting patient requests and requirements, and issues of patient safety and prevention of medical error, among others, and their intersection with the ethical principles of medicine and health law.

Each accompanying law student will discuss the legal and ethical issues that may result from the lack of bioethics training for this segment of the health care worker population. The panelists and moderator will then present a model protocol and training module curriculum for adoption by health care organizations regarding bioethics and legal issue training for health care providers and administrative staff. Following the panelists' presentation of the material, the presentation will be opened for questions from the audience. Panelists will answer questions posed, and the moderator will augment where necessary.

**Patient Understanding and Satisfaction Regarding the Clinical Use of Whole Genome Sequencing: Findings from the Medseq Project**

Archana D. Bharadwaj

Department of Health Behavior and Health Education, University of Michigan School of Public Health

The development of new techniques has reduced the time and cost of Whole Genome Sequencing (WGS), and the resulting increase in availability of genetic testing has generated excitement due its potential to tailor medical treatment. However, the integration of WGS into clinical practice poses challenges for informed consent and disclosure of test results. Few empirical studies have examined patients' understanding of and satisfaction with the clinical communication of WGS results in contexts outside of specialty cancer care such primary care and cardiology.

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The MedSeq Project is a randomized clinical trial examining the impacts of WGS in two contexts: general genomic medicine, modeled through the use of primary care patients, representing the use of WGS as a preventative measure and disease-specific genome medicine, modeled through the use of cardiomyopathy patients, representing the use of WGS to examine genomic causes for conditions in there is a family history. We analyzed survey data from two time points: 1) patients' initial enrollment and 2) immediately following disclosure of sequencing results by a physician. Domains of interest included understanding of informed consent, subjective understanding, satisfaction with communication of results, and decisional regret. Surveys included both validated (e.g., decisional regret) and novel (e.g., understanding of informed consent) self-report measures.

Survey responses were provided by 202 participants (mean age = 55 years; 51% male; 80% college graduates). At enrollment, participants understood the majority of key facts about the study (mean = 19.6 / 22 items (89%) answered correctly), although some participants incorrectly answered items addressing results to be returned (e.g., 18% believed they would receive their entire DNA sequence) and potential risks to genetic privacy (e.g., 14% did not recognize how widely their data would be shared). Higher informed consent knowledge scores were associated with female gender, greater genomic knowledge, higher subjective numeracy, and higher education levels (all  $p < .05$ ). After results disclosure, participants had low scores of regret regarding decision to participate in the study (mean score = 10/100 at results disclosure); they also reported high levels of satisfaction with their physicians' disclosure of results (mean = 5.9 on a 6-point scale), although ~20% of participants reported receiving "too much" information. Satisfaction with communication did not vary by participants' demographics or other characteristics (e.g. genomic knowledge).

This study of the clinical application of genome sequencing in medicine suggests that the intervention was generally well understood by patients, with low levels of decisional regret and high levels of satisfaction with the communication of sequencing results. Future research will be necessary to examine these issues in more diverse samples of patients (e.g., with broader ranges of health literacy), where misconceptions about the clinical use of sequencing identified here may be more pronounced and patient concerns about information overload may be magnified.

### **Embracing the Chiaroscuro: Rethinking Ambiguity in the Medical Treatment of Transgender Youth**

Lauren Baker

Albert Gnaegi Center for Health Care Ethics, University of St. Louis

In "Lives in chiaroscuro: Should we suspend the puberty of children with gender identity disorder?" bioethicist Simona Giordano argues that gender dysphoria arises due to the experience of life as ambiguously gendered, that transgender children who are denied treatment are at risk for violence and suicide, and that puberty suppression saves lives. Given the life threatening risks of delaying treatment, she contends that it is unethical to deny puberty suppression for children diagnosed with gender dysphoria. I agree with Giordano that there are many gender nonconforming children who experience the intense distress that she describes. I also agree that puberty suppression offers a wide range of benefits and is necessary for many children. But in this paper presentation, I will argue, contra Giordano, it is not gender ambiguity in itself which causes distress, but the *non-acceptance* of a child's gender ambiguity which leads to the psychological pain and violence that she identifies. Following, I will

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suggest that Giordano's position may in fact be harmful to children given that it reinforces the root cause of distress which many gender nonconforming individuals experience. My intent in this paper is not to dismiss the importance of early medical interventions such as puberty suspension, but to illuminate how biases towards a dichotomous understanding of gender shapes both how gender nonconforming youth are represented in medical literature, and how these children are medically treated.

### **Contextualizing the Reactions to CRISPR Following Centuries of Eugenic Medical Intervention**

Shawna Benston

Ethical, Legal, and Social Implications (ELSI) of Genetics, Columbia University

Reproductive genetic technologies (RGTs), including gene-editing technology like CRISPR/Cas9, are being discovered and refined at an exponential pace. The potential uses for CRISPR are wide-ranging and include both therapeutic and enhancement applications, either to somatic cells or to germ cells. Scientific and scholarly debate has erupted over various permutations of CRISPR application, especially its use for "enhancement" editing of germ cells. As these technologies continue being developed, it is worth investigating whether the fervidness of the ensuing debate is truly a warranted reaction to unprecedented innovations, or merely par for the course in the realm of medical technology.

In coining the term "eugenics," Sir Francis Galton defined it as the science that deals with "all influences that improve the inborn qualities of a race" and "those that develop them to the utmost advantage." In general terms, eugenics is viewed as detrimental when technology is used to select for particular traits deemed "desirable" at the expense of any people who have alternative traits, and as beneficial when the technology is focused on elimination of agreed-upon disease. Much opposition to CRISPR concerns the potential for detrimental eugenics, the slippery slope to a genetically engineered society favoring certain traits—intellectual, cognitive, emotional, physical, or racial—above others. We must seek to balance this valid concern with a perhaps equally valid attraction to beneficial eugenics: the parental desire to shape their children and provide them with an open future. As part of our exploration and in light of CRISPR's limitations, we must determine whether the surge of varied reactions to CRISPR is in fact disproportionate to the technology's potential promises and pitfalls.

We might view reactions to CRISPR as disproportionate when considering that this technology follows a long line of medical interventions designed to sustain and improve the human species. Since the onset of modern medicine, our survival and success as individuals and as a society have been a product of technological intervention. Whether saved from the potentially dire implications of breech birth, rendered disease-free by means of surgery or pharmaceuticals, or granted extended life via an organ transplant, human lives have been saved and prolonged by medical remedies for centuries. Such interventions themselves encountered initial, and even long-running, controversial reception by the bioethical and lay communities, who seek to assess whether benefits outweigh potential harms or the production of ethical dilemmas.

This paper will explore the context of medical and technological innovation in which CRISPR has emerged. When considering CRISPR's potential application, we must work to understand what is



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actually feasible, and to craft the continuing debate in the most productive way possible. Can CRISPR be used to engineer so-called “designer babies”? Is CRISPR more alarming than previously existing eugenics technologies? Are current reactions to CRISPR really much different than were reactions to such previously existing eugenics technologies when they first emerged?

### **Deceased Directed Donation: Considering the Ethical Permissibility in a Multi-Cultural Setting**

Rebecca Greenberg, Department of Bioethics and Pediatrics, University of Toronto (Canada)  
Andria Bianchi, Department of Bioethics, University of Waterloo (Canada)

This paper explores the ethics of deceased directed donation (DDD) and brings a unique perspective to this issue – the relevance of providing family centred care and culturally sensitive care to deceased donors, potential recipients, and their families. As the world is becoming more diverse with globalization, assessing the cultural aspect of the ethics of DDD is increasingly salient. We provide a brief overview of DDD across the globe, 2) review prominent arguments both for and against DDD, 3) consider family centred and culturally-specific considerations, and 4) offer considerations for the development of a policy or guideline. We determine that the practice of DDD is ethically defensible in certain circumstances and congruent with providing both family centred and culturally sensitive care. Our analysis is relevant to any country with a diverse population and any health care provider or institution that operates under a framework of family centred care.

### **Engineering Uncertainty at the Intersection of Agency, Autonomy, and Authenticity**

Timothy Brown and Laura Specker Sullivan  
Department of Philosophy, University of Washington

Engineered devices connecting brains to computers once appeared in science fiction alone; now they are becoming a reality. Researchers are experimenting with increasingly complex ways of stimulating and communicating with the human brain: transcranial Direct Current Stimulation (tDCS), Deep Brain Stimulation (DBS), and Transcranial Magnetic Stimulation (TMS), among others. The medical applications of these technologies are diverse as well. tDCS has been used on patients with depression and schizophrenia; DBS is widely used for patients with Parkinson’s disease and essential tremor; and TMS has been tested to improve patients’ motor function and relieve neuropathic pain. For many patients with pharmaceutical-resistant conditions, these neurotechnological therapies are their only effective options. Researchers are also working on integrating these one-way stimulators with existing neural sensors to determine how much to stimulate and when. These bi-directional brain computer interfaces (BCI) could detect when the user’s hand is trembling or when the user is experiencing symptoms of depression and respond by triggering stimulation.

Yet these treatments are not without side effects. As with pharmaceutical therapies, patients may experience changes to their energy levels, behaviors, and everyday interests. Unlike pharmaceuticals, patients may be unable to distinguish when the stimulator is active (and thus affecting their behavior) and when it is inactive. This can create a fundamental uncertainty about the source of the patient’s agency—is it the patient himself, or is it his TMS treatment that leads him to take time off work to lie in bed and watch television? Is it her DBS that makes her restless in the evening and eager to

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buy expensive items online, or is that just a feature of her personality? Is it stress from work or the tDCS treatment causing her body to tense up in ways that make it hard for her to relax? Furthermore, if someone with a BCCI is experiencing tension in his close relationships, should he locate the source of this tension in himself or in the effect that the BCCI has on his behavior? Understood in relational terms, these technologies can affect not only an individual's sense of self but also his or her relationships. One way of understanding this uncertainty is to say that people using these technologies take on new identities that intersect with their old identities. People using these technologies may be people with disabilities, people of color, research subjects, and so on, all at once. Taking on these new roles along with the old ones not only confuses agency, it can also frustrate autonomy and threaten authenticity as well. This means that in addition to complicating patients' intersecting identities, neurotechnological therapies also increase the complexity of conceptual intersections in ethical analysis. Ethical assessment of these therapies thus requires attention to two types of intersections: among patients' identities and among ethical concepts.

In this presentation, we analyze how neural engineering technologies generate uncertainty for patients' identities in terms of these three concepts: agency, autonomy, and authenticity. We propose that understanding and appraising the effects of these technologies requires sensitivity to the complex intersections of the user's shifting identities and acknowledgment of the interplay of all three of the aforementioned concepts. Finally, we provide suggestions for making sense of these intersections.

### **The Future of Psychiatric Deep Brain Stimulation: Dealing with the Unknown**

Laura Cabrera and Devan Stahl

Center for Ethics and Humanities in the Life Sciences, Michigan State University

Tyler Gibb

Program in Medical Ethics, Humanities & Law

Western Michigan University Homer Stryker M.D. School of Medicine

**Panel summary:** In 2008, 128 patients enrolled in the Broaden Trial, a multi-center, controlled, doubled-blind clinical research trial that investigated the efficacy of deep brain stimulation (DBS) for patients with depression. Since DBS for depression is not yet approved by the Federal Drug Administration, it was carried through out an investigational device exemption, which allows sponsors to skip the standard phase I and phase II safety and efficacy trials. After only six months, however, St. Jude Medical, the trial sponsor and maker of the DBS implant, terminated the trial when it failed to reach its benchmark of a 50% response rate according to the Hamilton Depression Scale.<sup>1</sup> Not only did St. Jude fail to release a public statement about the trial's termination, but also it did not inform the study's participants. Some of the participants in this multi-center study felt abandoned, with an unclear picture of whether or not they would receive follow-up care by the company. There are certainly many unknowns regarding psychiatric DBS, from whether or not its benefits are worth the risks, to whether more regulation is needed in order to protect study participants.

This presentation will survey past psychosurgery practice and compare them to recent debates over the use of DBS for psychiatric care. Although the FDA has approved the use of DBS for Parkinson,

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<sup>1</sup> Danielle Egan, "Adverse Affects: The Perils of Deep Brain Stimulation for Depression" *Mad in America: Science, Psychiatry and Community*, September 24, 2015.

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essential tremor and dystonia, DBS for psychiatric conditions, such as depression, OCD, and anorexia remains experimental and in the initial stages of research. Many worry that the risks for psychiatric patients are higher than those for movement disorder's patients, because the areas of the brain that are targeted are in the cerebral cortex, which controls many essential functions of the brain as well as patient's "personality." As we look to the future of neurosurgical interventions, we must consider the very real ethical and regulatory challenges that remain when so little is understood about the etiology of psychiatric disorders and the action of mechanism controlling DBS.

### **Selling under Uncertainty: A Prolegomena to an Account of the Morality of Selling**

Ryan Cobb

Philosophy Department, University of Iowa

Many of the ethical questions facing medicine concern selling. It is at times taken as a datum that the sale of certain items is morally wrong, or at least deeply troubling. For instance, the sale of human tissue is widely banned, and it seems that at least part of the motivation is moral (that is, not merely practical). New technologies—medical and otherwise—multiply such morally sticky issues, as new markets and new products emerge. So, we might wonder whether it is permissible to sell one's genetic code (or portions thereof), or instructions on how to use a 3-D printer to make a gun. Ideally, we would have an account of how to determine, for any combination of buyer, seller, and product, whether the sale is permissible. But there are preliminary questions that we must address before giving any such account—or before deciding that such an account is impossible. Failure to address these questions dooms us to incomplete, fragmented accounts and leaves us unprepared to address new questions in the ethics of selling. It would be nice to eliminate this uncertainty, if possible.

This paper addresses some of these preliminary questions. In particular, it addresses the question of what constitutes a sale, and it considers what makes a sale wrong. Thus, this paper functions as a prolegomena to developing accounts of the wrongness of particular types of sale. In the first half of the paper, I address the question of what constitutes a sale. I then address, in the second half, two differing accounts of what makes selling wrong. I consider the merits of each account, and conclude by reflecting on some potential future work.

In the paper, I defend the following account of selling. A seller S can be said to have sold an item or service I to a buyer B under the following conditions:

- i) S and B agree to conditions for the transfer of ownership of I
- ii) one of the conditions for the transfer of ownership of I is B compensating S with something (perhaps money, perhaps another item) of value perceived to be of roughly comparable value to I
- iii) S and B execute the conditions to which they agreed
- iv) B takes ownership of I

This account, while likely "missing" some cases around the margins of selling, captures, I contend, some essential philosophical features of the concept. With this preliminary account of selling in hand, I proceed in the second half of the paper to consider two accounts of the wrongfulness of selling. These are what I shall call the "human dignity" account and the "market pressures" account.

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### **Epistemology of HIV Transmission: Advancement, Uncertainty, and Dissemination of Information**

Lacey Davidson and Mark Satta  
Department of Philosophy, Purdue University

We utilize several recent studies concerning the transmission and treatment of HIV and philosophical thought experiments to identify two levels of uncertainty: uncertainty in personal sexual health and uncertainty that leads to epistemic public health injustice. First, we highlight *individuals engaging in sexual activity's* uncertainty regarding their sexual health and status information, and second, we demonstrate that uncertainties in the developing discourse around these new research conclusions leads to *epistemic public health injustices*. These injustices arise along faults of marginalization and privilege within and among discourse communities. We focus on communities of men who have sex with men (MSM) in particular. In light of these uncertainties, we must reconceptualize the nature of sexual education and the cultural conversation about HIV status, focusing on the uncertainty of transmission rates and protections, particularly as it pertains to the marginalized groups most affected by negative stigmas surrounding HIV.

We begin our paper by presenting the recent sexual histories of a number of fictitious characters. We ask our audience to think about which characters are at greatest risk of seroconverting and which characters are dealing with the highest levels of uncertainty in terms of information about likelihood of infection. We engage in this in order to challenge common assumptions about where risk lies and to highlight often unrecognized sources of uncertainty due to deficiencies in the general public's information about HIV.

We next analyze recent research advancements relevant to HIV and HIV transmission risk that provide the evidence for our claims about sources of risk and uncertainty, highlighting some of the immediate epistemic upshots as we go. These findings are divided into five research themes: 1) estimates about the percentage of people living in the United States with HIV who do not know they have the disease, 2) information about the lag time between acquisition of HIV and the ability to test positive for HIV, 3) information about the infectivity of those in primary HIV infection and estimates about the percentage of new transmissions resulting from serodiscordant sex (i.e. sex in which one partner is HIV-positive and the other HIV-negative) in which the HIV-positive partner is in primary infection, 4) an explanation of what an undetectable viral load is, how such a status can be obtained, and what current research suggests this means for infectivity, and 5) recent advancements in HIV prophylaxis (i.e. preventative health measures) beyond the use of condoms.

We then identify ways in which distributions of privilege and marginalization between and among MSM communities have led to distinct understandings and practices and some ways in which these understandings and practices move in the direction of rectifying or exacerbating various epistemic public health injustices related to HIV. We divide these epistemic public health injustices into three categories: 1) *structural-linguistic epistemic injustices*, as we will call them, resulting in widespread ignorance of HIV transmission risk among HIV-negative individuals, 2) *hermeneutical injustices* (Fricker 2007; Mason 2011) for HIV-positive people, and 3) and *credibility-deficit testimonial injustices* against HIV-positive people, in particular black men.

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### **Informational Opacity and Consent in Clinical Genomic Sequencing**

Michael Deem

Department of Multidisciplinary Studies, Indiana State University

Clinical expansion of whole-genome and whole-exome sequencing will compound difficulties involved with ensuring that patient and family decisions about clinical management are informed and responsible. Genomic sequencing yields an immense amount of data that must be analyzed and interpreted in order to provide potential benefits to clinical care. The sheer volume of raw data presents tremendous challenges to the effective communication of their potential clinical significance to clinicians and to clinical counseling.

This paper discusses and clarifies three such obstacles to informed consent in genomic medicine, all of which involve what I call 'informational opacity' in the interpretation and transmission of genomic information:

- (a) the lack of a clinical-grade general database of identified variant-disease associations;
- (b) interpretive discrepancies in genomic analysis that undermine high-fidelity transmission of information about the clinical utility of sequence variants from analysts to clinicians;
- (c) varying degrees of genetic literacy among clinicians and patients affects the handling and communication of diagnostic information from genomic sequencing

Informational opacity in genomic medicine requires a rethinking of acceptable standards of patient consent, especially because patients and their families are making decisions about a vast range of unknown analysis and health outcomes. After discussing these three forms of opacity, the paper develops and defends on ethical grounds a framework for communication of diagnostic information from genomic sequencing and acquisition of patient consent where traditional standards of informed consent cannot be satisfied. A new model of consent will become increasingly important as precision medicine advances and renders traditional models of informed consent unrealistic.

### **Just Caring: Parsimonious Care in Certain Uncertain Circumstances**

Leonard M. Fleck

Michigan State University

Uncertainty is a Hydra-headed phenomenon in health care. From a physician's perspective there often is uncertainty (many degrees) with respect to diagnosis (and the reliability of the technologies needed to establish a diagnosis), prognosis (and the infinite variety of genetic, physiological, pharmacological, behavioral, technological, economic, and cultural factors that affect the outcome of prognostic judgments), the appropriateness of a therapeutic intervention (perhaps related to medical disagreement), the likely effectiveness of a therapeutic intervention, the risk/ benefit ratio of a therapeutic intervention (potentially complicated by co-morbid conditions), the likelihood of a patient complying with the behaviors needed to maximize the likelihood of a therapeutic outcome, the applicability of a clinical guideline to *this* patient in the clinic, the reliability of the evidence and research behind that guideline, and, finally, the sheer randomness of natural events at various levels in the health care encounter. That is the background for this presentation.

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Our question, however, is this: How should all this uncertainty be addressed in the economic/political context of having to do health care rationing, and in the ethical context of having to do that rationing justly? Today there is an increasing emphasis on the obligation of physicians to provide parsimonious care, i.e., the prudent and cost-effective use of health care resources in caring for individual patients. To focus discussion I offer several common examples, such as \$100,000 precision cancer drugs, \$40,000 implantable cardiac defibrillators, PCSK9s for lowering “bad” cholesterol, access to ICU beds---- all of which represent uncertain benefit at very great cost. DRGs as a hospital payment mechanism are part of the same problem since they can motivate “premature” discharge of a patient, thereby putting them at uncertain risk for an otherwise avoidable bad health outcome. If physicians cooperate with the intent of DRGs (or other care protocols intended to promote parsimonious care), are they treating their patients unjustly? Must physicians be virtually certain that no harm will come to their patients in order to be just and justified in carrying out parsimonious protocols? “No” is the response I will defend. If a patient does not have a just claim to some health care resource, then the harm that “might” befall them as a result of that denial is properly regarded as being unfortunate but not unjust.

Access to health care resources is about access to a limited common good. This is what makes such access a matter of justice rather than a matter of informed consent wherein a patient weighs from their point of view the risks and benefits (and related uncertainty) they are willing to trade off. Matters of justice require social decisions. Patients do not have a presumptive just claim to a \$100,000 cancer drug if there is only a small chance that drug would yield an extra six months of life. What level of certainty would generate such a just claim? There is no objectively correct answer to that question. It needs to be resolved, I will argue, through a process of rational democratic deliberation, the results of which will be just and legitimate for all in the relevant clinical circumstances.

### **Preparing for the Future by Looking at the Past: The Biopolitical Fragmentation of Terri Schiavo**

Tyler Gibb

Program in Medical Ethics, Humanities & Law

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It has been over a decade since Terri Schiavo died. The drama she unfolded on television screens and across the media between her husband, Michael Schiavo, and her parents, Robert and Mary Schindler, captivated millions of people all over the globe. Fifteen years before her death, Terri collapsed in her apartment after suffering a cardiac arrest. She suffered devastating anoxic brain injury, which left her in a condition known as the persistent vegetative state. Over time, her husband and parents, who were initially unified in a commitment to get her the best treatment available, slowly drifted in different directions regarding how they believe she would be wanted to be treated as her prognosis became more certain. The dispute between them eventually entered the court system and captured the attention of the national international media. Despite hundreds of newspaper and magazine articles, blog post, academic articles, books and countless hours of television and radio coverage of what has become known as the Terri Schiavo case, several important questions remain unanswered. Why did this case, which is widely regarded as the most intensely media-saturated end-of-life bioethics case in history, hit the public spotlight? In a country where similar end-of-life decisions are made on a daily basis, what was unique about this case that propelled it into the national and international consciousness? Was the Schiavo case merely an anomaly, or does it represent something

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more fundamentally problematic about medicine, the law, and our society? In this paper, using the Schiavo case as an analytical lens, I offer ways to address these important questions. I argue that the development and notoriety of the Schiavo case is due to a fundamental societal shift—what I describe as biopolitical fragmentation. By reinterpreting the biopolitical theory of modern philosophy since Foucault, I argue that the radical fragmentation seen in the Schiavo case is understandable as symptomatic of a societal shift in how the human body, understood in its broadest sense, is fragmented through the institutions of law, medicine, and society. This presentation will highlight how this analysis illuminates a few specific fragments in the Schiavo case—the persistent vegetative state, and the role of popular media. By looking carefully at the Schiavo case, future cases that challenge the foundation of societal assumptions about good and bad in the delivery of health care can be better anticipated and meaningfully engaged.

**Special Obligations and Special Biases:  
Parents as Proxies and the Release of Incidental Findings in Genetic and Genomic Research**

Kelsey Gipe  
Department of Philosophy, University of Maryland

As technology advances in the field of genetic and genomic research and testing, ethical issues emerge. Particularly challenging are problems which arise from the discovery of incidental findings in the course of such research and testing. There is much debate concerning the consent process for release of incidental findings, and the question of which findings to disclose and how to obtain informed consent for the release of such findings is as of yet unsettled. These are problems which only intensify in regard to genetic and genomic research on children. In these cases, parents or guardians must act as proxy consenters on behalf of the child subject. In this paper I will explore the ethical issues surrounding parents acting as proxy consenters for their children in regard to the disclosure of incidental findings. I will focus specifically on unique challenges which may arise from the fact that a parent has particular obligations to her child which may be at odds with what the child would choose for herself were she capable of informed consent. When it comes to incidental findings which will likely be significant to the child only in adulthood, I propose a routinized opt-in system in which a child is informed upon reaching the age of majority of her right to inquire about incidental findings. Under the system I propose, the question of whether there are – for a given patient – any significant incidental findings is left open, and the subject is able to make the decision of whether she wants to be privy to whatever information might be available to her. If she opts in, then at that point she will go through the standard procedure for informed consent before receiving any findings. If she simply does nothing, then she will not face the prospect of being saddled with unwanted and potentially distressing information. In this way, the subject's "Right to Know" and her "Right to Not Know" are preserved.

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### **Can the Principle of Procreative Beneficence Justify the Non-Medical Use of Preimplantation Genetic Diagnosis?**

Biplab Halder

Faculty of Medicine, Memorial University of Newfoundland (Canada)

The Principle of Procreative Beneficence (PB) is a pronatal view in reproductive ethics which was originally formulated by Julian Savulescu in his paper “Procreative Beneficence: Why We Should Select the Best Children”. Further development of the principle was done in another paper titled “The Moral Obligation to Create Children with the Best Chance of the Best Life” in collaboration with Guy Kahane. The principle states that the parents have a moral obligation to select the best possible child, when selection is possible, by means of the genetic screening of the embryos. Preimplantation Genetic Diagnosis (PGD) is a reproductive technology that makes it possible to discover the medical and non-medical genetic traits of embryos. PB justifies employing PGD not only for medical reasons, but also for non-medical reasons. Moral controversy arises when PGD is employed in order to select the preferred sex or certain genetic traits such as the intelligence of the child. The central inquiry of the paper is to find out whether non-medical use of PGD can be justified by PB proposed by Julian Savulescu. To explore this issue, I put forward the question: can PB make such a strong claim that the parents have a moral obligation to select the best possible child by employing PGD? In other words, what are the justifications of PB for claiming a moral obligation for the parents? I argue against the pro-selection view of Julian Savulescu exploring the basic assumptions and moral justification of PB. PB presumes that the non-medical and medical use of PGD are mutually inclusive in the question of a moral obligation for the parents. However, I show that this is not the case if we consider the possible consequences of PGD in the potential life of the child; the non-medical and medical use of PGD are mutually exclusive in terms of their implication on the child. PB also presumes a *degree* of parental obligation in its concept of ‘significant moral reason’ in the case of employing PGD which is morally problematic. Finally, I argue that the moral foundation of PB is based on the ‘common moral intuition’ which is not an authentic source of a moral truth; hence, PB is not justified to claim a moral obligation for the prospective parents regarding the non-medical use of PGD.

### **Public Health and Risk Prevention: The Case of Ebola**

Melinda Hall

Department of Philosophy, Stetson University

I investigate reactions in the United States among the public and within public health institutions to the 2014 Ebola Virus Disease (EVD, or Ebola) outbreak in West Africa. I approach these issues within the context of analyzing risk, risk aversion, and risk analysis using the theoretical frameworks of Michel Foucault and Jacques Derrida. I argue that popular and public health responses to Ebola call us to construct ourselves as risk-averse subjects. In these various moments or arenas of bioethics discourses, one is encouraged to conceive of exercising one’s autonomy as a way to conquer chance, i.e., as a matter of risk prevention. In other words, in this setting, morally responsible subjects are those that attempt to manage risk through prediction and elimination, thus substituting choice for chance. Meanwhile, risk is conceived of as attached to particular individuals and ideas. In the case of prenatal testing, for example, the fetus is constructed as a vector of risk, which potential parents must manage. Disability, connected to the “impaired fetus,” becomes a floating signifier for risk. So, to



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whom does the concept of risk attach in public health settings? How did the social reception and public management of EVD in 2014 demonstrate that the desire to eliminate the risk of infection was also a desire to protect oneself from chance and manage those populations believed to embody risk?

I contend that an unintended consequence of public health discourse surrounding risk prevention in the case of EVD is the deepening construction of particular African bodies as inherently risky or vulnerable. Meanwhile, those in the West conceive of themselves as risk managers of these populations, rather than as vulnerable bodies themselves. Indeed, researchers found that stigma plays a role in misunderstandings with regard to the transmission and prevention of EVD (Davtyan et al. 2014). Further, I found that in public discourse surrounding the question of Ebola, race acts as a key floating signifier referring to risky persons, risky traits, and the idea of risk. For example, travel bans applying to affected countries, including Liberia, Guinea, and Sierra Leone, were widely called for by public figures and in social media. These calls and related discourse were racially inflected. United States President Barack Obama was accused of having special ties to West Africa which prevented him from seeing the need for a travel ban (e.g. Media Matters 2014). Obama rejected outright travel bans, but did set into place special screening procedures at airports for those traveling from affected countries into the US. Some calls for travel bans and screening procedures may not be remarkable, given that viral infection (unlike disability) is genuinely communicable. Yet, panic over the threat of Ebola (partially expressed as panic over the presence, or potential presence, of West African persons and those resembling West Africans) vastly outstripped its potential impacts, especially when compared to far more widespread and also deadly viruses such as seasonal influenza. In other words, travel bans were not necessary and were only called for as a result of race-related panic.

### The (Un)Certainty of Care

Raymond Higbea

School of Public, Nonprofit and Health Administration

Alyssa Luboff, Department of Philosophy  
Grand Valley State University

This paper examines two kinds of uncertainty in healthcare. One is a generic uncertainty present in all human endeavors, constantly increasing with the pace and intensity of our society. The second kind of uncertainty is one that is presently being built into our healthcare system as we transition from “fee-for-service” payment models toward outcomes-based reimbursement. These new models, linking payment directly to patient health and satisfaction, introduce a new layer of persistent and incorrigible uncertainty into the healthcare system. No administrator or financial planner can predict or control the feelings and well-being of patients with as much accuracy and reliability as phenomena that yield “harder” data. We will argue, however, that this second form of uncertainty, which seems to be more of a contingent than an inevitable feature of our healthcare system, stands not only to improve its overall efficiency and function, but to restore the ideal of “care” in healthcare.

Current models of care delivery are structured around the certainty of payment for performing physician-directed activities (fee-for-service). The new outcomes-based models, on the other hand, emphasize the uncertainty of uncontrolled patient activities (value-based purchasing, negative and positive risk sharing). The purpose of these new models is to incent improved patient outcome and more efficient use of resources, based on greater coordination of care.

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To a certain extent, the uncertainty of the new models can be managed by implementing control mechanisms. The drawback, however, of such controls is that they risk recreating the same problems of bureaucratic excess and informational overload that they were meant to address. We propose that what should be taken into account here is the greater shift reflected in the transition between these two kinds of models. The old models define the healthcare system as composed of separate, isolated pieces to manipulate and control. Its proper functioning, then, depends on the application of the proper practice heuristics, regulations, and rules. This reflects greater certainty not only at the financial level, but at the ethical level as well. Patient autonomy and respect of persons can be “measured” by signatures on consent forms, plans of care, and discharge instructions. Justice can be demonstrated by a count of how many disenfranchised, underrepresented, or minority individuals are served. The new models have the potential to define the system more holistically, as composed of intelligent, living pieces that work together. Such an interpretation of the healthcare system suggests not only new financial and administrative measures, but an ethical shift as well, informed by the feminist critique of an ethic of justice and concomitant call for the development of an ethic of care. This involves the infusion of relational values, such as communication, compassion, interdependence, attention, and context, into our current healthcare system. While these highly qualitative values introduce the greater uncertainty of reduced administrative control, they stand to make the system itself more intelligent and responsive. Relational values can increase the efficiency not only in the use of resources, but in the functioning of the resources themselves, because each piece of the system becomes empowered and intelligent in itself. In this way, a relational ethic can temper the bureaucratic and informational excesses that remain a danger even for the new outcomes-based models. Of course, adopting these new values demands a certain ethical and emotional maturity on the part of administrators and other large power-holders in the current system. This process may be helped by seeing that such values can restore to the healthcare system not only greater efficiency but *care* itself, the well-being of patients and of all actors involved.

### **Trying and Dying: Are Some Wishes at the End of Life Better?**

Oliver Kim  
Independent Researcher

Independent In 2015, both chambers of the US Congress considered two legislative proposals related to care at the end of life. One proposal passed the House of Representatives as part of a larger package, and this proposal paralleled a “right to try” movement. The other proposal failed to be amended into a larger package being debated by the Senate, and this proposal would have assisted in advance care planning efforts with seniors.

While these two pieces of legislations are unrelated, it is striking how easily the “right to try” passed as part of a larger bill while at the same time, a very modest proposal on the periphery of the “right to die” debate did not. And in state legislatures across the nation, such efforts are even more dramatic: “right to try” bills have passed in several states while “right to die” proposals have not seen even a fraction of the same success.

This debate says a lot not only about our politics but also our policies around end-of-life decision-making. While we want a society that values life, we also want a society that empowers individuals to make their own decisions, particularly about their health and well-being.

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**Examining the Psychosocial and Ethical Issues Arising from the Identification, Disclosure, and Communication of Genomic Results to Patients and Clinicians**

Lan Le, Natalie Bartnik, Michele C. Gornick and Nicole Exe  
Center for Bioethics, Social Science and Medicine, University of Michigan

Chair: Raymond DeVries  
Center for Bioethics, Social Science and Medicine, University of Michigan

**Panel summary:** Precision medicine relies on genomics to customize health data and provide novel insights about disease mechanism, disease risks, potential responses to medication, and alternative treatment options. For many patients with advanced or rare cancer, either the standard of care is ineffective or no standard of care therapy exists. Genomic sequencing of tumors from such patients could inform choices regarding clinical trials or targeted therapy based on the molecular characteristics of the cancer. However, little is known about how patients and clinicians will respond to the use of genomic sequencing in clinical oncology.

The proposed panel will include findings from part of the Michigan Oncology Sequencing Center (MI-ONCOSEQ) research study at the University of Michigan examining the psychosocial and ethical issues expected to arise from the implementation of genomic sequencing into clinical care. MI-ONCOSEQ uses integrative clinical sequencing to expansively profile genetic aberrations in both somatic and germline DNA of patients with rare, advanced or refractory cancers.

Specifically, the panel will discuss patients' understanding and expectations surrounding the use of genomic sequencing information, oncologists' use of genomic results in clinical management, the delivery of genomic sequence results to oncologists, and the public's preferences for the return of secondary genomic findings.

**Quarantining an A-symptomatic Carrier: A Reasonableness Standard**

Christopher Marker  
Western Michigan University Cooley Law School

The focus of the paper is the due process implications (both procedural and substantive) of quarantining an a-symptomatic carrier of an infectious disease. The paper discusses the rights of individuals and the ability of the government to infringe upon these rights to protect the health of the general public.

The paper begins with the story of Thomas Duncan, the individual who had the first confirmed case of Ebola that came to the United States from Africa during the 2014 outbreak. The paper then goes on to discuss the characteristics of Ebola and similar infectious diseases with a focus on diseases that have the ability to be carried by individuals without showing signs of infection, making them a-symptomatic carriers. This is followed by a discussion concerning the history of quarantine law in the United States and a brief explanation of the evolution of constitutional due process. The procedural due process portion focuses on the fact that individuals are entitled to a trial in most instances before their freedom can be infringed upon. This is meant to show why it would be impractical to hold a full trial prior to quarantining individuals because they could potentially spread a contagious disease to

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individuals attending the trial or other individuals in the local area. The question then becomes, How do you determine whether individuals have an infectious disease if they are not currently presenting any symptoms? The paper provides background information on substantive due process rights and how the government can infringe upon them because all United States citizens have the substantive due process right to bodily integrity (the right to determine what may enter their body and refuse medical treatment).

Next, the paper analyzes the reasonableness procedural due process standard and how it could be applied to the government's ability to quarantine an a-symptomatic carrier. The paper analyzes the Centers for Disease Control and Prevention's (CDC) risk factors for each known infectious disease. The paper then proposes that, with these risk factors as well as case precedent in other areas of law such as criminal procedure (exceptions to the warrant requirement), it is reasonable to conclude that the government has the ability to quarantine an individual based on a reasonableness standard.

The paper then analyzes the substantive due process right to bodily integrity and how it applies to testing an a-symptomatic carrier for an infectious disease. There is case law to suggest that the government has the ability to compel individuals to have diagnostic tests done if they are at high risk of exposure to the disease based on the CDC's risk factors. However, because this is a substantive due process right, the government will have to pass the strict scrutiny standard in order to infringe upon it, and this is very difficult.

The paper concludes that a case on point is necessary to decide whether subjecting an individual to medical exams without his or her consent to determine if the individual is an a-symptomatic carrier complies with substantive due process. However, quarantining a suspected a-symptomatic carrier of a contagious disease, like Thomas Duncan, without a prior hearing would likely be reasonable and therefore comply with procedural due process.

### **The Unintended Consequences of Neurotechnological Enhancement**

Tabitha Moses

School of Health Sciences, Human Services and Nursing, Lehman College, City University of New York, Bronx  
National Core for Neuroethics, Division of Neurology, Dept of Medicine, Univ of British Columbia (Canada)

Over the past decade the numbers of new and innovative neurotechnologies have increased exponentially, and these advancements seem only to keep growing. Scientists and even DIY inventors have succeeded in developing devices that could enable enhanced vision, hearing, and memory in addition to creating a whole new range of senses. While many of these devices have been designed with the intention of treating disabilities or diseases, they also have the potential to enable unparalleled enhancement. While we have previously had access to a set of chemical enhancements, these new technologies will open the doors to a tremendous growth of opportunity.

In spite of all the positive treatment outcomes associated with these technologies, and the possibilities for positive neurotechnological enhancements, there may be a darker side to them. Currently, the attitude of "bigger is better" is held by many who espouse the benefits of such enhancements, and there are certainly aspects of this approach that are irrefutably positive. However, there exists a host of unknown risks associated with the use of these new technologies for neuroenhancement; we are entering previously uncharted territory. While we have seen significantly positive effects of these

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advances, these positives do not prevent the likelihood of future negative outcomes when we attempt to use these advancements in technology for enhancement rather than treatment.

One major concern is whether our bodies and brains are able to cope with the additional inputs that may be created through the use of neurotechnological enhancing devices. It is possible to examine real life examples in which it appears that the individuals with a specific disorder have become overwhelmed in some way due to a natural neuroenhancement or alteration. Further examination of these pathologies (such as autism spectrum disorders, synesthesia, and hyperthymesia) will help reveal to what extent we should be concerned about the potential for a type of cognitive overload due to the use of neurotechnological enhancements. In the end, the concerns with these enhancements may not be based on potential internal limitations, but instead stem from the world around us and the way it may function to overwhelm a person should they become neuroenhanced. These technological advances have significant potential both in treatment and enhancement; however, it is important to be fully aware of the potential physiological and psychological risks of these devices.

**Author Meets the Critics: Mark Navin's *Values and Vaccine Refusal***

Mark Navin

Department of Philosophy, Oakland University

Mark Largent

James Madison College of Public Affairs, Michigan State University

Heidi Malm

Department of Philosophy, Loyola University Chicago

Jamie Lindemann Nelson

Department of Philosophy, Michigan State University

**Panel summary:** This panel focuses interdisciplinary critical attention on Mark Navin's *Values and Vaccine Refusal* (Routledge, 2016). In this first book-length philosophical treatment of vaccine refusal, Navin argues that we can best understand current debates about vaccines by placing them in a broader narrative about medical expertise and civic engagement. *Values and Vaccine Refusal* focuses on the shifting epistemic and moral terrain surrounding an educated public's relationship with health care and society – a relationship characterized by wariness of experts and elites, withdrawal from participation in public projects, and do-it-yourself models of reasoning and practice.

Navin argues that some parents have good reasons not to defer to the expertise of physicians, and to rely instead on their own judgments about how to care for their children. Unfortunately, epistemic self-reliance systematically distorts beliefs in areas of inquiry in which expertise is required (like vaccine immunology). Navin also observes that vaccine refusers and mainstream medical authorities are often committed to different values surrounding health and safety. For example, while vaccine advocates stress that vaccines have low rates of serious complications, vaccine refusers often resist vaccination because it is 'unnatural' and because they view vaccine-preventable diseases as a 'natural' part of childhood. Also, Navin argues that parents who refuse vaccines rightly resist the utilitarian moral arguments – 'for the greater good' – that vaccine advocates sometimes make. But he

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concludes that vaccine refusers also sometimes embrace a pernicious hyper-individualism that sanctions free-riding on herd immunity and cultivates indifference to the interpersonal and social harms unvaccinated persons may cause.

The “critics” in this session have expertise in diverse areas that are relevant to the arguments Navin makes.

Mark Largent is an historian of science, technology and medicine. His research and teaching focus on the role of scientists and physicians in American public policy. He is the author of *Vaccine: The Debate in Modern America* (Johns Hopkins, 2012). Heidi Malm is a philosopher who specializes in ethical theory, bioethics and law. Her academic research focuses on ethical issues involving autonomy and the prevention of harm, with a current focus on issues within the field of preventive medicine and law. Jamie Lindemann Nelson is a philosopher who works primarily in bioethics. Much of her work brings to bioethical questions resources from areas of philosophy that the current discussion tends to overlook. She is particularly interested in philosophical issues that arise from thinking about intimate relationships — including families and family-like contexts.

#### **Re-thinking Mendelian Genetics:**

#### **What are the Ethical Implications for the Use of CRISPR Together with Gene Drive in Humans?**

Michael W. Nestor, The Hussman Institute for Autism, Baltimore

Richard L. Wilson, Department of Philosophy, Loyola University, and Department of Engineering Management, The University of Maryland, Baltimore County, Catonsville, MD

CRISPR genome editing has already reinvented the direction of genetic and stem cell research. For more complex diseases it allows scientists to simultaneously create multiple genetic changes to a single cell. Technologies for correcting multiple mutations in an *in vivo* system are already in development. On the surface, the advent and use of gene editing technologies is a powerful tool to reduce human suffering by eradicating complex disease that has a genetic etiology. In this paper, we critically analyze this hypothesis from an ethical perspective by developing an anticipatory ethical analysis of the implications for the use of CRISPR together with gene drive in humans.

Modern molecular biology techniques have allowed genetic engineering for many decades, however this manipulation of the genome has been limited due to lack of specificity and off-target effects. Recently, the advent of CRISPR gene editing techniques has been used to very precisely edit the genes of cells and organisms in a highly efficient manner. CRISPR can be used to edit the germline of embryos, implying that any corrected or introduced mutations can be subsequently passed to offspring. However, the limitations of Mendelian genetics prevent rapid changes in the populations of some CRISPR-edited organisms. By combining CRISPR with gene drive, edited genes can be spread throughout an offspring population at rates significantly higher than Mendelian genetics would predict. In rapidly reproducing populations like insects the combination of these systems has the potential to wholesale change the genetic characteristics of entire populations rapidly. CRISPR and gene drive has been proposed to be used to induce negative ecological impacts on invasive insects or organisms, and prevent

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the reproduction of malaria-containing mosquito populations. These uses imply that this technology can be easily controlled and will benefit humans.

Although wholesale changes can occur in the population genetics of rapidly reproducing species, changes in organisms with a long life-span would take decades or centuries using CRISPR and gene drive. This, combined with the notion that over long periods of time natural selection may undo the effects of CRISPR and gene drive and artificial mate control can limit their scope, has been used as an argument against the effectiveness of these technologies in humans.

Using an anticipatory practical ethics based on Robert Audi's moderate intuitionism, we explore the implications of a CRISPR and gene drive system in humans and whether there are sufficient ethical concerns based on this analysis.

### **Accepting Uncertainty: Applying Uncertainty as a Heuristic Tool to the Issue of Medical Errors**

Angelika Potempa

Department of Philosophy, University of Texas-Rio Grande Valley

This paper combines ideas from Ignorance Studies, nepistologies, and Object-Oriented Ontology and applies them to the discourse on medical errors. Known knowns and unknown knowns concerning certainties and uncertainties with regard to improving the quality of the health care system are discussed. This approach allows for discussing uncertainty as epistemological and ethical as well as socio-economic and political problems.

### **Ethical Issues in Genome Sequencing in Research and Clinical Settings**

Michael Pritchard, Department of Philosophy, Western Michigan University

Elaine Englehardt, Department of Philosophy, Utah Valley University

A new generation of DNA sequencing tools has made it quite affordable to determine the complete sequence of a human genome. Our presentation focuses on ethical issues regarding the use of these tools both in research and in clinical settings. Some of the ethical concerns include: 1) the treatment of incidental findings that result from genetic testing; 2) potential conflicts of interest of physicians who use their patients as participants in research; and 3) communication challenges for researchers and clinicians who have to determine whether and how to inform participants or patients of findings, especially in light of difficulties researchers, clinicians, primary care physicians, participants, and patients may have in knowing how best to interpret the practical significance of the results.

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In exploring these questions, we will reflect on our recent advisory role in a project proposed by a University of Iowa team of medical researchers specializing in the area of severe visual impairment.<sup>2</sup> They proposed to use exome findings from their patients in their research as well as to use their findings in providing their patients with clinical advice. The use of the exome requires that a large fraction of each patient's genomic sequence be obtained and analyzed. However, in addition to uncovering information relevant to what they are looking for regarding their patients' visual disorders, the researchers can expect to encounter many incidental findings—findings that are apparently unrelated to those original questions. Such incidental findings will include variants of both known and unknown significance, information about carrier status, and information about risk for late-onset disorders. In the case of an incidental finding, there are numerous ethical considerations regarding when (and how) a result should be presented to a research subject or a patient. A common view is that individual sequence variation results should be provided to participants only in circumstances where this can be expected to have actual utility for them. For example, the results may suggest a preventive or therapeutic intervention, or the information could be used for reproductive decision-making or general life planning. However, as further research is conducted, earlier research results may acquire practical utility that was not originally evident. So, questions remain about the retention and possible future communication of data to participants.

In light of uncertainties about how to proceed in such rapidly developing areas, the Presidential Commission for the Study of Bioethical Issues' report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Finding in the Clinical, Research, and Direct-to-Consumer Contexts* (Dec. 2013) offers useful ethical guidelines regarding what types of information can, should, or should not be offered to participants in research contexts and patients in clinical settings. In our presentation we will give special attention to questions about *how* this information should be conveyed. Additionally, we will discuss difficulties in discerning participants and patients' wishes and expectations regarding the return of results during the informed consent process. Finally, we will discuss problems that genetic counselors and geneticists face in protecting participants and patients emotionally and physically, as well as in ensuring their confidentiality and privacy.

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<sup>2</sup> "Exome Sequencing for Clinical Care of Vision Disorders," proposed to NIH by Edwin M. Stone, M.D./PhD.; Val Sheffield, M.D./PhD.



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### **Dharma Traditions and Medical Professionalism**

Rajiv Rangrass

Department of Family and Community Medicine

Western Michigan University Homer Stryker M.D. School of Medicine

My talk is about the concept of Dharma as the foundation of ethical behavior. Dharma embodies the ethical principles for descendants of the Indus valley civilization who are not brought up following the Abrahamic tradition that is so common in Western society.

The Abrahamic tradition gives pre-eminence to the concept of one powerful God. We recognize these associated faiths to be monotheistic. In contrast, within many arising traditions in the Indian subcontinent, the concept of Dharma, described as 'righteous action and righteous thought', blends with the idea of a personal God, or 'Ishta-Deva'. This pluralism is often interpreted as polytheism by the Western mind. As an example, in Buddhism, there is not even a concept of the entity we commonly call God; Dharma forms the primary foundation of ethical behavior.

As a physician I am very much aware of the influence of the Greek philosophical thought processes and their blending with the teachings from the Old and the New Testament in shaping ethical behavior within the medical profession in the West.

While I am not a man of religion, I want to introduce the audience to the more ancient and universal concept of Dharma. This concept often enables me as a physician to arrive at the same conclusions from the standpoint of Ethics as the home grown Westerner. However, equally often it allows me a fresh breath of air in the midst of an ethical dilemma where sometimes I might find my colleagues stuck.

In this talk I share simple illustrations of these concepts and how they may be applied in daily medical practice to enhance professionalism.

### **The Social and Ethical Aspects of Fertility Preservation**

Robert Rebar

Department of Obstetrics and Gynecology

Western Michigan University, Homer Stryker M.D. School of Medicine

The first birth following in vitro fertilization (IVF) and embryo transfer was less than 40 years ago. Yet since that time the potential uses for this technology have increased to the point that as many as 4% of all births in developed countries occur as a result of IVF. We now have the ability to store spermatozoa, oocytes, embryos, and even testicular and ovarian tissue in the frozen state for future use as a part of IVF with varying degrees of success. Although these technologies were originally developed for infertile couples, it quickly became apparent that such technologies could be marketed to single individuals wishing to build families, to individuals with fertility ending diseases, and to young women who might wish to "guarantee" their future fertility and who were not yet ready to begin a family. In fact, companies such as Facebook and Apple have indicated that they will pay for younger women in their employ to cryopreserve gametes so that they can delay childbearing.

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These capabilities, this marketing, and these offers raise a host of ethical issues that are stirring debate both among the public and among professionals in the field. Despite the widespread publicity, very few programs have the capability of providing fertility preservation services that have a reasonable likelihood of ending in a pregnancy, a fact not widely appreciated by the public. Thus, we must consider just who is ethically qualified to offer such services. Are programs with little or no experience deluding themselves and their patients about their ability to provide reasonable services? Should there be minimum standards and experience before services for fertility preservation can be offered? As a corollary, should we arrange for patients who might benefit from fertility preservation to travel to the best clinics and sites at which to undergo these procedures? If the programs with these capabilities are limited, should we permit women who wish to preserve their gametes for “social” or age-related reasons to do so at the risk of having insufficient resources for individuals with life-threatening illnesses that need fertility preservation? Do we have an obligation to provide services for fertility preservation to all individuals with diseases such as cancer who will need treatments with a reasonable likelihood of diminishing future fertility? Or should such services be provided only to those who have the ability to pay for such services by themselves, without benefit of insurance coverage? Just what does social justice require? Given the limited numbers of births following fertility preservation worldwide, and the relatively low chances of success at this time, are we providing unreasonably optimistic expectations for patients?

If and when the technology improves and becomes more widely available, there still will be other ethical issues to consider. How do we make decisions about fertility preservation for children with serious but potentially treatable disorders (such as leukemias and lymphomas)? How should preserved gametes and gonadal tissue be handled after the death of the individual from whom they originated? How do we ensure that company-sponsored fertility preservation is not exploitive? Will the widespread availability of fertility preservation services increase women’s reproductive autonomy or merely lead to new and different pressures and ethical dilemmas?

These issues will be addressed, but certainly not definitively answered, in this presentation. Fertility preservation heralds a “brave new world” that demands discussion and scrutiny.

### **Development of a Psychological Framework for Patients with Chronic Pain and Depression and Its Impact on Ethically Appropriate Treatment**

Michael Redinger

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The psychological treatment of patients with chronic pain and depression has been under examined, despite their frequent co-occurrence in primary care and psychiatric settings and multiple challenges to the provision of quality care. It is common for physicians and other health care providers to encounter patients who present with severe depression and/or suicidal ideation triggered by the frustration, and, ultimately, the despair associated with severe, unrelenting, treatment-resistant chronic pain. These patients often display challenging behaviors that can frustrate and even demoralize their health care team and are often exacerbated by provider awareness that the common treatment modalities have significantly contributed to an epidemic of iatrogenic opioid addiction. This combination of factors frequently disrupts the ability to form and maintain a constructive physician-

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patient relationship, which is the foundation for ethical medical care and can, in turn, further exacerbate the patient's presenting complaints.

The ethical provision of quality care for patients with chronic pain and comorbid depression would likely be benefitted by a psychological framework which acknowledges and explains the challenging nature of working with these patients. This paper proposes such a construct utilizing the work of bioethicist Carl Elliott, who argues that the secular perspective on medical care in the West elevates the power of the medical sciences to deity-like status. Yet, when treatments are generally lacking, as in the case of chronic pain, providers inevitably find themselves incapable of meeting the expectations that patients' desire. I argue that when this occurs, patients may undergo an existential suffering analogous to a "crisis of faith" which can trigger the "difficult" behaviors that providers struggle to manage. However, knowledge of this construct may help providers better understand the psychological turmoil experienced by chronic pain patients and supply a robust platform upon which a mental health provider could base psychotherapy. As a result, proper utilization would help decrease the likelihood of rupture in the physician-patient relationship and result in higher quality and more ethical care.

### **Sleepless Nights: The Consults that Continue to Haunt**

Michael Redinger

Program in Medical Ethics, Humanities & Law  
Western Michigan University Homer Stryker M.D. School of Medicine

Stephen Jefferson

General Pulmonary Medicine and Critical Care Medicine, Borgess Medical Center

Robert Beck

Pediatric Intensive Care, Bronson Methodist Hospital

Chair: Tyler Gibb

Program in Medical Ethics, Humanities & Law  
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**Panel summary:** Over the course of their careers, Clinical Ethicists often see similar types of cases, or cases with similar themes—identifying surrogate decision-makers, end-of-life decision-making, navigating withholding/withdrawing inappropriate medical treatment, etc. These cases can become somewhat routine and unmemorable. However, during a career, Ethicists generally experience a handful of cases that are different. The reasons why any particular case sticks in the mind may vary. Sometimes appropriate, well-considered ethical recommendations are ignored. Sometimes the ethical analysis required by a case is uniquely nuanced or novel. Sometimes the emotions of a patient, the family, members of the healthcare team, or even the ethicist, are particularly poignant. These cases can cause significant emotional anguish, disquiet, may prompt introspection, reflection, and, possibly, a change in consultation practice, and, even years afterwards, these cases continue to haunt clinical ethicists.

This panel, comprised of individuals who collectively have been engaged in clinical ethics consultations for many years, will each present one case that continues to haunt him or her. By confronting, discussing, and analyzing these difficult cases, this panel will offer reflections on difficult

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cases and offer insights for the training of other healthcare professionals who have or will experience their own particularly troubling cases. This panel will also allow for significant question/answer time for audience discussion of additional cases.

**The Ableist Conflation:  
Empirical Folly, Inductive Risk, and Disability Bioethics**

Joel Michael Reynolds  
Department of Philosophy, Emory University

In a 2015 article in the *Boston Globe*, Stephen Pinker argues, “even a one-year delay in implementing an effective treatment could spell death, suffering, or disability for millions of people.” Despite the growing number of bioethicists that address or engage disability critiques of bioethical positions, the ableist conflation of disability with pain, suffering, and death continues. In this paper, I argue that this conflation commits four errors—empirical, epistemic, conceptual, and ontological in nature—and I explain how these errors bear on applied debates ranging from selection criteria for IVF PGD to death with dignity.

The first error is empirical: much social scientific literature attests to the flourishing of lives lived with disability. Furthermore, longitudinal studies in psychology on psycho-social adjustment suggest that attitudes of able-bodied people towards disability are misguided. Upon receiving a life-altering diagnosis or suddenly becoming disabled, a combination of ableist expectations and catastrophizing leads subjects to be depressed for the first six months and up to a year or two. After this time period, however, new normals are created and people typically report that they are flourishing, even if in a very different way from before.

The second error is epistemic: because the relation between a given form of embodiment and the flourishing it will experience is largely unknowable, judgments over quality of life pose great inductive risk, i.e., the epistemic and non-epistemic risks of being wrong. While selection for or against race or gender are widely condemned, there is no widespread consensus that it is ethically wrong to select against Down syndrome, e.g. This is despite no evidence to suggest that people with Down syndrome *necessarily* live less flourishing lives, which renders judgments over it to have high inductive risk. The third error is conceptual: disability studies scholars distinguish between impairment and disability, healthy vs. unhealthy disability, and visible vs. invisible disability, among other designations. Much of the disability stigma latent in bioethical discourse trades on this lack of knowledge about and conceptual imprecision concerning various forms of disability.

The fourth error is ontological: if disability is understood as any state outside of the healthy able-body, we all experience disability in infancy, via injury and illness, and, if we live long enough, aging. On such a definition, disability is an ontological fact about the course of life of the human organism. Yet, given the ADA, disability is also a legally protected *minority* in the United States of America. Also, many of its forms are distinct *cultures*, as with Deaf culture or some who identify as Neurodiverse. Conflating disability with pain, suffering, or death ignores the different meanings of disability and the multiple ontological registers on which it operates. In doing so, the ableist conflation

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hinders bioethical debates by promoting empirical folly, indefensible inductive risk, conceptual confusion, and ontological oversight. It perpetuates the historical denigration of disability and exacerbates genuine issues of uncertainty with respect to disability and bioethical concerns.

**PARADIGM SHIFT: How the Opioid Epidemic is Driving Change in Perception, Treatment & the Law**

Lauren Rousseau

Western Michigan University Cooley Law School

In December 2015, the federal Center for Disease Control released new numbers concerning drug poisoning fatalities in the United States. Drug overdose deaths have again surged, from 43,982 in 2013 to 47,055 last year, which means that every day, nearly 129 people die from drug overdose. Drug overdose deaths have almost tripled since 1999, and more than half of the 2014 overdose fatalities were due to opioid medications and heroin.

This presentation explores the reasons behind our nation's current drug epidemic, as well as how that epidemic is driving change in policy, addiction treatment, and the law. One driver of the exponential increase in opioid and heroin use has been the systematic overprescribing of opioid medications by physicians during the past decade. The Substance Abuse & Mental Health Services Administration recently reported that four out of five heroin users begin with abuse of prescription opioid medications.

Historically, our country has viewed addiction as a moral failing warranting criminal sanctions, rather than as a health issue requiring treatment. This is true despite the fact that the medical community has recognized addiction as a brain disease for decades. Until recently, our approach to drug abuse and addiction has centered on criminalization and incarceration. Over 50% of those incarcerated in our federal prisons are there due to drug-related offenses, yet for the most part, our jails and prisons do not offer addiction treatment. Moreover, the criminal record a person carries upon release from prison creates barriers to recovery from addiction.

The current drug epidemic is driving public policy and perception away from the "addiction as moral failing" paradigm, and towards an "addiction as disease warranting treatment" paradigm. This shift in thinking is demonstrated in many ways, including by the increased availability of health insurance coverage for addiction treatment, increased access to medications that reverse drug overdose and help stabilize recovery, and changes within the criminal justice system to direct persons struggling with addictions to treatment rather than jail.

A number of ethical issues are raised by some of these changes. For example, to what extent might the availability of medications that reverse drug overdose and changes in the criminal justice system encourage continued drug use? To what extent might medication-assisted treatments actually perpetuate addiction, rather than support recovery?

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In addition to the above issues, two controversial ideas that have been less widely embraced deserve mention – needle exchanges and safe injection sites, both of which focus on harm reduction rather than treatment. Lastly, Portugal’s approach to its own addiction crisis is instructive. In 2001, Portugal decriminalized all drug use and possession, and focused its resources on addiction treatment, with encouraging results.

Addiction has become a public health crisis in this country that can no longer be ignored. Solving the problem requires a paradigm shift in perception, treatment, and the law, driven by recognition that addiction is a disease, and not a crime.

### **This Medication May Kill You: Cognitive Overload and Mandated Informed Consent**

Devin Schindler and Tracey Brame  
Western Michigan University Cooley Law School

The Federal Government requires pharmaceutical manufacturers to provide prospective customers with an extraordinary amount of information. Justified under the doctrine of informed consent, the Food and Drug Administration has imposed comprehensive guidelines that regulate virtually every aspect of how medications can be marketed. Similar obligations are imposed on physicians involved in biomedical research.

Although informed consent is a cornerstone to the ethical practice of medicine, recent studies employing fMRI technology suggest that mandated disclosure of “too much” information can result in cognitive overload and irrational decision making. The paradoxical effect of the mandated disclosure requirements is that they likely lead to patients choosing to not take beneficial medications. This paradoxical effect arises from three well-studied psychological phenomena: (1) “Recency-Primacy, (2) “Satisficing” and “Probability Neglect.” The combination of these three effects in patients who have been inundated with excessive information results in decision making based on anecdote and emotion, instead of logic. Studies also suggest that most people are extraordinarily bad in assessing risk, particularly when an activity poses an infinitesimal but highly consequential risk. In plain language, people overreact to miniscule risk. Hence, when the government requires pharmaceutical manufacturers to disclose in advertisements such risks, the effect is for patients to err on the wrong side; i.e. not taking medication that could provide great benefit.

Government-mandated messages also raise serious First Amendment concerns. Government action that compels physicians and pharmaceutical companies to convey mandated messages sits at the crossroads of two divergent legal doctrines. Compelled speech of “political” messages are strongly disfavored under the First Amendment. Regulation of commercial speech, however, is generally subject to a lower level of scrutiny. These two doctrines, one focused on laws compelling speech and the other on laws which restrict speech, conflict in situations where the government imposes informed consent requirements which are contrary to the speaker’s favored message.

This multidisciplinary study combines case law, the philosophical underpinnings of the First Amendment, political theory, and emerging research into how the brain organizes and manages information to come to the conclusion that many of the rules imposed by the government to insure informed consent are counterproductive and likely unconstitutional.

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This presentation is adopted from an article previously published by the authors in the *Whittier Law Review* entitled “This Medication may Kill You: Cognitive Overload and Forced Commercial Speech,” 35 *Whittier Law Review* 1.

**Anticipating Future Effects:  
The Role of the Doctrine of Double Effect in Medical Care and Research**

“The Doctrine of Double Effect in End-of-Life Decisions,”

Adam Shatsky

Department of Philosophy, Kent State University

“Research on Children, Placebos, and the Doctrine of Double Effect,”

Jeffrey Byrnes

Department of Philosophy, Grand Valley State University

**Panel summary:** When faced with an unknown future, physicians, researchers, and regulatory bodies are often ethically compelled to reconcile their intentions with a variety of anticipated consequences and numerous possibilities. This is familiar territory to the ethicist acquainted with the Doctrine of Double Effect. Philippa Foot (1967) introduced what is typically regarded as the most influential version of the Doctrine of Double Effect (DDE). As she writes, “By DDE I mean the thesis that it is sometimes permissible to bring about by oblique intentions what one may not directly intend.” Foot’s intention was to bring to fore the moral distinctions between intended and unintended consequences, and between positive and negative duties—that is, the duty to render aid weighed against the duty not to inflict harm.

The implications of Foot’s work sparked a debate not only in moral psychology, but also in applied philosophy, particularly in healthcare ethics. Those who invoke some variant of DDE (in the medical field) raise interesting questions as to both the nature of physician-patient relationships and the relation of researcher to subject. As we shall discuss, these questions seem to arise because who invoke DDE often do so from a very specific picture of what those relationships should be. Our papers examine the occurrence of DDE in clinical, specifically palliative, care and in medical research, offering a critique to each. In so doing, we recognize the explanatory power of DDE, but are suspicious of its normative value in matters of health care.

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### **The Google of Personalized Healthcare: 23andMe and Enabling the Privatization of Genetic Biobanking**

Kayte Spector-Bagdady

Center for Bioethics and Social Sciences in Medicine, University of Michigan

23andMe is back on the market as the first direct-to-consumer genetic testing company that “includes reports that meet [Food and Drug Administration] FDA standards for being clinically and scientifically valid.” Its current product includes 36 health-related carrier-status reports and consumers’ raw genetic data (in addition to ancestry and other non-medical information). Forbes reports recent investors estimate its value at \$1.1 billion. But that valuation is not on the basis of 23andMe’s \$200 test kits. While its frontend product is selling individual genetic tests online, its back-end business model is amassing one of the largest privately owned genetic databases in the world. 23andMe offers an inexpensive product to consumers (personalized genetic analysis) to generate broader consumer data, and then leverages that data to generate profit becoming—as board member Patrick Chung put it—“the Google of personalized health care.” And it recently surpassed its goal of 1 million consumers. While the focus of the debate surrounding direct-to-consumer genetic testing has been on whether FDA regulation is necessary to protect consumers receiving potentially sensitive medical information without a physician intermediary, the more important question moving forward will be how to regulate use of consumer data.

Private control over genetic databanks has important implications for public health and genetic epidemiology. While some argue that commercial interest and funding is critical to encourage innovation of therapies, others point out that it is only through open access that researchers can work with the breadth of data needed to make advancements in the field—as well as verify the results of others’ research. Genetic epidemiology can contribute to preventative public health measures by, for example, isolating environmental versus genetic risk factors. But access to a large dataset is required to do this research, with some hypothesizing that a cohort would need at least 500,000 participants. Research of isolated families at risk for genetic disease has met with less success than largescale genome-wide association studies that require data across a large population. President Obama’s new Precision Medicine Initiative biobank is founded on the concept of the centralization of already existing research and data. While the goal of the Precision Medicine initiative is individualized clinical care, the process requires public health research and analysis. But the privatization of a large cohort of genetic data tied with epidemiological factors can stagnate the advancement of such research and possibly the field of personalized medicine itself.

As HHS revises our decades-old human subjects research structure, it is necessary to consider a cohesive approach to regulating private genetic databanks. This strategy should allow FDA and other department agencies to play a role in expanding current regulatory coverage. Approaching data- and bio-banks as assets that are as vulnerable and valuable as the individual datum that creates them will be critical, as we increasingly rely on their use, to both ensuring that federal funding continues to be the gold-standard research resource and that as much research is covered by federal protection as possible.



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**Ethical Communication in Human-Subjects Research:  
Creating an Informed Consent That Effectively Communicates Risk and Promotes Personal Autonomy**

Chris Trudeau  
Western Michigan University Cooley Law School

One of the main purposes of the Federal regulations regarding human-subjects research and the recently released Notice of Proposed Rulemaking (NPRM) that seeks to update these Federal regulations is to enhance the protection for those individuals who contribute their time and assume risk to advance the research enterprise, which benefits society at large. As such, the primary goal of human-subjects research is not to aid the specific person treated – it is to advance scientific research for society’s gain, not the specific individual’s (as the NPRM, itself, suggests). Because individual participant interests aren’t the primary focus of research trials, there are unique ethical implications that researchers and their legal counsel must consider regarding the method and manner in which they communicate with these participants. In fact, one of the goals of the NPRM is to “increase human subjects’ ability and opportunity to make informed decisions . . . .”

This session will address two of the challenges of communicating the required disclosures under the current and proposed federal regulations – the method and manner of presenting the 15-18 disclosures to research participants. Specifically, this paper will propose regulating the informed consent process – rather than just the form – and it will discuss creating a functional risk hierarchy of the mandated disclosures under Federal law. In the end, these two changes should dramatically improve participant understanding of the risks and benefits of engaging in a research trial.

**Ethical Omission and Aspect-Blindness**

William Vaughan  
Department of Philosophy, Ashland University

The theme of this conference is *Bioethics: Preparing for the Unknown*. Yet the title confronts us with the age-old problem of how is it possible to prepare for something about which little is known. This paper seeks to explore some of the deepest unknowns in medical ethics, the issues of *ethical omission* and *aspect blindness*. The problem of ethical omission is in regard to how to classify the morality of non-actions, or the omission of acts. The problem of aspect-blindness is when people (in medical contexts) seemingly lose, or have revealed to be totally lacking in, their most basic ethical concepts, such as in the recognition of another human being in affliction. The paper tries to make sense of these circumstances.

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### **Minors and Health Care**

Hollian Willekes

Western Michigan University Cooley Law School

This paper gives an overview of what minors' rights are when it comes to their health care and treatment. Additionally it details several unique ethical and legal situations that providers may face when treating minors.

Michigan recognizes the common-law right to be free from non-consensual physical invasions and the doctrine of informed consent and its corollary, the right not to consent. In the case of minors, who are generally considered legally incompetent to consent to medical treatment, parents generally have the right to consent to medical treatment or refuse medical treatment for their children. There are situations, however, when parents might not have an absolute right to consent to care for their child, and health care providers are confronted with the question of what to do. Sometimes what the parent wants for their child is not in their child's best interest. At other times the minor may be allowed to consent to a specific treatment without parental consent, or even without parental knowledge of the treatment. Adolescents in particular have several exceptions to the general law that parental consent is necessary for medical treatment to minors. Providers routinely face legal and ethical issue which may interfere with the provider's ability to deliver care to a minor patient.

Sections of this paper include parental rights, non-parent decision makers, minor consent laws, and access and disclosure of medical information and medical records. The importance of gaining parental consent, while at the same time ensuring minors' rights and wellbeing, is discussed in the context of health care situations that providers often find themselves in.

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### **BCIs and Robotics: An Anticipatory Ethical Analysis**

Richard Wilson

Department of Philosophy, Loyola University Maryland

Robotics research is merging with the latest medical technology to create a new generation of prosthetic feet, legs, hands, and arms to give users a more natural feel and capability. Developments began with comparatively simple microchip-controlled actions, then processors that translate muscle movements into prosthetic responses and clinical trials on controlling prosthetic movements through computer-interpreted brain waves. As these developments push the human-mechanical interface further along, the ultimate result-one seen as achievable, at least in part, during this decade-is a form of symbiosis. "In some discussions with the international standard-setting body for prosthetics, there is talk of no longer speaking of prosthetic arms but of wearable robotic devices because today's prosthetics are increasingly more robotic," says Dr. Robert Jaeger, director of deployment health research in the Veterans Health Administration (VHA) Office of Research & Development. "The biggest breakthrough for arms is the brain-computer interface. The dream of upper extremity prosthetic researchers is acquiring signals directly from that part of the brain that controls the arm and processing those with a computer, so the person using the arm doesn't have to do a lot of conscious movements. Instead, the prosthetic reacts to them simply thinking about a movement. It's still a long way off, but there could be a breakthrough at any time and certainly is an area the VA, the U.S. Department of Defense (DOD) and NIH are looking at for potential breakthroughs"

This analysis will focus on the current state of prosthetics, BCI's (Brain Computer Interfaces) and robotics for members of the military and members of society while performing an anticipatory ethical analysis of expected developments in the same areas.