

RUTGERS

# Journal of Bioethics

Vol. 4 Issue 1



**THE ORGAN DONATION  
PROBLEM**

**Gene Patenting**

**NEUROSCIENCE AND SPIRITUALITY - BIOETHICS EDUCATION**

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## The Bioethics Society Mission Statement:

As members of the Bioethics Society of Rutgers University, we hope to raise general awareness of bioethical issues through discussion and publications created by its members. Although the beliefs and opinions regarding bioethical issues of this group are not unanimous, we are united by our ardent belief that Rutgers students should understand the implications of biological research, medicine, and other topics of bioethical controversy. We thus provide a forum for the Rutgers community to debate and get informed about these issues.

# Acknowledgements

We would like to acknowledge the following Rutgers University Organizations for sponsoring the Rutgers Journal of Bioethics:



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# Letter From the Editor

In last years issue, in her address to readers, former Editor-in-Chief Maryanne Murtagh referenced the frenzy over the 'impending', 'Mayan-predicted', December 21<sup>st</sup>, 2012 doomsday. Unfortunately, on that day there was only a smattering of showers, meaning in the coming years we will be forced to debate, hash out, deliberate, deal with and eventually decide upon how to approach the multitudes of bioethical issues currently facing the world. It's an enormous task (endless actually) and it will get very technical and very serious. However, as anyone who has ever been to a Bioethics meeting at Rutgers University can tell you, if met with passion and imagination, contemplating and debating bioethical issues isn't all that bad. It can be fascinating. It can be rewarding. It can even be fun. (Endless task = Endless fun) Our goal for the fourth publication of the Rutgers Bioethics Journal is to convince a few more people to regularly incorporate bioethical discussion into their lives. It's these discussions that will shape the boundaries and capabilities of science and medicine in the years to come.

This year we brought back two sections from previous issues, RU Speak Up and Bioethics Across Borders, in order to encompass more topics and points of view into the journal. The two sections consist of blurbs written by Rutgers students and the journal staff highlighting and responding to different bioethical controversies/news around the world. Typically, the topics are unrelated to our full-length articles. However, this year in the creation of the RU Speak Up section, an incredible thing happened: one of our club members, Boluwarin Adunbarin, decided that instead of writing the requested 100 word response to the prompt about the legal policies surrounding and ethical implications of organ sale, he wanted to write a full-length article. Because of this interest in the topic, we found it would be a great idea to dedicate a portion of this year's journal to the ethical controversies surrounding organ donation. Along with Boluwarin's article, we cover the topic in the RU speak up and Bioethics Across Borders sections, and feature an article written by Karlene Chi, a senior at William Paterson University, about the state of organ donation in The United Kingdom. The other articles cover the implications of gene patenting with regards to the diagnosis of genetic diseases, the use of neurophysiology to describe religious experience and the current state of bioethics education.

I would like to thank all of our authors, Sarah Mayes, Timur Shah, Boluwarin Abundarin, Karlene Chi, Zach Davidson, Dheeraj Duggineni, and The Bioethics Society at Ohio State, for all the work they put into their research and writing. This is their journal. I would also like to thank my journal staff for their dedication, the bioethics club for continual inspiration, the RU Speak Up writers for their contribution, our faculty mentors for their guidance, RUSA allocations for money and our publisher, Michael Aslett, for his enthusiastic involvement with this project.

Sincerely,



Editor-in-Chief of the RJB  
Major: Genetics---Minor: Spanish

# Letter From the President

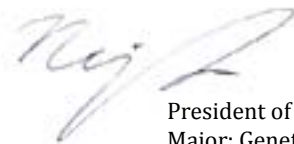
I very often refer to the Bioethics Society as a toddler organization in the sense that we have only existed as an organization for four years. As a freshman, I had the pleasure of joining right when it started. I was at the Fall Involvement Fair actually looking for the Breakdancing Club when the Bioethics Society founders, Ami Amin and Nate Jones, stepped in front of me. While I wasn't initially interested, I respectfully listened to them describe the club and took an information brochure about their next meeting. I decided to go to the first general interest meeting the following week and was absolutely blown away. The meeting was beyond interesting and immediately I felt connected to all of the members there. The questions were so provocative and the hypothetical situations so intricate that I couldn't believe the entire meeting had been planned by students! I fell in love with the club and with Bioethics ever since.

I am very proud to have been honored with the position of President in my senior year. Certainly, it is a great way for me to end my collegiate career. It has been my goal ever since that first meeting freshman year to let more people know about the enjoyment and the knowledge available to them through this organization. This journal that we publish annually has certainly helped that. Through it, we have been able to collect and share opinions of undergraduates, graduate students, and professors, both within Rutgers University and even internationally. Further, we have worked tirelessly to have multiple co-sponsored meetings with other organizations on campus to demonstrate how bioethics can tie into nearly every subject. We teamed up with the American Medical Student Association (AMSA) to discuss the bioethical implications of the health care reform back during the election season and we plan also to lead two breakout sessions at their annual conference this year. We worked with the SAS Honors Program in inviting Rebecca Skloot, author of *The Immortal Life of Henrietta Lacks*, to come speak at the university. The Association of Undergraduate Geneticists, the Phi Delta Chi Pharmacy Fraternity, and the Student Society for Stem Cell Research are just a few of the organizations we are currently planning joint meetings with for the upcoming semester. Even aside from our work with other groups, we have planned quite a few interesting sessions of our own, with topics ranging from cultural bioethics to surrogacy to overmedicated children. In the background, we are working to establish an academic minor in Bioethics at Rutgers University.

But to me, enhancing our school internally was analogous to thinking, but not speaking. I felt the need to take a step farther, to project our success, share our experiences, and learn from others not only outside of the school, but outside of the state. We were fortunate enough to link up with Dr. Eric Singer of Robert Wood Johnson University Hospital who has allowed our board members to sit in on actual ethics committee meetings to learn about applied and practical bioethics. We will be competing this year again at the National Undergraduate Bioethics Conference (NUBC) at Georgetown University in the bioethics debate competition where we hope to place even higher than we did the last time we competed, debating against schools from all over the country. Our largest event, the annual Bioethics Symposium, is being finalized with us expecting to invite double the number of organizations that we partnered with last year, experts in the field and academic groups from universities in the area.

To everyone that has helped made this year our most successful year yet, thank you. I hope our group discussions and events have inspired people to question all aspects of a situation, especially in our time of exponentially advancing technology, medicine, education, and innovation.

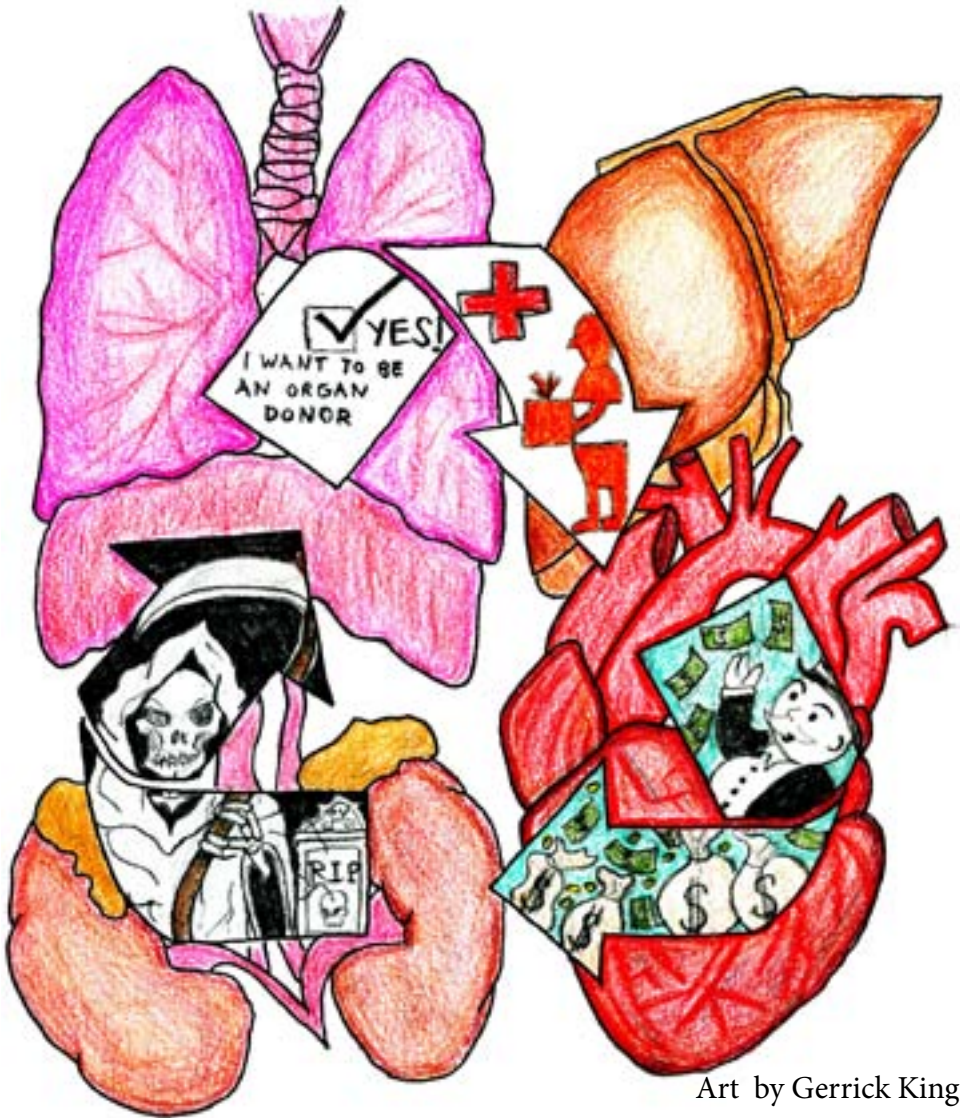
Sincerely,



President of the Rutgers Bioethics Society  
Major: Genetics---Minors: Astronomy, Psychology

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Art by Gerrick King

## In this Issue:

The topic for our journal this year is organ donation. It is an issue that brings into light the limits on human dignity and life that exists within our society and our world. We encourage you to think deeply on the following question: What value does a life hold?

*Life from death. Sacrifice. The Waiting List. Organ shortage. Incentive. Black Market. Social inequality. Priority and bias. Consent.*

# An Appeal on Behalf of Bioethics The Formalization of an Informal Field: The Role of Bioethics in Undergraduate Educa- tion

Dheeraj Duggineni, Zach Davidson, and The Bioethics Society at Ohio



Bioethics

## ABSTRACT

As bioethical issues and debate become increasingly relevant, students often find that the lack of formalized education in the field of bioethics can be hindering. Although there are a handful of universities that are creating robust programs to educate students in the field, there are too few to make this a significant trend. Bioethics organizations often act as informal surrogates for an area that desperately needs formal education.



### THE PROBLEM

Upon graduation, many undergraduate students are discovering that bioethics plays an integral role in their professions, signifying an increasing need for bioethics education at the undergraduate level. Yet, because universities have been slow to adapt their curriculum to reflect this growing need, these graduates are finding they lack the bioethical knowledge and experience to face these issues. Currently, most universities lack the formal educational system to equip their students with these necessary mental tools, leaving this challenge to be tackled by student organizations. While student organizations make a valiant attempt to meet this challenge, students will not receive the bioethical education they need until universities address it in a formal matter.

At the moment, student bioethics societies exist at universities across the country, not limited to but including: The University of Pennsylvania, Cornell University, Johns Hopkins University, The Ohio State University, and Rutgers University. These groups provide an open forum for students to discuss and debate core issues, encouraging personal growth and developing critical thinking skills. Complex and controversial

discussion topics such as abortion, palliative care, and tissue engineering require more than a linear perspective. Political, economic, social, and practical elements need to be accounted for in order to create a more holistic understanding of these issues. At Ohio State, a recent group discussion on abortion allowed for avenues of debate that included the economic burdens from an unwanted child, the rights of the father, and the socioeconomic consequences of abortion. Such meetings, ethical debates, and discussions create an environment that promotes holistic understanding and subsequently fosters the aforementioned personal growth and development of critical thinking skills.

As it turns out, many students that would benefit from these conversations never end up participating in them and are often even unaware that these groups exist. Young adulthood is a critical period when students are imparted with core principles and reasoning skills that they refer to and employ throughout their lives. Thus, the failure of universities to impart these fundamentals is a disservice.

It has been confirmed that bioethics education increases students' understanding of the connection between science

and society, ability to listen to different viewpoints, and ability to analyze and make well-justified decisions about issues related to science and society<sup>1</sup>. In a Washington study that investigated these abilities, students that participated in a 5-lesson Bioethics 101 unit earned significantly higher ( $p < 0.001$ ) composite mean scores on exams assessing these factors than students in comparison classrooms. The Bioethics 101 unit group received a 10.73/20 mean test score, while the comparison group received a mean score of 9.16/20. Overall, students that had taken the Bioethics 101 unit showed improvement between a pre-test and post-test assessing their skills in the aforementioned areas, while comparison groups showed little to no change<sup>2</sup>. In an academic climate where it is not only accepted but expected that university graduates have a suitable understanding of these principles, all future graduates would be better equipped to handle real-world ethical issues, both in their professions and in their lives as a whole.

Some readers may contest that reasoning skills are present in other university classes. Math, science, philosophy, and related courses consist of curricula that are grounded in problem solving and the dis-

cussion of complex ideas. Certain reasoning skills are generally introduced and developed in these courses. However, bioethics provides a mode for practical application of such skills that involve real world topics that the student could potentially encounter. It doesn't matter how successful one is at solving calculus problems or interpreting genetic pedigrees if the student can't apply that knowledge to actual issues that they will face in their professional lives. Bioethical skills are practical. A comprehensive understanding of palliative care will allow a doctor to better conduct a conversation with her patient with terminal cancer. A lawyer who began contemplating morality in his undergraduate days will arguably be able to speak on his client's behalf with a better perspective. These skills are not limited to medical or legal fields, and can extend to other professions such as business and academia. Entering any of these fields is difficult, and many of the careers that motivated undergraduate students seek out generally require an upper-level degree. Studying bioethics builds the high level of ethical and reasoning skills required for such degrees and allows students to have the ability to enter these fields and be successful in them. It is through

practical skill development that bioethics stands apart from other university courses.

Any student of Bioethics can recognize that the subject is grounded in multiple disciplines, ranging from the philosophical to the scientific. Arguably, bioethics has become a natural intersection of the leading edges of medicine, law, and business. In medicine, this interdisciplinary effect can be seen as remarkably clear in the restructuring of the MCAT exam, the standardized exam for prospective medical students. In 2015, the current MCAT exam, focusing primarily on physical and biological sciences, verbal reasoning, and writing will change to accommodate new sections. These new sections will cover psychology, sociology, and critical reasoning (including philosophy, cultural studies, and ethics). In reference to why the MCAT is changing, the Association of American Medical Colleges (responsible for developing and administering the exam) responded, "Science advances rapidly, the health care system is transforming in big ways, our population is becoming more diverse every day and tomorrow's doctors need to be prepared."<sup>3</sup> The importance of an interdisciplinary foundation for our future doctors is prefaced and

underscored by the entry exam into the field of medical practice. If there was a clear-cut case for the importance of a holistic bioethical understanding in health, it is the future MCAT exam that the next generation of physicians will be required to take.

Considering other pre-professional exams, such as the LSAT and GRE, it is evident that an education with bioethics components would be significantly beneficial for students considering pre-law, business, or graduate school routes. The LSAT, the standardized exam for hopeful legal students, consists of sections measuring reading comprehension, analytical reasoning, and logical reasoning questions.<sup>4</sup> The GRE, which is required for prospective business and graduate school applicants, consists of verbal reasoning, quantitative reasoning, and analytical writing sections.<sup>5</sup> Complex issues and articles are analyzed in bioethics, and analytical reasoning skills are developed in discussion and debate of these topics. Therefore, a bioethics education would be excellent preparation for these career paths in addition to medicine.

#### MOVING FORWARD

The primary reason that students

are unable to receive in-depth bioethics education is because of a lack of any formalized institutional backing on behalf of academic universities. Student organizations may informally provide critical thinking development and opportunities for related enrichment, however there is no set of standards in these organizations and no set of learning objectives to ensure appropriate development is occurring. One solution that universities are employing to address this issue are formalized academic minors. While not mandatory for students in related bioethical fields, a bioethics minor presents an opportunity to increase exposure to bioethical issues and promote development. Johns Hopkins University and Georgetown University have formed bioethics minors that have been available to students for years. Yet even universities without John Hopkins' storied medical history or Georgetown University's deeply-rooted ethics foundation are starting to take initiative by creating bioethics minors of their own.

Other universities with undergraduate minors in bioethics include: the University of Rochester, the University of Washington, Cedarville University, Loyola University, the University of Akron, and

the University of Virginia. Most recently, Pennsylvania State University announced its minor in Bioethics and Medical Humanities in early 2012. The minor is based out of an intercollege program grounded in the Rock Ethics Institute and the College of Liberal Arts at Penn State. Currently, a bioethics minor is in-development at The Ohio State University, with collaboration between the Center for Ethics and Human Values, the Center for Life Sciences and numerous departments across the university.

While the bioethics exposure from a minor is a promising step in formalizing bioethics education, it is far from complete. For one, this minor is absent at most universities in the United States and even fewer provide majors in the field. Additionally, minors are optional for undergraduate students, and for students pursuing a career in a field where bioethical issues are constantly at stake, developing a firm ethical foundation should hardly be an elective decision. So what steps should universities take to solve this problem? Ultimately, it is short-term solutions that will encourage long-term institutional support. It begins with creating a larger bioethics presence on university campuses. This semester at Ohio State, the

campus bioethics organization, The Bioethics Society, is leading a joint student-faculty panel on the ethical implications of tissue engineering regarding the freshman reading book, The Immortal Life of Henrietta Lacks. The group also puts on an annual keynote lecture, which is attended by the CEO of The Wexner Medical Center at Ohio State, the dean of the medical school, multiple members of Ohio State faculty and administration, and large numbers of undergraduate students. These events serve to promote the visibility of bioethics at Ohio State.

Once universities recognize the importance of bioethics, truly integrating bioethics into undergraduate education will be possible. The eventual incorporation of bioethics core classes into related majors and providing access to educational resources, growing faculty involvement and mentorship, and increasing funding to bioethics programs will allow universities to succeed in truly arming their graduates to face the ethical dilemmas that they will encounter in their future fields.

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## Gene Patenting: Effects on Genetic Disease Diagnosis

Sarah Mayes  
University of Virginia

### ABSTRACT

Scientists have identified particular gene sequences that dictate certain genetic disorders and have developed many tests that can identify genetic evidence of diseases. However, an urgency to gain possession of such telltale sequences has pushed gene patenting past the point of both philosophical and practical acceptability. The universality and natural development of genes prevents genetic sequences from satisfying the criteria for patentable commodities. Gene patents also allow for a dangerous centralization of power over life and death situations within biotechnology companies. Finally, gene patents create a financial and procedural block that impedes genetic testing. The current system of genetic patenting presents an unacceptable impediment to genetic disease diagnosis. Implementing a new, practical system that does not infringe on the accessibility of genetic disease testing—and also promotes both expediency in testing and the continuation of genetic research and development—is extremely pressing.

## INTRODUCTION

Genetic counselors frequently order DNA testing that will either confirm or deny their hypotheses concerning patients who are suspected of having certain genetic disorders. Genetic testing is useful beyond diagnosis of genetic diseases because it can also specify which type of a certain disease a person displays. This testing can be useful in deciding what treatments would be appropriate to pursue. Such tests often entail extracting DNA from the patient and sequencing it. Certain probes such as expressed sequence tags (EST) and single nucleotide polymorphisms (SNP) are often used to identify and subsequently sequence genes. However, patents on experimental techniques, genes, and probes create a technical snare that scientists must navigate in order to perform certain tests. This sort of “red tape” not only heightens the legal risk of performing genetic testing, but also creates excessive expenses for the laboratory. Patents also greatly increase the amount of time required for a patient to receive the results of his testing, which could potentially have life and death ramifications for the patient, depending on the disease and the urgency of treatment.

In this age of scientific innovation, knowledge of the human genome is increasing exponentially. With this vast expansion of information comes a responsibility to practically apply it in order to better people’s lives. The mapping of the human genome has opened up a world of possibilities, including the opportunity to locate the biochemical basis for many diseases that affect the world population. Gene therapies, along with many other treatments, can ease or eliminate the effects of certain genetic diseases. In many cases, genetic testing is necessary to identify either the presence of a particular disease or the most appropriate treatment for it. If laboratories cannot deliver this information in an accurate and timely manner, the well being of the patients awaiting results may be severely affected. If genetic patents inhibit genetic testing for financial or technical reasons, then a reevaluation of the gene patenting process is not only imperative but pressing.

## THE PROBLEM WITH PATENTS

Patenting certain parts of the human genome is a much more commonplace phenomenon than the

average layperson may realize. The United States alone has issued up to 5,000 patents on human genes alone, and 47,000 patents worldwide in some way concern DNA and/or RNA.<sup>1</sup> The Hastings Center describes the variety of technologies and discoveries that merit the protection of these patents to include the following:

“Associations between a DNA variant and a disease, condition, or function; the DNA sequence that makes a particular protein, regulates a gene, or is useful for studying genetic variations; RNA sequences that turn genes on or off, or control other functions; cell lines, methods of treatment, and diagnostics; transgenic animal models of disease and genes used to make them.”

Given this vast array of categories that such gene patents cover, one can easily imagine the difficulties researchers and doctors encounter when working with or testing genetic materials. In order to perform diagnostic tests on samples submitted by a genetic counselor, a laboratory must obtain the rights to perform specific DNA tests, many of which involve multiple levels of patented associations between sequences,

the methodology of obtaining information about DNA, and the technology used to procure the DNA sample.<sup>2</sup> As a result, laboratories must tread carefully so as not to infringe on any patents which fall within these various categories. They must research the types of patents for which they will need to apply in order to test samples for a specific genetic disorder, a necessity which no doubt incurs numerous legal fees as well as time. The time delay extends further as laboratories must apply for each of the pertinent patents and wait indefinitely for licensing from the Patent Trade Office, an institution not widely known for celerity.<sup>3</sup>

This entire process forces the patient who submitted the samples for testing to wait on often time-sensitive results whose delay could potentially cost him his life or a certain level of well being, depending on the nature of the potential disease. Thus through the limitations of time and money, patents limit the ability and efficiency of diagnostic testing to an unacceptable level.

Furthermore, these monetary and time constraints limit the quantity of laboratories licensed to perform certain diagnostic tests, creating a bottleneck effect. This phenomenon contributes to



a processing backup in which the few laboratories licensed to perform specific tests may be rendered unable to return results in a time-efficient manner.<sup>4</sup>

### THE NATURE OF GENES AS PROPERTY

The essence of naturally occurring, unaltered genetic sequences does not align with the subjects of other items of intellectual property, as their nature requires that they remain in the commons to a certain degree, accessible to all. Patents serve to allow an inventor to reap the full benefits of his creation before opening up the new information to the advantage of the public. In order to merit such a system of private then public benefit, a new idea, method, or technology must qualify as an invention. The United States PTO dictates that in order for something to be patentable, that entity must satisfy a “novelty and non-obviousness” condition.<sup>5</sup> Stephen Munzer outlines a method to qualify labor as sufficient enough to constitute a new product. First, he recognizes that all patentable items find their origin in the commons of nature. A second premise states that someone performs labor on one such item to create a different version of it. As a result of this

labor, a new and nonobvious product exists. Munzer concludes that this effort should allow the laborer to appropriate the new product.<sup>6</sup> This line of reasoning can assist in the determination of whether governments can—or should—allow gene patenting. Genetic sequences exhibit the first principle, as they are naturally-occurring products in human DNA. They also satisfy a portion of the second idea since labor must be performed to identify, locate, or map out their sequences. This labor often consists of costly and meticulous investments of time and financial resources. However, such toil fails to result in a new invention. Although gene sequences are nonobvious to the average layperson and even to the experienced scientist, they do not constitute the core qualification of a patent-eligible product. Scientists have merely identified and characterized them—they did not create anything. This simple failure of genes to qualify as inventions should prohibit them from being patentable entities. One cannot patent something that naturally exists and operates, simply because he has learned more about its nature and composition.

Resnik rejects the claim that gene sequences cannot bear patents based on

their failure to constitute as an invention. Rather, the distinction between an invention and a discovery should not play a role in determining whether or not to allow gene patenting. He asserts that the “fundamentally misguided” judgment of gene sequences as products of nature unnecessarily enslaves gene patent policy to the definitions put forth by the US Patent and Trade Office.<sup>7</sup> Instead, Resnik calls for an assessment of the benefits of patenting and not patenting genes as the determining factor of whether to permit them. With the ultimate aim of healthcare in mind, he focuses on maximizing benefits to determine which is the most appropriate system. Resnik’s view appeals to a desire to optimize the healthcare advantages of whichever legal framework surrounds gene sequencing. Yet because responsible ethical considerations should take priority over this mere consequentialist view, his outlook is insufficient to propose a method for handling such issues.

The framework for gene patenting should be based on the nature of genes themselves and the subsequent implications of their study. Macer urges patent offices to “devote sufficient human resources to examine the morality of patent

applications in order to better represent the concerns of society...[including those] the issues associated with human genetic information...to fulfill the moral expectations that society, including scientists, expects of them.”<sup>8</sup> This more appropriate approach focuses on the nature of genetic sequences in order to determine how legal institutions should consider them.

In light of such an approach, human gene sequences possess a unique characteristic of universality and ancient classification that few other entities can boast. Gene sequences have established thriving diversity of life while consistently maintaining the characteristics necessary for survival and adaptation. While distinguishable in different people, human genes maintain a certain consistency throughout the world’s population. Genes have evolved without the assistance of laboratory techniques or a scientist’s innovation. Thus they are products of nature. Scientific discoveries of these sequences and their phenotypic purposes do not imply the creation of new entities. As such, genes should remain readily available for appreciation and use. In terms of research and development, withholding the

sequences of specific genes by tying them up in patents is inconsistent with the scientific goal of acquiring information. Genetic research aims to use developing knowledge of genes to improve the lives of those with genetic disorders through understanding the nature of the disease and the development of appropriate gene therapies. To award a particular company or person the right to appropriate genes would be to unnecessarily remove them from common access and stifle resulting research possibilities. Gene sequences clearly do not fit the well-established criteria of a patentable product, and current policy should reflect that.

#### THE PROBLEM OF POWER

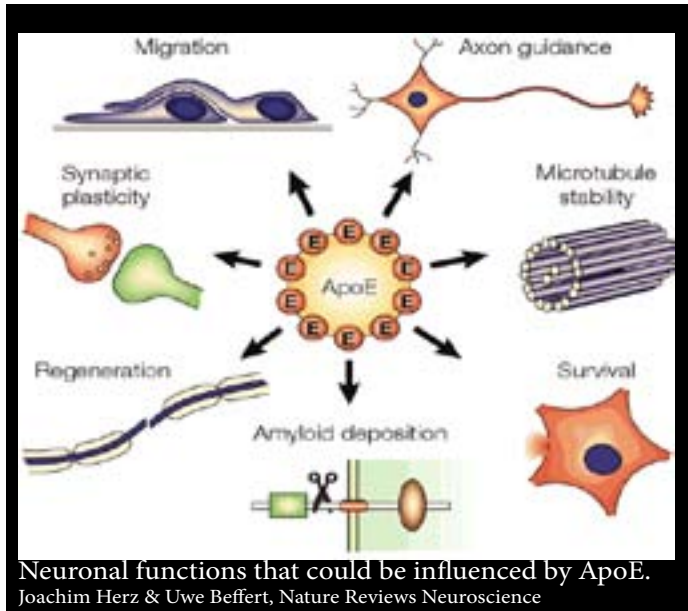
Another objection to gene patenting lies in the fear that permitting any one biotechnology company or laboratory to appropriate too many gene patents will allow that company to retain undue amounts of power. Munzer identifies the reality of the danger of patent suppression, a perfectly legal practice in the United States. With property rights comes the ability to set the conditions of access to a particular entity. This kind of power over gene sequences could have monumentally grave implications

for healthcare worldwide. Under current conditions, biotechnology companies who successfully sequence a gene have the right to do with the sequence what they please, within reason. This means that if a company were to discover the genetic mutation causing a particular disease, that firm could obtain a patent and refuse to license the information to other laboratories while also neglecting to perform its own research on the sequence. Thus by sequestering a gene from the research community, the company who sequenced the DNA would possess the power to prevent singlehandedly any drug development, genetic testing, or other investigatory research geared toward that particular genetic disease as long as the company maintained the patent. Although Munzer dismisses patent suppression as economically improbable and therefore not a “genuine problem”, the mere possibility of such unregulated power over such a sensitive and vital unit is extremely problematic.<sup>9</sup>

In fact, excessive centrality of power constitutes much of the debate currently surrounding the patenting of methods and testing involving apolipoprotein E (APOE), a telltale protein involved in Alzheimer’s Disease (AD). Research performed by

Duke University revealed information regarding the production, identification, and isolation of APOE in relation to AD. Duke granted exclusive licenses to these three APOE patents to Athena Diagnostics. Athena and Duke maintain joint control over research that pertains to APOE, including access to certain

SNPs. They claim that this prevents rampant and unnecessary testing for AD.<sup>10</sup> While this concern is legitimate, the responsibility of restricting access in a preventative manner should not lie in the hands of a biotechnology company and a university. Regardless of the fact that they developed the AD testing kits that resulted from their research, conflicts of interest could very easily arise. A better method of regulating access to genes and gene products would be to assess the results of research produced by research facilities at a federal level. Those who performed the research should present to a panel, similar to the PTO's application process, and suggest regulations. If the federal panel deems



constraints necessary, then restrictions to access could be implemented. These regulations would insure proper genetic testing and expedite the testing process by eliminating unnecessary sample backup. These measures would alleviate the fear of placing too much power in the hands of biotechnology companies.

### DIAGNOSTIC IMPEDIMENTS

Aside from the issue of privatized power, gene patents present unacceptable diagnostic impediments for individuals requiring genetic testing. The paradigm example of these diagnostic issues lies in the patents on the breast cancer type 1

and type 2 susceptibility protein (BRCA1 and BRCA2) sequences owned by Myriad Genetics. The BRCA1 and BRCA2 genes encode respective proteins that repair damaged DNA. Heritable mutations or other damage to these genes significantly increases susceptibility to specific types of cancer, most commonly breast cancer. Tests for mutations in the BRCA1 and BRCA2 genes can predict the risk of getting cancer with astounding accuracy. The landmark case of *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.* concerning patents on the breast cancer BRCA1 and BRCA2 genes delineates the issues which gene patenting raises for diagnostic testing. The complaint centers on the fact that patents disable second opinions because of the nature of diagnostic testing and interpretation. Because the licenses to access BRCA1 and BRCA2 information are so expensive, the number of laboratories with the resources to regularly perform these tests is extremely low. The Association for Molecular Pathology recognized the difficulties that patients face in terms of the high price of diagnostic testing, the slow result returns due to backup, and the lack of access to second opinions due

to the limited number of testing facilities available. Thus the Association challenged the validity of the patents on the grounds that genes and the diagnostic methods surrounding them should not be patentable entities. After a series of decisions and appeals, the court finally ruled in July 2011 that methods lacking innovation are “patent ineligible,” but ruled that the patents on specific gene sequences were valid.<sup>11</sup> This case brings to light the practical issue that gene patents create in disabling second opinions through licensing selectivity.

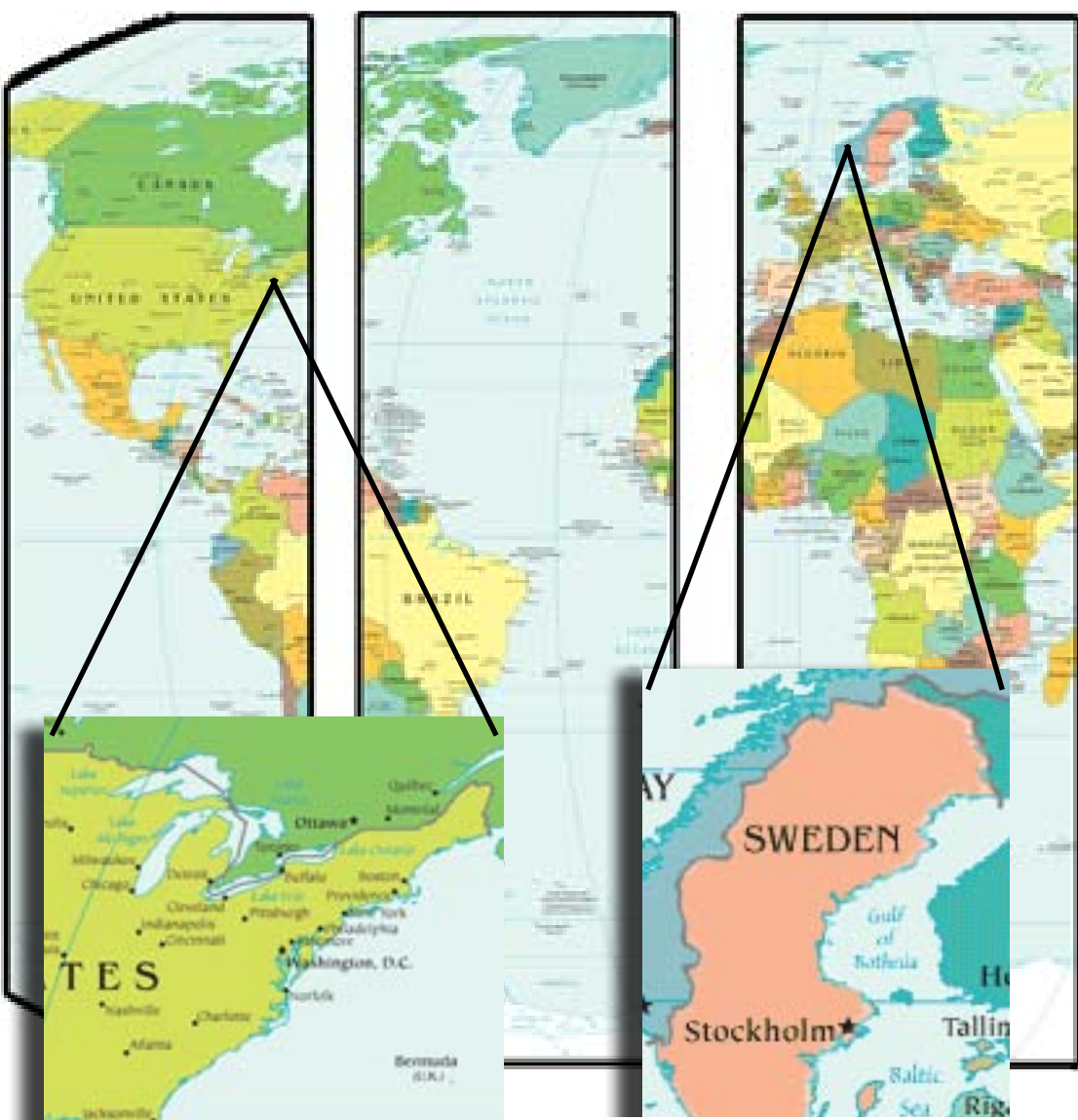
### CONCLUSION

In conclusion, the current patent system fails to appropriately deal with research and development of genes and gene products. Intellectual property over gene sequences removes too much power to biotechnology companies. Current examples of these issues with the patent system are revealed in the debates surrounding Alzheimer’s Disease research as well as specific breast cancer genetic predisposition testing. A fresh framework that simultaneously accredits biotechnology companies for genetic research and

development, facilitates quick turnarounds for labs, and eliminates the legal “red tape” surrounding currently patentable units is both essential and urgent. Improvements to the efficiency and success of genetic diagnoses are matters of life and death for patients bearing genetic diseases.

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### **Connecticut Shooting<sup>1</sup>**

Following the shooting at Newtown Elementary School in Connecticut, unconfirmed news reports stated gunman Adam Lanza had been diagnosed with a mild form of autism, implying a link between autism and planned violence. Experts, however, have strongly disagreed – Dr. Donnah Nickerson-Reti, a neurodevelopmental psychiatrist, clarifies, “Autism is related to different ways of processing information in the brain, but not in those areas related to violence.” With mental illnesses already having such negative stigma, how will this recent controversy affect society’s view of autism?

### **Mother-Daughter Womb Transplant<sup>2</sup>**

This year, two Swedish mother-daughter pairs have become the first to participate in a cutting edge uterine transplant surgery. While the surgeries went according to plan, whether they were successful in conferring childbearing ability to the daughters has yet to be confirmed. Past uterine transplants, one in 2000 and one in 2008, using live and dead donors respectively, have reportedly failed. Will this new approach be the hope for thousands of woman who want to have children but lack a uterus? In 12 months, these women will receive an embryo via embryo transfer, meaning we could know in just under 21 months.



# Bioethics Across Borders



## Woolly Mammoth Cloning<sup>4</sup>

Using tissue samples from Woolly mammoth remains found in North-western Siberia and eggs taken from the modern Indian elephant, a lab in South Korea led by Hwang Woo-Suk will attempt to clone the Woolly mammoth, an animal that has been extinct for ~4,500 years.

Will they be successful?



## Drug Patents<sup>3</sup>

The ability of leading Indian pharmaceutical companies to make generic copies of patented foreign drugs is set to be decided in the coming months by the Indian Supreme Court. On one side of the argument stand defenders of intellectual property laws. On the other, stand international aid groups who site Indian pharmaceutical companies as leading suppliers of low-cost HIV/AIDS and tuberculosis medication to developing nations.

What's more important to you?

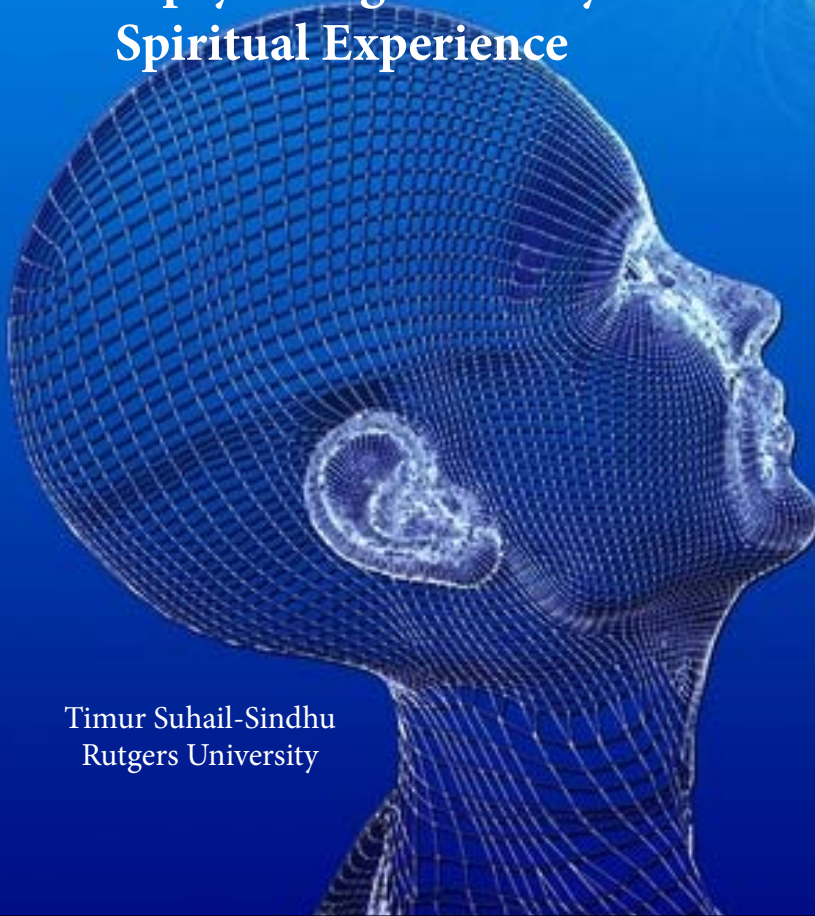


## Induced Pluripotent Stem Cells<sup>5</sup>

John B. Gurdon of Great Britain and Shinya Yamanaka of Japan won the 2012 Nobel Prize in Physiology or Medicine for their research demonstrating that a mature cell could be reverted to an embryonic-like state. The ethical implications of cellular reprogramming have been boundless. While it has made the once-philosophical cloning question a pressing possibility, it has allowed us to sidestep classical bioethical debates surrounding stem cell procurement and the use of humans in clinical research.

What will be the next discovery to shake the foundations of science and morality?

# Problems in the Neuropsychological Study of Spiritual Experience



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## ABSTRACT

Advances in modern neuroscience have led to an unprecedented understanding of the relationship between human experiences and brain processing. In recent years, neuroscientific studies have been extended to religious experiences within a new and emerging field called “Neurotheology.” Neurotheology attempts to explain religious experience in neuroscientific terms by uncovering correlations between neural phenomena and subjective experiences of spirituality. This kind of inquiry holds great promise for furthering our understanding of religion, and the ways in which it interacts with the human brain. One such study was conducted by cognitive neuroscientist Micheal Pers-

inger in his book “Neurophysiological Bases of God Beliefs.” Persinger argues that beliefs in God, and more specifically experiences of the spiritual state, are due to epileptic seizures within the temporal lobe. Persinger reduces spiritual experiences to a pathological process within the brain, and in so doing, potentially depreciates centuries of religious traditions. There are good reasons for believing that Persinger’s theory, however, is false. There are important discrepancies between Persinger’s theory and descriptions of the spiritual state within Christian and Buddhist contemplative literature. Persinger’s theory suffers from methodological and conceptual problems that may confront all neuroscientific studies of religious experience. In particular, Persinger fallaciously attempts to map the phenomena of religious experiences onto brain states, in his case brain pathology, that are currently well understood. Also, in the development of his theory Persinger uses brain imaging technology, the limitations of which make their results open to interpretation.

When studying religious experiences as mental phenomena, it is important to consider how qualitatively unique the religious domain is. Spiritual experiences should not be expected to fit any currently understood pattern of brain activation. Rather, a more fruitful strategy for future research would be to first become familiar with descriptions of spiritual experiences within the religious literature and from there uncover the brain processes that fit these descriptions. Given recent advancements in neuroscience and brain imaging technology, the neuroscientific study of spiritual experience has the potential to uncover important aspects of the relationship between religion and human beings. But unless done with serious care, these studies also run the risk of “explaining away” religion and religious experiences as *merely* pathological neurological processes.

## THE OBJECTIVE OF NEUROPSYCHOLOGICAL STUDIES

Neuropsychology is the study of brain regions and mechanisms of brain activation that correspond with particular kinds of mental or physical activity. For this reason, a large part of neuropsychology involves the study of “neural correlates” of mental and physical activity. Enough stress cannot be given to the important observation that these studies only uncover the neural structures and mechanisms that co-occur with certain events. Many have mistakenly taken the results of neuroscientific study into the neuropsychology of certain mental and physical events as representing the *causal antecedent* or *the reason for* the occurrence of those mental and physical events. This is incorrect. The correct objective of neuroscientific study into the neuropsychology of spirituality, then, is to correctly identify what kinds of brain activity and mechanism correlate with spiritual experience. A correct theory would identify those and only those parts of the brain involved in spiritual experiences, as well as the correct mechanism of neural activation.

## DESCRIPTIONS OF THE SPIRITUAL

## STATE WITHIN CHRISTIANITY AND BUDDHISM

Descriptions of the spiritual state within religious literature will play a central role in determining the accuracy of the Persinger theory. Tibetan Buddhist practitioners describe a spiritual state called *Samatha* in which all mental activity becomes dormant and in which “all appearances of oneself, others, one’s body, and one’s environment vanish”.<sup>1</sup> Tibetan contemplatives report that “what remains is a state of radiant, clear consciousness” in which “all phenomena appearing to sensory and mental perception are imbued with the innate luminosity”.<sup>2</sup> While experiencing *Samatha*, practitioners also report the experience of *alaya* which is described as the “empty space of the mind” and which “like space, (is) a blank, unthinking void”.<sup>3</sup> Furthermore, the state of *Samatha* is reported to be marked by the property of “all embracing, unconditional loving-kindness and compassion”.<sup>4</sup> The spiritual state of *Samatha*, then, is characterized by a multidimensional experience in which, psychologically speaking, the representation of the distinction between oneself and the external world dissolves. Also, this state is reported to be characterized by the

experience of bright luminosity and also by a deep sense of void and seemingly infinite space. Interestingly, the experience of this state is also reported to be highly emotional. The practitioner who attains *Samatha* feels deep compassion and love which does not seem to be directed at any particular object.

In the contemplative Christian tradition, the highest spiritual state is the realization of the union with God. The description of this state is similar, but not identical to, the Tibetan Buddhist descriptions of *Samatha* just considered. Christian contemplatives describe the union with god as entering “the silent land” in which the “sense of separation goes”.<sup>5</sup> Also, the experience is described as “an open field of awareness” and a “depthless depth”<sup>6</sup> in which ones “Heart-mind is...brimming over”.<sup>7</sup> Importantly, the “awareness is somehow about the presence of Christ”.<sup>8</sup> Here, just as in the Buddhist description, emphasis is given to the elimination of the representational distinction between oneself and the external reality. The images of “open fields of awareness” and “depthless depth” seem to suggest that Christian contemplatives experience something similar to the Buddhist *alaya*, a deep sense of void and space. Also, the

description of the state as having a “Heart mind” that is “brimming over” suggests that the experience includes an emotional component marked by love and compassion.

### PERSINGER’S NEUROTHEOLOGY

Persinger locates the neural correlates of spiritual experience in the right temporal lobe. Furthermore, he posits that spiritual experiences are correlated with epileptic seizures in this area of the brain. His evidence for these claims comes from the reported symptoms of patients who suffer from temporal lobe epilepsy. The symptoms include “olfactory, auditory and visual temporal hallucinations, feelings of dissociations, and the experience of strong emotions”.<sup>9</sup> Furthermore “subjective experience can be either explicitly religious (meeting god) or can be interpreted through a religious lens (seeing light and feelings of unlimited love)”.<sup>10</sup>

These descriptions of the symptoms during temporal lobe epilepsy are in many respects very similar to the Buddhist and Christian descriptions of the spiritual state. For example, visual hallucinations of light correlate well with Buddhist descriptions of luminosity and the emotional epi-

sodes that epileptics incur may correspond to the feelings of “loving kindness” and “Heart-mind” that Buddhist and Christian practitioners describe, respectively. Furthermore, the reported experience of “meeting god” seems to be somewhat indicative of the Christian state of mystical union. Persinger concludes that similarities between symptoms of epilepsy and spiritual religious experience give good reason for believing that spiritual experiences are correlated with the neuropsychology of an epileptic seizure in the right temporal lobe.

Persinger also provides evidence from brain imaging studies to justify his claims. Since according to Persinger’s theory spiritual experiences are correlates of temporal lobe seizure-like activity, one would expect to detect such activity in the temporal lobe of a contemplative practitioner having a spiritual experience. Persinger carried out the experiment using electroencephalography technology and produced positive results. “Using routine EEG measures, Persinger tracked a Transcendental Meditation teacher for 10 seconds during a peak experience...EEG patterns exhibited transient focal, epileptic-like charges in his temporal lobe”<sup>11</sup>

## PERSINGER’S NEUROTHEOLOGY

### CRITICIZED

Persinger suggests that the experience of hallucinations produced by epileptic seizures and the reported experience of contemplative practitioners are so similar that the latter accurately corresponds with the former. There are good reasons for believing that this is false. The hallucinations produced by epileptic seizures in the temporal lobe vary in their content due to variability in the location of the seizure. Maselko writes “Depending on the specific location of the seizure, it can cause a diversity of symptoms”<sup>12</sup> Because of this, it is unlikely that seizures would constantly correlate with the same set of hallucinations for an individual suffering from epilepsy, over time. It seems more likely that the content of hallucinations, if there were to be any at all, would vary in each seizure episode. Therefore, Persinger’s theory predicts that religious practitioners would have a wide variety of experiences that would vary over time, due to the variable nature of epileptic seizures. However, our descriptions of their experience show that Buddhist or Christian practitioners experience little variability in the content of their respective spiritual states. That is,

for the contemplatives we have considered, each spiritual experience exhibits the same characteristics. For example, the Buddhist spiritual experience consistently includes feelings of vast space, perceptions of bright luminosity, and feelings of deep compassion. As mentioned, episodic seizures are not expected to show such consistency in the hallucinations with which they produce.

Furthermore, Persinger's theory does not adequately account for important fundamental characteristics present in both Buddhist and Christian descriptions of spiritual states. For example, the disengagement from the distinction between self and surroundings that is present in descriptions of Buddhist *Samatha* and Christian union with God does not seem to be the kind of phenomena that corresponds with the function of the temporal lobe. These experiences seem as though they should implicate areas such as the parietal lobe and somatosensory cortex since they are recognized as areas that play a role representing spatial relations between one's body and the external environment. A theory that includes the parietal lobe and its function would be equipped to account for the Buddhist experience of *alaya*, the "empty space of the mind." Similarly,

epileptic seizures in the temporal lobe alone do not adequately account for the deep emotional salience of religious experiences. Remember, the Christian experiences of "heart-mind" and union with a loving God are deeply infused with feelings of compassion. Such experiences would be better associated with the area of the amygdala which functions in producing and regulating emotion. A neurophysiological theory that included the amygdala and its functions would serve to better account for this aspect of spiritual experience than a theory that referenced only the temporal lobe.

These considerations sufficiently demonstrate that Persinger's neurophysiological theory of religious experience is inadequate in identifying those and *only those* parts of the brain involved in spiritual experience, as well as the correct mechanism of such neural activation. The inadequacy of Persinger's theory can be accounted for by two distinct problems. One of which concerns the methodology of his verification, and the other has to do with the conceptual development of his theory. These issues are neither unique nor limited to Persinger's study. Rather, these problems may generalize to all attempts of

understanding the neuropsychology of religious experience. Therefore, it is important that they be brought to light so that future studies do not commit similar errors.

### PROBLEMS WITH BRAIN IMAGING

The first problem concerns the method by which Persinger purports to have verified his claims. By utilizing EEG technology, Persinger believed he had identified epileptic like charges in the temporal lobe of a Transcendental Meditation instructor having a peak meditative experience. These results were taken to verify Persinger's claims that spiritual experiences correlate with seizure like activity in the temporal lobe. However, this is not completely obvious. EEGs detect brain activity by measuring fluctuations in voltage on the scalp that occur with neuronal activity within the area. That there was a fluctuation of the electrical field on the scalp above the temporal lobe tells us only that the temporal lobe and the surrounding structures were active while the test was being conducted. It tells us little to nothing about the specific neurological processes (e.g. epileptic activity) within the temporal lobe itself that caused the change in electri-

cal activity on the scalp in the first place.

EEG data of activity in the temporal lobe underdetermined the specific mechanism that actually occurs. "(EEG) patterns are non-specific, and may occur with a variety of different sets of brain functioning".<sup>13</sup> That is, detection of temporal lobe activity via EEG might or might not be the result of seizure like activity. Rather, it might have resulted from non-pathological neuronal firings of other kinds within the temporal lobe and the surrounding structure. This is especially important considering that EEG studies of spiritual experiences are studying a process of which very little is known. It may be true that spiritual experiences are correlated with increased neuronal firing within the temporal lobe and that this may be represented in the results of an EEG scan. However, this does not imply, nor give evidence for, the existence of epileptic seizures within that area. Those investigating the neuropsychology of spiritual experience, or any mental phenomena for that matter, should be cautious of data gained in neuro-imaging studies.



**PROBLEMS IN CONCEPTUAL  
DEVELOPMENT**

The second problem concerns the conceptual issue of understanding religious phenomena within the context of our current body of scientific knowledge. When attempting to study the neural correlates of religious experience, it is natural to first consult findings in the field of neuroscience in order to recognize relevant similarities between experiential states of which the neuropsychology are well understood and the spiritual states that are under examination. In so doing, one might hope to attain a greater understanding of the process under investigation by assimilating it to a process that has been well researched. There are good reasons to believe, however, that the neuropsychology might not accurately assimilate into any currently understood pattern of brain activation.

The experiences of the spiritual state are qualitatively unique and only beginning to become scientifically investigated. They should not be expected to include the kinds of experience that fit any currently understood model of brain activation. In the earlier discussion of the spiritual state within Buddhism and Christianity, descrip-

tions of *Samatha*, *alaya*, and “union with god” were introduced. Experiences like *Samatha* in which “all appearances of one-self, others, one’s body, and one’s environment vanish” are unique in their content. Indeed, their profundity and near incomprehensible descriptions give good reason for believing that these states are far from most ordinary experiences. On the other hand, our current understanding of the relationship between experiences and brain activity comes from studies done on healthy and unhealthy brains under everyday normal conditions. It is not at all clear if the brain of a contemplative practitioner during the height of a spiritual experience fits perfectly into either of these two categories, considering their extra-ordinary content. It is unclear then, whether the patterns of neural activation that correlate with spiritual experience will resemble neural mechanisms that have been well understood within neuroscientific research. Therefore, it should not be expected that the pattern of neuronal activity associated with spiritual experience will map onto any currently researched brain process. Any theory that does so should be met with great suspicion.

In his attempt to understand re-

religious experience scientifically, Persinger fallaciously assimilates the religious phenomena in question to an already existing and well-understood neurophysiological pathology. Since temporal lobe epilepsy is an already well-understood neural process, Persinger seems to have hoped to produce a parsimonious theory that would accord with our current understanding of neural mechanisms due to certain affinities between symptoms of epilepsy and descriptions of spiritual states. Though the theory accords with what is known about current brain function, as has been demonstrated, it is inadequate in correctly identifying the neural correlates of religious spiritual experience.

### SUGGESTIONS FOR FUTURE

#### STUDIES IN NEUROTHEOLOGY

The fault in his approach lies in the fact that he seems to begin conceptually with what is currently known about brain processes and then attempts to fit descriptions of religious experience into one of the already well-understood mechanisms. A more accurate and scientifically fruitful method would be to move in the opposite direction. Those interested in the neuropsychology of spiritual experiences should

begin their investigation by examining what is understood in religious literature about spiritual experience. From there, scientists should use this understanding to guide investigation of brain processing. Earlier we employed such a method to show that Persinger's theory did not adequately take into account important characteristics of spiritual experiences. By examining the Buddhist description of the state of *alaya*, for example, we recognized that an accurate neurophysiological theory should most likely make reference to the parietal lobe and its function. Similarly, from the descriptions given in Christianity of union with god, we recognized that an accurate neurophysiological theory of this experience should include structures that play a direct role in producing and regulating emotion, like the amygdala. Once we have determined the relevant parts of the brain that might be involved in religious experience, by relying primarily on religious description, we can then attempt to uncover the neurophysiological patterns that relate these relevant neural structures. Given recent advancements in neuroscience and brain imaging technology, the scientific study of spiritual experiences has the potential to uncover

important aspects of what it is to be religious. This mode of inquiry, I believe, could play an important role in initiating research for an accurate understanding of the neural underpinnings of spiritual experiences.

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# An Introductory Case Study to Organ Donation: The United Kingdom

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## ABSTRACT

The topic of organ donation has always been a heated debate between the rights of the donors to give up their organs for strangers and the rights of the recipients in their fight for survival. Though many countries have some sort of legislation that outlines organ donation, the results are often disappointing and often many potential donors are lost along with their viable organs. Last month, the British Medical Association released a report that not only outlines the current laws and practices in effect, but also proposes a series of initiatives that have sparked controversy from pro-life activists to patients' rights advocates. The suggestions are radical in their approach, but did the British Medical Association go too far? Is the increase in donors worth the risk that patients will face as the recipients of these organs from questionable sources?

## INTRODUCTION

There is no denying that the organ donation shortage has hit the crisis point all over the world. According to the *Nursing Standard*, “there are around 8,000 people in the UK waiting for an organ transplant. The average wait for a donor is three years, and everyday three patients who never make it to the top of the waiting list die.<sup>1</sup>” The British Medical Association’s Medical Ethics Committee’s recently published the report, “*Building on Progress: Where next for organ donation policy in the UK?*”, describing the current measures employed by the UK for the procurement of organs and comparing their policies with other countries such as the United States, Spain and various other European countries. One particularly controversial section entitled “Increasing the Number of Donors” endorses the use of high-risk tactics and policies in order to increase the number of viable donations from DCD (Donors following Circulatory Death) and DBD (Donors following Brain Death). Some of these tactics include seeking transplants from trauma patients in the emergency room who have little chance to regain consciousness and live a normal life, expanding the types of organs retrieved from

DCD/DBD’s, the use of “higher risk” donor organs from drug addicts, former cancer patients, and those who have high-risk sexual lifestyles. Other methods would include elective ventilation just to keep patients alive for their organs, retrieving organs from disabled newborns, adopting a presumed consent system for donations, creating a market for organs, instituting a “shame campaign” to spur donating, and using funeral payments as an incentive to increase donations. The public and professional community can agree that measures must be taken in order to save lives, but where does medicine draw the line between reward and risk?

## SCIENTIFIC BACKGROUND

The process of transplantation itself is fraught with possible complications that could arise from surgery, post-operation infections and illnesses, transplant rejection, and a lifetime of immunosuppressant medications and antibiotics. The danger of using transplanted organs from patients who either have been diagnosed with cancer or have abused their organs through either high-risk sexual behavior or drug abuse cannot be ignored. Recent studies show that cancer can sometimes reoc-

cur in donor recipients who have received a lung, liver, heart or kidney transplant. "Patients who undergo organ transplantation are now known to be at an increased risk of the development of de novo malignant tumors. This is primarily a consequence of immunosuppression, which may provide tumor development and progression by a variety of mechanisms."<sup>2</sup> Under further scrutiny, the UK Registry also stated that "This first detailed registry study of cancer occurrence in British transplant recipients has shown evidence of different patterns of cancer occurrence in recipients of different organ types...The overall incidence of cancer (excluding NMSC) in recipients of a heart, kidney or liver, is over twice that of the general population...and over three times higher in recipients of lung or combined heart and lung transplant."<sup>3</sup>

Another source that the BMA cited that could yield usable organs is among drug addicts and those who have high-risk sexual behaviors. This poses yet another potentially lethal outcome for the transplant patient. Drug addicts, especially those who abuse heroin, use and often share needles with other abusers. This increases the exposure to various infections and illnesses

(such as HIV), which could possibly transfer to the transplant patient. Furthermore, according to a study released by *Human and Experimental Toxicology*, the use of drugs such as MDMA and cocaine on mice not only caused paradoxical sleep deprivation (due to the effects of the drug) but also genetic damage to multiple organs. "Cocaine was able to induce genetic damage in the blood, brain and liver cells of sleep-deprived mice...Ecstasy is a genotoxic chemical at the highest concentration tested, inducing damage in liver or brain cells..."<sup>4</sup> The damage to the DNA in a human organ transplant may hinder the organ from performing normally within the human body. In addition, organs already damaged by drugs may already prove to a source of potential health complications later in life as the organ ages. For those who practice unsafe sex, a plethora of STDs, especially syphilis, can affect the organs of the infected, and thus prove hazardous to the health of the transplant patient. Recipients are especially susceptible to STDs as a result of taking immunosuppressant medications to avoid transplant rejection.

#### THE BIOETHICAL ISSUES AT HAND

One of the biggest bioethical di-

lemmas concerns the well-being of the patient exposed to high-risk organs. A procedure already fraught with danger could be further complicated by transplanting a potentially abused organ of a heroin addict, who may have been exposed to various other illnesses such as HIV/AIDS due to using shared intravenous needles. By allowing patients access to these questionable organs, patients put themselves into dire circumstances as dangerous as the transplant operation itself. Even though organs from cancer patients, drug abusers and high-risk individuals are screened for various diseases before the procedure, the patient's safety and the organ's viability are still at risk.

Another issue is the concept of informed consent among trauma patients and newborns and the "presumed consent" law. Currently, only the Human Tissue Act of 2004 outlines the protocol for organ donation in the UK. "The Human Tissue Act requires explicit consent for organ removal and use for transplant."<sup>5</sup> Because trauma patients and disabled newborns are unable to communicate their desires, medical professionals must carefully tread the line between respecting the rights of their dying patient and trying to save another

patient's life. Oftentimes, the autonomy of the patient is in question. This is not only a question of consent for the deceased but for those who support the "presumed consent" law, including the BMA itself. According to Slowther, "Those in favour of presumed consent, including the British Medical Association, argue that the ethical balance is weighted too much towards respect for autonomy, as articulated in the need for explicit consent at the expense of avoidance of harm to patients in need of a transplant."<sup>6</sup> If the presumed consent law is passed in the future, the autonomy of a person's choice to donate is in jeopardy as well.

Another problem is the life quality of elective ventilation patients. Though consent was obtained, one could argue that it is morally wrong to keep a person alive for someone else's benefit, regardless of the altruistic nature of organ donation. The quality of life of these patients in a permanent coma is far from ideal. In the report, the BMA states that "the use of elective ventilation is not intended to be for the clinical benefit of the individual but to facilitate donation."<sup>7</sup> Family members may feel that the patient has lost his or her identity as a human being, having turned

solely into a vessel for organ donation.

As mentioned earlier, the risk of infections and complications in using compromised organs raises the stakes for the patient's health and well-being. Doctors swear an oath of nonmaleficence to protect patients and maximize benefits over risks. Robert Veatch, a leading author in bioethics, defines nonmaleficence as "The moral principle that actions or practices are right insofar as they avoid producing bad consequences."<sup>8</sup> Veatch continues to say, "according to the Hippocratic formula, the physician's duty is to promote the total well-being of the patient."<sup>9</sup> The doctor must make a difficult call as to whether the exposure to unforeseen illnesses from the compromised organs is worth the risk to the patient, both in short-term and long-term care.

One final problem medical professionals must face is the conflict of moral obligation that people have towards each other and whether using monetary incentives is morally right. Various religious backgrounds advocate that it is a person's moral duty and obligation to help his neighbor when in need. They also emphasize the principle of acting selflessly and without physical incentive. In this particular case,

can that mindset be applied to organ donation? Is one morally obligated to sacrifice something as precious as an organ in order to save his neighbor? Is it morally correct to essentially guilt people into donating in exchange for money or paid funerals? In the UK and United States, both women and men are being compensated for ova and sperm donation. "According to the HFEA (Human Fertilisation and Embryology Authority), this level of compensation 'better reflects' the costs experienced by donors, but is not enough to attract those who are merely financially motivated."<sup>10</sup> However, many people still feel uneasy about being compensated for whole organs and some feel that if compensation becomes common practice, "We [The human race] will continue to face a dual tragedy; on one side the thousands of patients who die each year for want of a kidney; on the other, a human-rights disaster in which corrupt brokers deceive indigent donors about the nature of the surgery, cheat them out of payment and ignore their postsurgical needs."<sup>11</sup> Others feel monetary incentives for healthy organs could provide people, including but not limited to drug addicts, the impetus to stay fit and healthy, which



would be a boon for public health services.

### A GOOD IDEA

Though these ideas are radical, the propositions on the table currently are not enough to save the eight thousand patients currently on the list waiting for a life-saving transplant. If the UK does ultimately implement all these measures, “deceased donor rates would increase by 50% by 2013.<sup>127</sup>” This could mean that many lives could be saved over the next few years and viable organs would be put to good use. Monetary incentives for healthy organs could provide people, including but not limited to drug addicts, the impetus to stay fit and healthy, which would be a boon for public health services.

### A BAD IDEA

These suggestions not only infringe on the rights of patients whose organs will be taken from them, but also on the rights of the millions of healthy individuals that do not want to give up their organs, regardless of their personal beliefs. For those who are on the verge of cardiac death, the line between life and death is often a blurred one. Doctors, in their haste to collect viable organs, might be too quick to

judge the patient as being “cardiac dead” and not allow the patient to have adequate time for possible recovery or pressure the patient’s family to act rashly instead of taking the patient’s wishes into thought. This becomes an even more delicate situation when disabled or dying infants are involved.

Another argument against these radical measures is the unnecessary risk that doctors might expose to their patients and their families when suggesting transplants from “higher-risk” donors. As previously mentioned, cancer can reoccur in transplant patients and the organs of drug addicts can be damaged or tainted with infection. Furthermore, if the patient contracts an STD or disease from the received organs, it exposes them to a wide array of other detrimental side effects and conditions. In either case, the organs, being unhealthy or possibly damaged, may not work as well as a healthy donation and may be ultimately rejected by the patient’s body.

A final point that raises concern is that for those who are on elective ventilation, harvesting their organs undermines their autonomy and identity as a person. This practice could “lead to the commoditization of people, and that goes against the percep-

tions of dignity and personal autonomy.<sup>13</sup>”

## **CONCLUSION AND RECOMMENDATION**

The medical and public communities must come to an agreement as to what is acceptable practice in the organ donation debate. Politicians must work with both communities in order to create legislation that increases donations but protects the rights of all involved. Though recent propositions are becoming increasingly radical, adjustments and compromises could make them more socially acceptable. The development of stringent screening processes for the organs of cancer patients, drug addicts and other high-risk individuals must be taken into serious consideration. Financial incentives must prove to be a valuable and effective method in recruiting healthy individuals as donors. The “presumed consent” law could be enacted, but must receive strict oversight from the government, and must allow individuals to opt out without bias or legal persecution. Finally, the definitions of DBD and DCD need to be clarified. Organ donation protocol and procurement will remain a sensitive, complex topic until all needed organs become readily available in the future.

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11. Carol Levine, ed. *Taking Sides; Clashing Views on Bioethical Issues*, 14th ed. New York: McGraw-Hill, pg 300.
12. Ibid. 7. 69.
13. Ibid. 1. 21.

# RU Speak-Up

**Q:** In 2008, Israel incorporated

a non-medical factor into their organ transplant list formula. The new law gives transplant list priority to individuals who are registered organ donors or who have had a close family member donate in the past. The numbers suggest this law has been a success, as it has resulted in a 60% increase in organ transplants. While many support the law, others feel the law is discriminatory—specifically against individuals who refuse to donate for religious purposes.<sup>6</sup> What do you think? Is this law fair? Should non-medical factors, such as number of dependents, lifestyle choices, willingness to donate an organ and occupation, be weighed alongside medical factors when making the organ transplant recipient list?

**A:** I think Israel's law is very fair. Although everyone is entitled to their own beliefs, it seems difficult to understand that one might be opposed to donating their organs for religious reasons – but not to accepting others' organs. Nowadays, so many people are waiting for organ transplants that many of them will be given medical priority. Still, since there is such a shortage of organs for people who need transplants, health systems will have to start taking non-medical reasons into account. Whether or not someone is an organ donor him/herself is a good place to start. This law does not restrict individual choice when it comes to being an organ donor; it just shows that the choice may have consequences.

Olivia Shabash

Class of 2015

**A:** Through treating countless lives every day, health care providers ultimately strive towards the greater goal of improving the wellness of the human population. However, while the larger picture is to find solutions that will benefit society, we must not forget to adhere to ethical guidelines when we deal with individual accounts. When patients are admitted to a hospital, non-medical factors should only serve as a background to understanding the current conditions. These factors should never undermine the ability for a patient to receive optimal treatment or allow them to be put below others who fit the specific non-medical criteria better. The 60% increase of organ transplants in Israel is a false success built upon corrupt moralities.

Winnie Zhang  
Class of 2014

**A:** With the enactment of Obama Care, we now recognize health-care as a right, not a privilege. However, this right only exists in situations where we have the resources to provide for everyone in need. In the case of organ donation, where there is far more demand than supply, we must create criteria for deciding who gets the lifesaving treatment they need. While we currently use only medical factors, Israel has started requiring that recipients be donors themselves or have family members that have donated organs. People should not feel entitled to an organ when they need one if they are not willing to donate themselves. If certain groups with not to donate for religious reasons, then they are choosing not to save lives, one of the most important tenets of most religions. Because they are choosing not to help others, they are affectively opting out of the whole organ donation system.

Aaron Levin  
Class of 2014

# RU Speak-Up

**Q:** Currently, 114,000 individuals are waiting for life saving organ transplant surgery.

Today, 18 of them will have died waiting. In 2011, in the United States, there were 8,127 deceased organ donors and 6,017 living organ donors resulting in 28,535 organ transplants. Living donors donated non-essential organs. Others on the list attempted to acquire organs illegally. Each year 10,000+ organs are sold illegally across the world, many to Americans. In most cases, the organ donors aren't adequately screened and cared for and are rarely "fairly" compensated for their donation. Black market organ donations results in a higher percentage of donor and recipient deaths and increase the proliferation of diseases such as HIV and Hepatitis. The existence of the black market, however, proves that there are people out there willing to part with organs for money.<sup>7</sup> Assuming sellers will receive medical treatment on par with that received by the 6,017 living organ donors and would be adequately screened, would it be ethical and prudent for the United States government to legalize the sale of organs in order to try to meet demand?

**A:** I strongly believe healthcare is a right, not a privilege. Legalizing the sale of organs completely undermines this idea. Allowing the principles of economics to take over would be nothing more than exploitation of the poor- the very same people who are, arguably, the most likely to end up on the list. However you look at it, the demographics of the new privatized system would be skewed. With the risks of the black market no longer a deterrent, the list of donors would be primarily comprised of the poor (those willing to risk quality of life for recompense) and the receivers would be the well-off (those able to meet the mar-

ket price). The results of this maneuver would be utterly reprehensible.

Bianca K. Patel

Class of 2013

**A:** I think the legalized and government regulated selling of organs would be prudent. If strictly regulated to ensure safe surgical procedures there would be no harm in it. Those who can afford it may receive necessary organs leaving less people on the waiting list for those who cannot. I also think it is a good way for people who are in need of money to support their families if they're willing. Legalizing it would also lower the number of deaths due to transplants done through the black market. The "fair compensation" would have to be thoroughly researched and calculated but other than that, I think that it would be beneficial for the country.

Monica Thi

Class of 2015

**A:** Allowing for the legal sale of organs would only serve to drive a larger wedge between the healthcare of individuals on opposite ends of the socioeconomic spectrum. While the wealthy could afford to continuously destroy their livers and simply purchase new ones, individuals of lower socioeconomic status would start selling their organs in order to meet financial pressures. Ultimately, we'll never see a wealthy organ donor or a poor organ recipient. While trying to end the black market of organs sales is a noble cause, I'd rather see a black market persist underground if the alternative is allowing our healthcare system to descend to that level.

Neil Raju

Class of 2014



**Legalizing Human Organ Trade**  
**Boluwarin Adunbarin**  
**Rutgers University**

Keith, a husband and father of five, is suffering from acute kidney failure. Too sick to work, Keith lost his job with the Red Cross. He has been on dialysis for six years now, and is on the waiting list for a kidney donation. Unfortunately, being placed on the waiting list for organ donation is not a sure sign that one will receive an organ donation. In fact many medical patients on waiting lists, approximately 6,000 per year, die in wait of an organ.<sup>1</sup> With such staggering figures, the need to improve the current system becomes increasingly evident. Could the legalization of organ trade, the selling and buying of organs, be a viable alternative to the current organ donation system, which relies solely on altruism?



Globally, organ trade is virtually illegal on the basis that it contains elements of socioeconomic class bias and creates an atmosphere that likens humans to commodities. These ethical concerns that prevent us from placing monetary value on nonessential organs, while understandable, have led to the black market commoditization of longevity. The illegality of organ trade has provided a platform for black market organ trade to flourish. The World Health Organization has estimated that about 10,000 organs are obtained through underground markets every year.<sup>2</sup> Criminalization of the practice of buying organs, combined with the shortage of donated organs, has left many at the mercy of unethical black market cultures. Reportedly, brokers are charging between US\$ 100,000 and US\$ 200,000 to organize a transplant for wealthy patients. Donors — frequently impoverished and poorly educated — may receive as little as US\$ 1,000 for a kidney.<sup>3</sup>

Unlike in black market practice, organ donations in the United States can only be done altruistically; “In living-related (donor is related to recipient) kidney donation, the principle of non-maleficence is outweighed by other tenets of ethics,

namely autonomy and beneficence.”<sup>4</sup> Other countries have put in place similar restrictions; according to the Transplantation of Human Organs Act in India, organ donations must be from a relative or spouse or for reasons of “affection.” The need for an interpersonal emotional connection between a donor and recipient in order for a donation to take place is a idealistic restriction that is not conducive to meeting the challenges of the current organ supply shortage. While “affection” may appear more humane to the external observer, the need for “affection” kills 6,000 people every year on organ waiting lists. The number continues to increase.<sup>5</sup> The uncertainty of ever receiving an organ has rendered the waiting list medicine’s equivalent of purgatory.

Given the ineffectiveness of the current organ donation system, legalizing the sale of nonessential organs is practical because it incentivizes organ donation. Such a system (further mentions of system refer to this system) would combat the current dearth of organ supply. The list of organ donors can only lengthen. An improved donation system should include the stipulation that while anyone could be a seller, only the government could be the

buyer. Furthermore, the system should restrict sellers to American citizens to reduce the number of transactions taking place through the black market, which primarily targets impoverished people from underdeveloped nations. Given that there are 220 million adults in the U.S. and 117,000 patients on waiting lists,<sup>6</sup> there is a more than sufficient number of possible donors even when accounting for those with poor physical health who are not fit to donate. Much of the unethical activity in the black market is because of the lack of regulation and oversight of the interaction between the donor and the middleman. In the proposed system, the middleman is taken out of the equation. Organs removed prior to entering the clinical center for donation would not be accepted. This proposal would fall into the category of a social program.

The government should be the sole buyer in this system in order to prevent a situation in which only the wealthy can obtain an organ for transplant. As a government-funded social program, patients would not be at the mercy of a profit-driven corporate agenda. Under this system, corporations and individuals would not be allowed to pursue the grossly unethical behavior of buying

organs from people for the sole purpose of making profit. The purchased organs should be distributed using the status quo criteria of giving to those in most dire need first. This eliminates class bias on the organ-receiving end of the spectrum; that is, priority is based on need, not socioeconomic class.

Unfortunately, it is more difficult to eliminate class bias on the donating end; sellers will more than likely come from economically disadvantaged backgrounds. The fact is that many illegally bought organs are already being obtained from the poor, many of whom are not being informed about the potential effects on their health and are deceived by the black market traders. A legally regulated system would ensure proper debriefing on the possible medical repercussions and provide the means to informed consent. Other than policy concerns, the idea of legalizing the sale of organs can be disconcerting.

“The medical profession compromises its deontological commitments (that all individuals have a value beyond price) by adopting a mainly utilitarian ethic (maximizing the good for the largest number).”<sup>7</sup> The proposed policy would not place a price tag on life, only

nonessential organs. Deontological commitments are not being neglected, especially given that donating does not usually compromise ones' health or lifespan. This argument could be justified if hearts, stomachs, or intestines were being bought, but this is not the case, since only the sale of nonessential organs would be legalized.

Organ trade opponents are also disconcerted by the idea of selling organs, because of a lack of familiarity with the practice. What if people received a one-hundred-dollar compensation for a more common donation, such as blood donation? That idea sounds much less objectionable than being paid several thousand for an organ. Much like how the human body produces more blood after a blood donation, the liver regenerates itself when portions of it are removed. While kidneys do not regenerate, donating a kidney is still a safe process. The remaining kidney will work harder to compensate for loss of the other one. Current research shows that there is not a decrease in life expectancy. In fact, some cases show a longer lifespan of donors relative to the population average.<sup>8</sup>

Legalizing organ sale elicits the fear that humans will be killed and har-

vested for their body parts. This is, in fact, the present situation in many underdeveloped countries because of the illegal status of organ trade and the resultant black market. Fortunately, under the proposed system, this will be highly improbable given the protocol for organ trade; organs removed prior to the arrival of the donor will not be accepted, in order to make sure the process is taking place completely of the donor's will.

"Although there is pain, anxiety and some risk involved with the nephrectomy [kidney removal] procedure, the benefits to the recipient and the psychological, spiritual, and emotional advantage to the donor, along with the fact that kidney donation increases self-esteem, justify the act of kidney donation."<sup>9</sup> The fact that sellers will be receiving monetary compensation for their organs does not necessarily eliminate the emotional compensation of organ donation. One can be paid for an organ and still feel the satisfaction of saving another's life. While money might make parting with an organ easier, there will always remain a sentimental hurdle that the individual must overcome to give up the organ. For this reason, sellers should still be respected for their contribution to society and be regarded as donors.

Giving an organ does not need to be solely an act of altruism. It is understandable that being guided by an altruistic policy is the best initial approach to tackling the issue of organ procurement, but the United States has been facing an organ shortage for much too long. It is simply unethical for the current system to persist. Families should not have to lose loved ones for the sake of maintaining the pseudo-ethical principle that altruism should be the only means by which giving an organ occurs. Our strong “ethical” values are causing the waitlist to be symbolic of the near hopelessness of being in need of an organ; thousands of patients spend years on waiting lists without ever receiving an organ donation. The question of legalizing organ trade must be faced soon here in the United States and worldwide. It must, however, be approached carefully.

The practice of organ trade has previously been implemented and failed in several countries. Organ trade was outlawed in India in 1995. What used to be a flourishing system became marred by the frequent breach of moral law. There have been instances of alleged removal of organs by the middle man without the knowledge of the donor, which is one of the reasons

why commercialized organ trade became outlawed in India.<sup>10</sup> Citizens were being lured to specific locations, such as job interviewing sites, where they would then be held up at gun point and forced to undergo kidney removal. This is why the aforementioned proposal reduces the organ donation process to a direct transaction between the buyer (government) and the donor, cutting out the middlemen that have been the cause of past unethical activity. Another interesting case to study is China’s history of obtaining organs.

China had the practice of procuring organs from executed prisoners. The legitimacy of the prisoners’ consent had been called into question by human rights groups and because of international condemnation of this practice, China has vowed to implement a different system.<sup>11</sup> The system has been described as “a gross violation both of human rights and of the ethical guidelines which have been drawn up by various international organizations to set the standards of acceptable practice both within and without the medical profession.”<sup>12</sup> Fortunately, this will not be an issue if the proposed system is practiced because the issue of obtaining consent has been accounted for. The system

mandates that donation must be solely of an individual's volition. The history of organ trade is not entirely one of failure.

Currently, Iran is the only country in the world that practices compensated organ donation. Until 1988, all living donors were related to the recipient in Iran. Due to national demand and the increasing number of patients needing organ transplants, a controlled living unrelated donor (LURD) program for renal transplantation was adopted in 1988. As a result, the renal transplant waiting list was eliminated by 1999.<sup>13</sup> The success of this program shows that matching every single patient with a donor is attainable and not simply a theoretical assumption. Further research on the organ transplantation program in Iran has shown that the fears of a socioeconomically biased system are exaggerated. "All living-unrelated donors (LURDs) have been from the low or middle socioeconomic classes. In one study, 84% of LURDs were poor and 16% middle class. However, 50.4% of recipients were also poor, and 36.2% and 13.4% were middle class and wealthy, respectively."<sup>14</sup> The success of the organ transplantation program in Iran should encourage more nations to pursue the le-

galization of compensated organ donation.

The United States, although far from having a perfect system, is taking steps toward initiating organ trade. In 2004, Wisconsin passed the 2003 Wisconsin Act 119, which provides income tax deductions to living donors who donate one or more of their organs.<sup>15</sup> This measure was taken to increase the number of living donors. New Jersey, New York, and Indiana have also implemented similar legislation.<sup>16</sup>

The fact that Keith's story is becoming increasingly typical is a clear signal that the United States must reevaluate its organ donation policies. Our current "altruism only" system is ill-equipped to handle the current challenge of scarceness in the organ donation pool and allows the black market to flourish. Legalizing compensation for organ donation is now the most logical measure to take, and if responsibly implemented, will maintain a safe environment for American citizens. The futility of signing up to be on a waiting list must end.

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