RUTGERS JOURNAL OF BIOETHICS

VOLUME I, ISSUE i
FALL 2009

The Bioethics Society of Rutgers University

presents its premier issue of the

Rutgers Journal of Bioethics

FALL 2009: VOLUME I, ISSUE i

As members of the Bioethics Society of Rutgers University, we hope to raise general awareness of issues in bioethics in the Rutgers community by method of discussion and publications written 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 the student population at Rutgers should be made aware of the implications of biological research, medicine, and other topics of bioethical controversy. This organization serves the general Rutgers population by introducing a forum where students can discuss and debate issues of bioethics, as well as educating the general student body.

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From rallying for better facilities to organizing fun programs for students, the Livingston Campus Council has over the years succeeded in making Livingston one of the most unique campuses at Rutgers University. Serving as Livingston's governing body since 1969, the LCC has worked with students, faculty and administrators to improve the campus and the community as a whole. If you are interested in being part of the action, the LCC meets every Monday at 7:30 in the Livingston Student Center room 113. Come out and let your voice be heard!

Letter from the Editors

Dear Readers,

The world is complicated by day-to-day difficulties that derail our personal consciousness from observing and criticizing issues of real human impact. We live in a time that is dismantled by hunger and food crises, economic meltdown, nuclear development, and political tumult. However, on the brink of important healthcare reform in the United States, bioethics is poised to take center stage in thoughts and minds across the country, which shows that 2009 is a perfect inaugural year for the publication of the *Rutgers Journal of Bioethics*. This issue will stop us in our tracks and focus our attention to bioethics, despite the surrounding adversities. Over the past year, we, along with our editorial staff have worked continually in creating the journal that you hold in your hands.

In these pages, you will find various topics covered from **Posthumous Sperm Procurement** to the ethical issues involving the use **Dwarfs in the Entertainment Industry.** Our goal was to include a wide breadth of topics in order to appeal to a large audience. We also thought it was important for the reader to understand the opinions of Rutgers students, because it is that backdrop that frames our own perceptions of bioethical issues. As such, you will get a sample of how the Rutgers University undergraduate population feels about clinical trials of new drugs in underdeveloped countries and also unbalanced funding for medical programs (HIV vs. Cancer funding). Bioethics is not confined to our university nor is it confined to our country. Although health care reform has only recently reached our attention, other parts of the world have been grappling with their own bioethical contentions. We urge our readers to stay tuned into global affairs. You will find a **Bioethics without Borders** section included in this journal to satisfy just that.

Finally, we would like to thank our hard working faculty advisors, associate editors, and editorial staff. Without their commitment to editing, review, research, creativity and design, we could not have assembled the journal we have today. We would also like to extend our gratitude to our dedicated authors for joining in our cause for bioethical awareness and spending their time reviewing with us. Being as though this is our first jump into the world of journal publication, we have a strong feeling of pride in what we have accomplished over the past year. We hope that you will not only enjoy the articles and features that we have published, but mostly, our hope is that we challenge you to think critically about the issues in front of you. So without further pomp and circumstance, we proudly present to you the premier issue of the *Rutgers Journal of Bioethics*.

Sincerely,

Ami Amin
Molecular Biology & Biochemistry, History

Nathaniel Jones
Cultural Anthropology

Sajel Shah
Psychology

Rutgers University Class of 2010

Should We Help Them Die?

Stephanie Golubic, University of Pennsylvania, Graduate Student[1]

Physician Assisted Suicide (PAS) has been, and continues to be, a common topic of ethical and political debate. People tend to have very passionate stances on the topic, often rooted in personal experience and influenced by the frequent media coverage of end-of-life family feuds and court proceedings of physicians accused to carrying out PAS. In this article, an argument opposing the legalization of PAS is presented.

Physician Assisted Suicide has been subject to ethical and political scrutiny for many years. The United States has been very critical towards the legalization of Physician Assisted Suicide (PAS) as is attested by the fact that Oregon is the only state in the country that has legalized the practice thus far. There are certain scenarios which support the legalization of PAS; however, the potential risks of legalizing the practice overwhelm the benefits of providing the option.

Proponents of legalizing PAS claim that doing so would provide patients with the option of dying with dignity. Palliative care is not always successful in managing pain and PAS would offer patients the option of relieving their suffering when palliative care fails. Legalization of PAS would also provide accountability; thus allowing the practice of PAS to be more highly regulated. Therefore, legalization of Physician Assisted Suicide would minimize the number of unreported and unregulated incidents of PAS.

Despite the validity behind some of these claims, it is important to consider the risks associated with legalizing PAS. One of the most common potential dangers foreseen by those in opposition to PAS is the inability to properly regulate and restrict PAS, which may lead to the ongoing expansion of the inclusion criteria. In addition, the occurrence of skewed decisions made by patients to undergo PAS due to undiagnosed clinical depression or other motives not recognized by the clinical staff, also pose a great risk. While the proponents of PAS may offer possible solutions to these raised concerns, there is not enough evidence supporting their claims to justify legalizing PAS. Therefore, upon weighing both arguments, the benefits of legalizing PAS do not justify the risks associated with it.

Proponents of Physician Assisted Suicide emphasize that legalizing PAS would benefit the individual in numerous healthcare settings. PAS offers a patient more choice at the end of life to decide when their dignity, as they perceive it, is tarnished. This, however, is very subjective because every person holds a different perception regarding what makes life valuable and what is the extent to which it is no longer valuable. Patient advocates might argue that the patient can avoid being seen in a degenerate, helpless state by his loved ones, enabling family and friends to remember him the way that he was prior to the illness. The patient would be remembered by his best qualities, rather than by the image of diminishing mental and physical health.

Supporters of legalizing PAS also argue that PAS would offer relief of suffering for people when palliative care fails. If palliative care efforts are unsuccessful and PAS is implemented, it would prevent the patient from enduring severe pain and relinquish the family and friends from watching their loved one suffer. There are many patients who experience severe pain prior to death, while some endure disabilities that require complete dependence on caregivers. The availability of PAS could enable patients to take control of their condition.

Advocates of the legalization of PAS claim that doing so would result in an increase in palliative care efforts. Due to regulatory procedures, the patients seeking PAS would be required to exhaust palliative care efforts prior to being granted PAS. As a result, relief can be found in a form of palliative care and less people would have to resort to PAS in the end. With palliative care measures being utilized and scrutinized to a greater extent, more efficacious therapies would be developed in order to maximize the care prior to determining that it is ineffective for a patient and going forth with PAS.

If PAS is legalized, it could potentially lead to a decrease in palliative care efforts. When PAS is sought by a patient who passionately believes that PAS is his best option, he may bear an attitude that nothing else will work. There may be somewhat of a reverse-placebo effect during the attempts at palliative care. A patient may convince himself that the therapy that he is receiving is inefficacious with a strong belief that no palliative care methods will relieve his suffering. In an alternate situation in which palliative care is the only option available (where PAS is illegal), the patient may be more willing to accept that the therapy offered will benefit him, seeing no alternative or more effective course of treatment. If a patient believes that

palliative care will not provide any relief, the palliative care treatments may only be tried very briefly in order to fulfill regulations Fewer people will benefit from palliative care if more people opt for PAS, so less emphasis and confidence will be awarded to palliative care over time. Current palliative care minimizes pain and suffering in many chronically ill patients. Since these therapies are generally considered effective, there may be less incentive to further research when PAS is an available alternative. On this basis the difficulty of achieving pain relief would retard and limit, rather than expand, research to improve palliative care as well as decreasing confidence in the capabilities of these therapies.

A final argument in support of the legalization of PAS is that there will be an increase in control over the medical practice and a minimization of the number of unregulated underground cases occurring now. One such case is the one facilitated by Dr. Jack Kevorkian. One may make the argument that other undetected illegal cases of PAS occur. If legalized, these cases can occur legally and would be subject to scrutiny and strict regulations. Physicians and patients would be required to attempt all other palliative care efforts and be subject to a thorough evaluation of the patient's case. This would lower the chances that PAS will be abused.

There is no strong justification or evidence supporting the claim that legalizing PAS would minimize the number of unregulated cases. In actuality, there may be more underground cases taking place to circumvent the regulations placed on PAS. The restrictions imposed by legalizing PAS would require many expensive, time-consuming hurdles to be overcome prior to qualifying for PAS. If PAS is generally accepted by the public and the physicians are familiar with the practice, physicians may be more inclined to skip necessary requirements and testing prior to prescribing the barbiturates. The physician may feel that he is competent to accurately evaluate the patient without consultation and would be less concerned with legal consequences due to the general acceptance of the practice of PAS. With more underground cases or abbreviated evaluations occurring, there is an increased likelihood that physicians will make incompetent decisions and will attribute less attention to the practice of informed consent. The legalization of PAS threatens to push the many moral and ethical boundaries in which we frame our current medical system.

Despite isolated cases in which the PAS option would be favorable and validated, legalization of PAS would be irresponsible. While the individual may benefit in certain situations, societal protection would be compromised to too great an extent. It is more important to protect society as a whole from the potential unethical use of PAS. This obligation to protect society outweighs the obligation to any one individual who may benefit from the option of PAS. The paramount concern is the inability to properly regulate and restrict PAS leading to the ongoing expansion of the inclusion criteria. Regardless of efforts made to regulate the practice of PAS, there is no way to ensure that PAS would be used only as it is initially intended. People may seek PAS when they are not faced with a terminal illness, but rather simply wish to be aided in painlessly committing suicide. Furthermore, legalization of PAS in cases of terminal patients can lead to it being applied to patients with less severe illnesses, such as Schizophrenia or Multiple Sclerosis. It may even stretch to allow parents to request PAS for a child with a severe, life-altering disability. Relatives may be permitted to request it for elderly patients in order to avoid heavy medical burdens issued with hospital care and prolonged treatment. With more and more acceptance, PAS may expand indefinitely to allow almost anybody to seek aid in committing suicide. It would be difficult to prevent such things from occurring and to enforce the regulations put in place initially. Finally, it would be difficult to regulate who is permitted and qualified to elicit PAS and what liability the prescriber should assume. Technically anyone who can prescribe medication may be able to provide a patient with barbiturates. This complicates the ability to regulate PAS and creates scenarios in which a clinician untrained in the regulation and practice of PAS would be facilitating it.

In response to this claim, proponents of PAS would argue that strict regulations and reporting systems would be set up in order to standardize who qualifies for PAS and who is permitted to provide the prescriptions to patients. Testing would be done ahead of time and all treatment options exhausted before PAS is granted. There has been no need for the expansion of regulations in Oregon, which has a very re-

stricted usage of PAS. Therefore, there is no reason to believe that any other states would experience a different outcome.

While detailed regulations can be established, this cannot ensure prevention of abuses and the expansion of PAS. As seen with failures in advanced directives, each situation is unique and it is very difficult to outline exact inclusion criteria. There may be cases which challenge the inclusion criteria or fall into a gray area that is not well defined. One by one, these cases may lead to expansions in the criteria required to qualify for PAS so that more of the population is included. Although not seen thus far in Oregon, it is currently under the ongoing scrutiny of 49 other states. Without distinguished opposition if PAS were legalized in more states, there would be less concern for a regulation that is overlooked now and then, allowing potential for regulations to get lax and the use of PAS to expand overtime.

Another major concern with legalized PAS is the likelihood that patients will make uninformed or undereducated decisions to undergo PAS due to undiagnosed clinical depression or other motives not detected by the clinical staff. A person previously of sound mind may experience deleterious psychological effects when faced with the end of his life or with pain associated with a disease or treatment. In such circumstances, PAS may be sought by patients who are not in a sound mental state to make these decisions. Irrational decisions and actions are likely to occur. Additionally, there are many other factors, such as monetary concerns and family coercion, which may sway a patient's decision to end his life . Burdens including stigma, inability to walk, physical deformities, difficulty speaking, or a requirement for chronic administration of many medications may make someone consider death as a solution. A possible example of such motives can be observed in Oregon. Though not every case is due to depression or skewed decision-making, AIDS patients are at a heightened risk for abuse of PAS [1]. Due to current drug therapies, AIDS patients generally live a high-quality, average life. The reputation of AIDS in the US has changed; it is often considered to be a chronic disease, rather than a terminal one because of the new drug therapies. Some of the decisions to undergo PAS are made in a vulnerable and irrational state, influenced by undetected motives such as stigma or depression rather than choosing PAS as a last resort to avoid suffering due to a terminal illness.

PAS advocates argue that there will be thorough psychological evaluations required for people seeking PAS to rule out depression and preclude possible coercion. While ideal circumstances permit accurate psychological evaluations to be completed in every situation, psychological evaluations often do not recognize clinical depression, at least in a single assessment. Yet if a patient knows that he is being evaluated and that the availability of PAS relies on the evaluation, the patient could intentionally give a false impression of being of sound mind. It would be very difficult to assert that psychological evaluations would ensure that every patient choosing to seek PAS is in a clear and rational state of mind.

Legalization of PAS offers many valid and substantial arguments, but there are many more serious concerns that oppose this assertion. Although proponents of PAS may counteract the objections and likely risks, there is still a substantial likelihood that the potential risks may result in severe consequences if PAS was to be legalized. There is no evidence that the solutions suggested by proponents would eliminate the impending negative results. While certain individuals may benefit from gaining the option to choose PAS, there are overwhelming societal risks and problems related to the many people lacking the autonomy and mental stability to make rational decisions regarding PAS. The possible benefits of PAS do not justify assuming the risks associated with legalizing the practice.

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The Possible Impact of iPS Cells on the Ethical Dilemma of Stem Cell Research

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The polarized atmosphere surrounding the stem cell research seems more daunting as time goes by. Presently in the United States, both supporters and naysayers of stem cell research are taking legislative measures in order to further their own agendas, whether it be pushing for embryonic stem cell research to take place or halting embryonic stem cell research. Induced pluripotent stem cells (iPS) may provide a bridge to gap these two perspectives. These iPS cells are somatic cells that have been induced to become stem cells by changing the cell's genetic makeup. This theoretically solves the ethical dilemma surrounding stem cell research but there is still a long way to go before iPS cells can be utilized for therapies. There are many obstacles that stand between therapeutic use of iPS cells, however, the possibilities that iPS cells can provide are something to be optimistic about.

In today's medical landscape, ethics serve as the gates of action. They serve as a test to determine right and wrong, to provide an efficient and fair protocol to practicing medicine, and to develop solutions to ethical issues within medicine. One major issue that is being largely debated in the field of medical ethics is the usage of stem cells for medical means. The topic has evoked massive polarization among numerous notable political, religious, and cultural figures. This sensitivity towards stem cell research is understandable because both sides are presenting ideas that can potentially and radically redefine how we view ethics and how we view the practice of medicine in the future. Stem cell advocates have pushed for furthering research in order to discover capable uses of stem cells in medicine while pro-life activists have fought hard to rally public support for legislation that would restrict the use of embryonic stem cells in research. The clashes between the two viewpoints have gotten more frequent and as a result, tension has developed between the supporters of both sides.

Recently, legislation passed in the United States has pushed both the sides' agendas further. For example, in the state of North Dakota, a new bill passed in February 2009 gave a fertilized egg all the rights of a human being.[1] The nuances of this newfound social contract directly equate stem cell research with murder. Some aspects of stem cell research do involve embryonic destruction and under new legislation, this destruction is now legally equated with taking a life. While stem cell research is limited in North Dakota due to new legislation, Michigan has stepped out in support for this issue. Last year Michigan passed Proposition 08-2, a bill that amends the restrictions that were previously held on stem cell research in the state.[2]

Most notably, the Barack Obama administration has brought a positive outlook towards stem cell research to the executive office. Just recently, Obama lifted the embryonic stem cell funding ban that had been issued under the Bush administration, which limited the National Institute of Health from funding various research regarding embryos and embryonic stem cells. By lifting the ban, the federal government has now put forth new, more lenient, regulations on stem cell research and has made it possible for federal funding to be directed towards developing these cells for medical therapies in the future. This legislation has excited many leaders in the scientific community but has been heavily scrutinized by many of the conservative and religious leaders.[3] As both sides push for their agenda, it is evident that this polarizing issue is far from finding a unified solution with regards to the merits of a possibly revolutionizing medical technology.

The hope of developing a universal view on the ethics of this issue is dwindling away. Does this mean that there is no way to circumvent this ethical dilemma in the near future? Developments in biology

may have set up a foundation to the eventual discovery of an answer to this ethical dilemma. In 2006, a team of scientists discovered a way to genetically transform regular mouse skin cells into stem cells by implanting certain genes that controlled the cell's identity. Using a retrovirus, four genes (c-Myc, Sox2, Klf4, and Oct3/4) were inserted into the host skin cells. These four factors were incorporated into the host cells' DNA genome, which reprogrammed the cells' properties. The goal of this method was to create cells that have the capability to become various different types of cells without implementing embryonic stem cells. While the idea was innovative and the first batch of induced Pluripotent Stem cells, or iPS cells, was a major breakthrough in the field of biotechnology, work was still needed in order for iPS cells to be considered a viable alternative to regular embryonic stem cells. The success of the initial batch of iPS cells fueled other teams to pursue similar experiments in order to make more efficient iPS cells. In 2007, another team produced iPS cells that were almost identical to embryonic stem cells, sending shockwaves throughout the scientific community.[4] The scientific community is still exploring the possibilities that iPS cells could provide; iPS cells are certainly being looked at more closely as a viable source for stem cell therapy.

In terms of ethics, iPS cells hail as the future's most promising answer to the dilemma of stem cell use for medical research. If these cells can live up to their theoretical potentials, iPS cells will diminish any moral baggage that may be tagged with the present day notion of 'stem cell research' since embryos will be preserved in the process. The technology used to make iPS cells is greatly advancing and it is hard to say at which point iPS cells themselves may be deemed unethical similar to stem cells. Genetically engineered cells hold potential for the creation of genetically engineered individuals, which could lead to a discussion regarding eugenics. Eugenics refers to the ideology, which suggests that the human qualities can be “improved” genetically. This ideology has been met with much opposition in the past and iPS cells may force leaders in the world community to consider the pros of iPS technology to the cons of eugenics and “improvement” of the gene pool. At this point, future speculations are moot; it is certain however that iPS cells may be the solution to a current polarizing ethical issue.

From a biological standpoint, it is important to consider the influence of iPS cells on the practice of medicine. Stem cells were originally valued upon their ability to adapt to multiple organ systems and the recent successes surrounding iPS cells may allow iPS cells that same adaptability. A notable theory that has emerged considers iPS cells to treat diseases that were thought to be untreatable. One group has already found a method to convert regular fibroblast cells from individuals that are afflicted with Parkinson's Disease into iPS cells, which then in turn, have developed into dopaminergic neurons. The development of these iPS cells into these dopaminergic neurons may eventually become a legitimate treatment for Parkinson's Disease. This is a groundbreaking development because in the past, Parkinson’s patients have not had many legitimate treatments to counter the effects of the disease.[5] This is just one of the numerous examples of how iPS cells are being utilized in medicine.

Is it too early to say that iPS cell therapy is the modern panacea? In reality, because iPS cells are still in their infancy in terms of development, little is known about their full potential and even possible repercussions. One main concern with using iPS cells is that they are very similar in properties to cancer cells. In fact, one of the four integral genes that were used to transform the somatic cells into stem cells, c-Myc, showed some tumor inducing properties in a reasonably small, yet evident, percentage of the mice that were used during the experiment. [6] One should note, this method has been reworked to exclude the c-Myc gene and has produced astonishing results in which iPS cells still developed, although to a lesser degree, without producing any tumors in the mice. [7] More recently, discoveries have been made in terms of developing new ways of inserting these four genes to form transgenic cells. A new method that is being looked at involves the PiggyBAC system in which the genes convert the cell but then are excised out safely, thus lessening the chances of the cell becoming cancerous.[8] This new method effectively reduces the concerns that are currently attributed to iPS cells and should be further explored in order to maximize safety and efficacy. With that said, however, it is still too early to rule out any possible negatives of iPS cells because they are still not fully explored.

In conclusion, we note that embryonic stem cells are still perceived as a major ethical issue on the world stage. This ethical disagreement seems like it is far from being settled as each side lobbies to instill their beliefs into government. Hopefully iPS cells can provide this closure to the topic and circumvent this pressing ethical problem. While one must be cautious before jumping to conclusions about what can be achieved using iPS cells, it is hard not to ignore the possibilities of developing these cells for public use in medicine. The concerns that have been brought up about iPS cells are very real; however, legitimate solutions seem like they are underway, providing hope that one day untreatable diseases may be effectively treated.

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Bioethics Society of Rutgers University

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The Bioethics Society is offering a "Journal Design Contest" to all interested in designing the cover page for its upcoming publication. Use your creativity to design the cover page for a bioethics journal. Winners will have their original designs published in a Rutgers publication. In short, bioethics deals with the ethical issues that concern current advances in science and technology. Abortion, euthanasia, human drug experimentation, environmental studies, and human cloning are some examples of issues within our scope. We are looking for a unique image that might pertain to any one of these topics as well as other bioethical topics.

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Ethical Implications of Psychopharmacologic Drug Direct-to-Consumer Advertising

Michael P. Donnelly MBE[1] and Shivram Sankar JD, MBE[2]

Direct-to-consumer advertising of psychotropics, as compared to general pharmaceuticals, has unique ethical implications: heightened safety and misinformation concerns, pathologization of normal states, greater off-label use, and reduction in alternative treatment-seeking. More stringent FDA advertising requirements for psychopharmaceuticals may be a viable way to address these issues.

I. Introduction

Until recently, pharmaceutical companies' main targets for the marketing of drugs were clinicians. "The major vehicles for 'educational promotion' were advertisements in professional journals and visits and gifts from pharmaceutical representatives."[1] However, direct-to-consumer advertising (DTCA) has dramatically altered this dynamic. Although pharmaceutical companies began advertising to consumers in 1981, it was not until 1997 when the U.S. Food and Drug Administration (FDA) loosened regulations on marketing that there was an explosion in DTCA. Over the last several years there has been a drastic increase in direct-to-consumer psychopharmaceutical or psychotropic advertising.[2] This has ranged from treatment for depression to hyperactivity to sleep disorders to even schizophrenia.

While there are significant ethical issues involved in general pharmaceutical advertising, psychotropic DTCA introduces unique ethical issues that have yet to be considered by FDA. The safety and efficacy of psychotropics is not as well-established as other pharmaceutical drugs and the potential for misinformation is much greater. In addition, advertising of psychotropics can lead to pathologizing of a normal state, increased off-label drug use, and reduction in alternative treatment-seeking, such as cognitive therapy.

Enacting more stringent and drug class-specific FDA advertising requirements for psychotropics as compared to other pharmaceutical drugs may be one way to address these issues. Although there are some negative implications for heightened requirements, these measures may be necessary to address some of the profound negative consequences of psychopharmaceutical DTCA.

II. Marketing Psychopharmaceuticals

Since 1997, psychopharmaceutical advertising has grown parallel to general pharmaceutical advertising. In 2000, Paroxetine (Paxil), a Selective Seratonin Reuptake Inhibitor (SSRI), was the fourth most advertised of all prescription drugs, with $92.1 million spent in DTCA and was thus also one of the most widely prescribed that year.. In the wake of Paxil's success, there has been a dramatic increase in the advertising of SSRIs, or anti-depressants, such as Zoloft, Prozac, and Effexor. One result of DTCA is that growth occurs in the therapeutic class as a whole, rather than increasing individual market share of the individual drug.[3] In fact, DTCA have little effect on choice of medication, but instead dramatically impact overall growth in that class of pharmaceuticals, as seen in anti-depressants and psychostimulants.

While advertising for psychotropics has risen, dramatically increasing psychopharmaceutical prescription and use, FDA has yet to review psychopharmaceutical advertisements independently from other pharmaceutical advertisements. As this paper will discuss, psychotropic drug advertisements raise a host of unique ethical issues, distinct from general pharmaceutical advertisements. As the amount of advertising for psychopharmaceuticals continues to increase, it is crucial that FDA and other related oversight bodies recognize these issues.

III. Heightened Safety and Misinformation Concerns

One of the major ethical concerns regarding DTCA is that they downplay potentially serious safety issues, normalizing highly potent prescription medication, and misinforming consumers on the effectiveness of the drug. For example, the massive DTCA campaign waged by manufacturers of Cox-2 inhibitors, such as Vioxx, caused dramatic growth in sales, even though these drugs were never proven statistically to be more effective than drugs over the counter.[4] In addition, the significant side effects of Cox-2 inhibitors were not disclosed to the public in advertising.[5] There have been as many as 140,000 serious cardiovascular events due to Vioxx alone.[6]

In addition, surveys have shown that consumers have misconceptions about DTCA. One survey noted,

"50% of consumers believed that DTC advertisements had to be preapproved by the government and 43% believed that only 'completely safe drugs' could be advertised."[7] A 2002 FDA survey found that "42% of consumers said the [DTC] advertisements made it seem that the drug would work for everyone."[8] This is serious cause for concern, particularly because, as discussed later, FDA's ability to regulate DTCA is extremely limited.

These potential safety and misinformation concerns are heightened for psychopharmaceutical advertisements. Psychiatric disorders are distinct from other disorders, because unlike other maladies, they are defined more by symptoms rather than etiology, or underlying causes. For example, rather than assessing whether there are low serotonin levels in an individual patient's brain and then prescribing an SSRI, a patient is evaluated behaviorally, deemed to be depressed, and subsequently prescribed an SSRI on the presumption that they must have low serotonin levels.[9] Because neurological disorders are not as well defined as other disorders, with a focus on symptoms rather than causes, there is an increased risk that explanations of treatment and disorder will be over-simplified and drug efficacy will be exaggerated. For example, antidepression advertisements for SSRIs, such as Zoloft, Prozac, or Effexor, misinform consumers by claiming that SSRIs correct a "chemical imbalance" caused by a lack of serotonin in the brain.[10] Television advertisements, such as those for Zoloft, show a simplified version of a neurochemical pathway to explain how the drug works to increase or correct the lack of serotonin imbalance. However, there is considerable controversy regarding the serotonin hypothesis. The primary studies justifying the theory have had small sample sizes and confounding variables.[11] In addition, attempts to induce depression by depleting serotonin have failed, and contemporary research has failed to confirm any serotonergic lesion in any mental disorder.[12] In fact, studies have shown that significant increases in brain serotonin, administered by high-levels of L-tryptophan, have no discernable effect on relieving depression.[13]

Even if an increase in serotonin does mitigate or treat some symptoms of depression, the way SSRI advertisements are presented is incomplete at best. By focusing on a single neurotransmitter, pharmaceutical advertisements mislead consumers into believing that there is a cure for depression and that depression treatment is simple and straight-forward. This can potentially lead to over-prescribing patterns, a reduction in alternative treatment seeking, and increase in off-label use.

Safety concerns are also not fully addressed in psychotropic DTCA. This is troubling considering that safety implications are far more profound in mental disorders than other areas, involving loss of "self," abuse and addiction, and even death. For example, although there is potentially a 2-3% increase in risk of suicide associated with SSRIs, the risk is not addressed in most of the major anti-depression advertising campaigns.[14] In fact, the DTC advertisements that do discuss suicide, such as one for Zoloft, try to dissociate the drug from suicide. FDA issued a notice of violation to the maker of Zoloft to remove one of their print advertisements, which claimed that, "[a]lthough there has been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients, a causal role for antidepressants in inducing such behaviors has not been observed."[15] While FDA finally required SSRI manufacturers to include information about the potential for increased suicide among adolescent users, it has yet to address this issue in adult-users.[16] While the casual relationship between depression and antipsychotics is complex, it is still important that the public be made aware of this potential danger.

Perhaps more alarming is the failure of SSRI manufacturers to report on the potential addictiveness of the drug in their DTC advertisements. Once started on the SSRI chemical regime, trying to reduce dosage can result in severe withdrawal symptoms. There is mounting evidence that SSRIs with longer half-lives, such as Prozac and Zoloft, also have a potential for addiction.[17] Despite this, both Zoloft and Prozac advertisements and websites assert that their drug is non-habit forming. Ultimately, the addictive nature of these drugs has become apparent, leading to significant social problems such as abuse.

Although FDA must ensure that prescription drug advertisements are "truthful, balanced, and effectively communicated", FDA has systematically failed to respond adequately to psychopharmaceutical advertising. Between 1997 and 2006, FDA has issued only twelve "notice of violation" letters regarding psychopharmaceuticals.[18] These letters "direct drug companies to remove or correct advertisements that contain false or misleading information."[19] In fact, as psychotropic advertisements have increased, the number of notice of violation letters have decreased, with six in the first three years and only six in the subsequent seven years.[20]

IV. Pathologizing Normal Conditions and Experiences

While all DTC advertisements can potentially result in over-prescription, DTC advertising campaigns that promote psychopharmaceuticals have the unique potential to

pathologize normal experiences and conditions.

A. Misdiagnosis and Over-Medicalization

Because psychiatric disorders are, by their nature, less clearly defined than other disorders, there is an increased risk that patients will be misled into believing that they need medication. As discussed earlier, most neurological disorders are defined by their symptoms. Brain scans are usually only reserved for the most severe neurological conditions, and most people with neurological disorders, such as ADHD, depression, or anxiety, are categorized as such based on self-evaluation of symptoms.[21] As a result, there is an inherent risk for people to believe that they suffer a neuropathology, rather than something that can be objectively verified, like a heart condition.

This risk is exacerbated by DTC advertisements, such as those for Zoloft, which say: "depression can affect anyone" and "more people suffer from depression than you think."[22] The pharmaceutical industry touts that diagnosis and treatment of depression doubled in the 1990s as a result of greater awareness of the disease through DTCA.[23] However, this may only reflect an increase in patients requesting the medication and a greater physician willingness to prescribe. A recent study by Kravitz *et al*. found that pseudo-patients (actors trained to behave as patients) presenting symptoms of adjustment disorder, a condition for which anti-depressants are not usually prescribed, were frequently prescribed Paxil if they specifically asked for it.[24] Before the creation of antidepressants approximately 50 to 100 people per million were thought to be depressed; now, the estimated figure is 100,000 to 200,000 per million.[25]

B. Expanding List of Potential "Disorders"

In addition to concerns about misdiagnosis, drugs such as Zoloft, Prozac, and other antidepressants have been approved for an ever-expanding list of conditions including anxiety, obsessive-compulsive disorder, post-traumatic stress disorder (PTSD), premenstrual dysphoric disorder, panic disorder, and social phobia/ social anxiety disorder.[26] As the classes of disorders expand and the availability of drugs to treat these disorders expands with it, there is a greater potential for physicians and psychiatrists to prescribe SSRIs or similar psychotropics for ordinary behavioral conditions and experiences.

Pharmaceutical marketing departments employ an "ever-greening" strategy, whereby once one use for an SSRI or antidepressant is found, the company then explores other "green" pastures for potential markets.[27] Once the most lucrative potential market is determined, it is capitalized on through the launch of another advertising campaign. McHenry, argues that the expansion from depression and anxiety to other disorder symptoms was part of a systematic strategy developed by pharmaceutical companies. Once the SSRI was approved for a new "disorder," a new public relations "awareness campaign" would be instituted for the disorder, paid for by pharmaceutical interests.[28] The result is increased anxiety among normal people regarding the disease and more people seeking unnecessary treatment in that area. He argues that the marketing campaign will continue to expand into new potential areas, as already

indicated by industry-led clinical trials, into more ordinary psychological experiences, such as binge-eating, premature ejaculation, obesity, alcoholism, smoking cessation, compulsive shopping, and premenstrual syndrome.[29] DTC psychopharmaceutical advertising campaigns can therefore not only expand sales of that specific drug and class of drugs, but because of the nature of neurological disorders, expand the kinds of disorders that the drug can treat.

V. Reducing Alternative-Treatment Seeking

The emphasis on pharmaceutical solutions in DTC psychopharmaceutical advertisements not only increases the potential scope of mental disorders but also reduces the potential for patients to seek alternative, non-pharmacological, treatment options.

An empirical study cited in the *Journal of Public Policy & Marketing* found that while DTCA spending is positively correlated with the number of anti-depression prescriptions filled, they are not correlated with the number of depression or anxiety diagnoses.[30] This indicates that while DTCA may not necessarily increase the number of people diagnosed with depression or anxiety, DTCA are increasing the potential for those diagnosed to be treated with prescription drugs.

To support this, there is evidence that by specifically focusing on a "chemical imbalance" in the brain, DTCA for anti-depressants limit the kinds of treatment that patients will seek. One study found that patients who are convinced they are suffering from a neurotransmitter defect, a common claim of SSRI anti-depression advertisements, "are likely to request a prescription for antidepressants, and may be skeptical of physicians who suggest other interventions, such as cognitive-behavioral therapy, evidence-based or not."[31] These patients can exert a profound effect on how doctors view treating a disorder. As discussed earlier, in the Kravitz study, pseudo-patients were of high likelihood to be scripted Paxil if they directly asked for it, even if they showed symptoms of adjustment disorder where antidepressants are not usually prescribed.[32] Psychiatrists do so even though researchers have shown that cognitive behavioral therapy can be as effective as medication for treating depression.

VIII. Conclusion

In the past several years there has been dramatic growth in the amount and scale of psychopharmaceutical DTCA. There are profound and unique ethical implications associated with these advertisements that must be addressed. Psychopharmaceutical advertisements have the potential for heightened safety and misinformation concerns because of the nature of neurological disorders. Such advertisements further have the potential to pathologize normal human experiences and reduce the use alternative, non-pharmacological treatments. Also, while not discussed in this paper, as neuroenhancement becomes more viable, DTC neuroenhancement advertisements may fundamentally alter the physician-patient relationship and blur the line between normality and disorder. DTCA in regards to pychopharmaceuticals could potentially abrogate the role of physicians from health care providers to lifestyle enhancers. It is imperative that FDA and other government oversight bodies, and other advocacy organizations consider these ethical issues in regulating psychotropic DTCA, before this line has been crossed.

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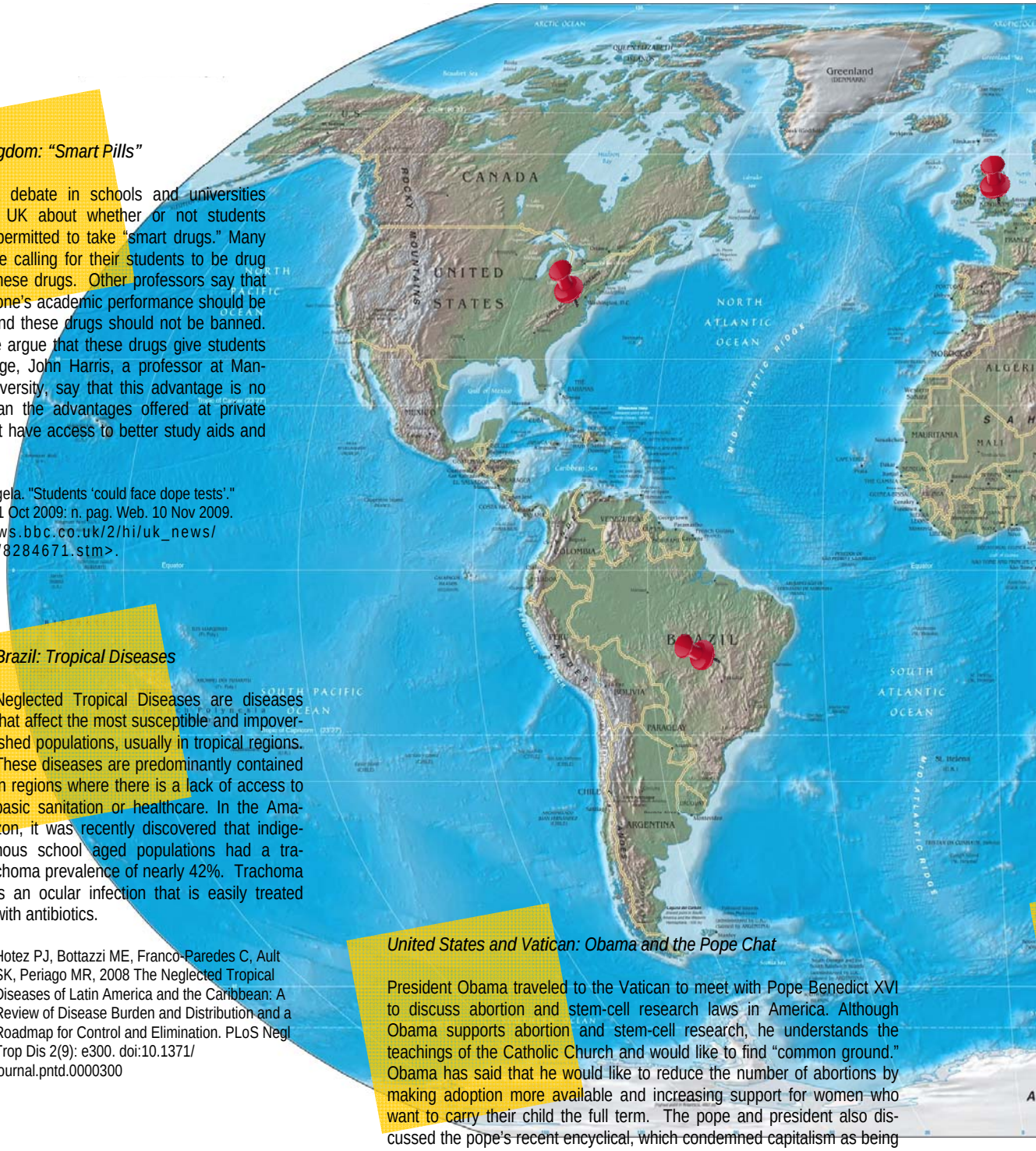


United Kingdom: "Smart Pills"

There is a debate in schools and universities across the UK about whether or not students should be permitted to take "smart drugs." Many teachers are calling for their students to be drug tested for these drugs. Other professors say that enhancing one's academic performance should be permitted and these drugs should not be banned. While some argue that these drugs give students an advantage, John Harris, a professor at Manchester University, say that this advantage is no different than the advantages offered at private schools that have access to better study aids and technology.

Harrison, Angela. "Students 'could face dope tests'." BBC News 01 Oct 2009: n. pag. Web. 10 Nov 2009. <http://news.bbc.co.uk/2/hi/uk_news/education/8284671.stm>.

Brazil: Tropical Diseases

Neglected Tropical Diseases are diseases that affect the most susceptible and impoverished populations, usually in tropical regions. These diseases are predominantly contained in regions where there is a lack of access to basic sanitation or healthcare. In the Amazon, it was recently discovered that indigenous school aged populations had a trachoma prevalence of nearly 42%. Trachoma is an ocular infection that is easily treated with antibiotics.

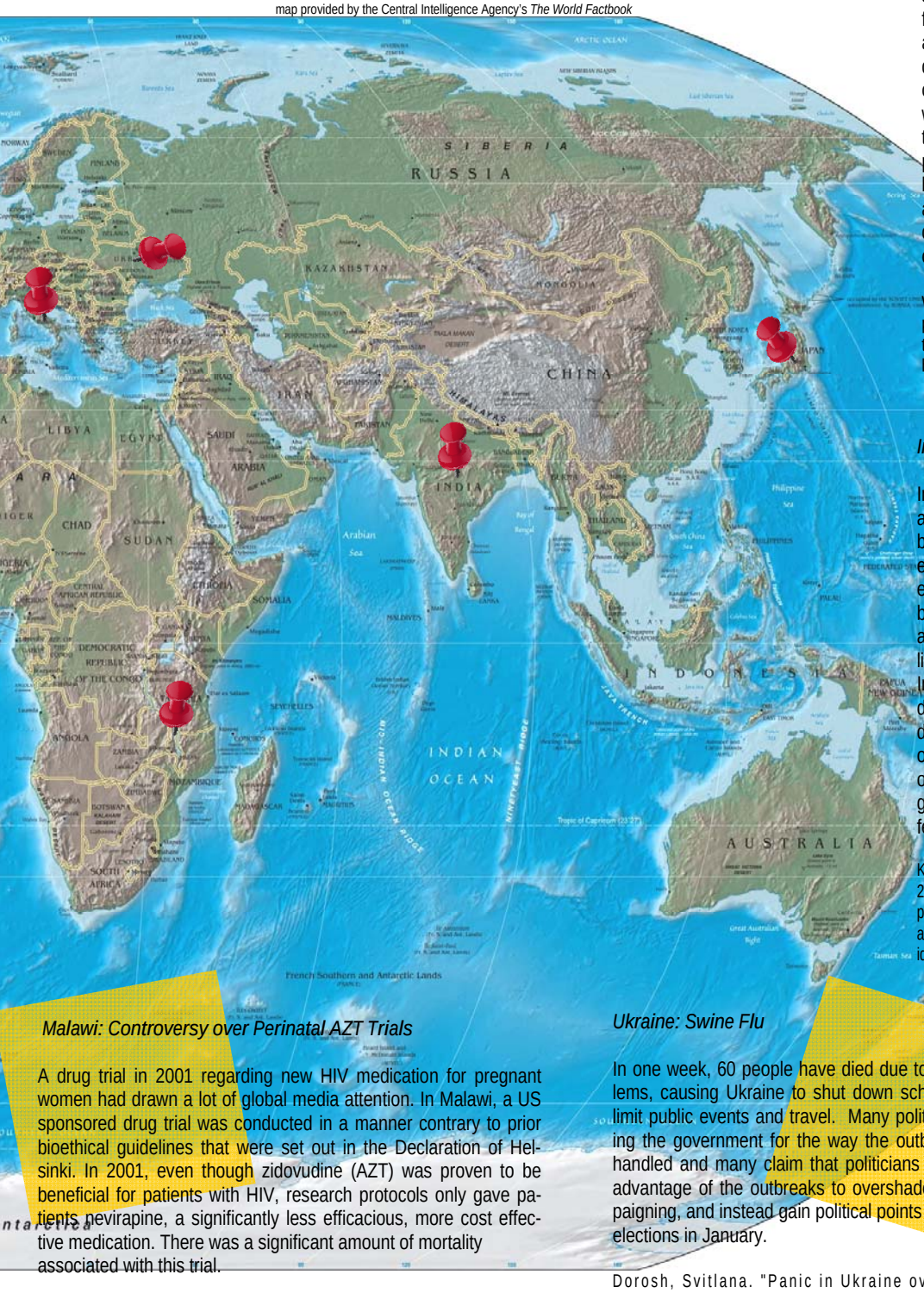
Hotez PJ, Bottazzi ME, Franco-Paredes C, Ault SK, Periago MR, 2008 The Neglected Tropical Diseases of Latin America and the Caribbean: A Review of Disease Burden and Distribution and a Roadmap for Control and Elimination. PLoS Negl Trop Dis 2(9): e300. doi:10.1371/journal.pntd.0000300

United States and Vatican: Obama and the Pope Chat

President Obama traveled to the Vatican to meet with Pope Benedict XVI to discuss abortion and stem-cell research laws in America. Although Obama supports abortion and stem-cell research, he understands the teachings of the Catholic Church and would like to find "common ground." Obama has said that he would like to reduce the number of abortions by making adoption more available and increasing support for women who want to carry their child the full term. The pope and president also discussed the pope's recent encyclical, which condemned capitalism as being unethical.

"Vatican, White House: Abortion one topic of Obama-pope chat." *CNN News/ Europe* 10 Jul. 2009: n. pag. Web. 10 Nov 2009. <http://www.cnn.com/2009/WORLD/europe/07/10/obama.pope/index.html>

map provided by the Central Intelligence Agency's *The World Factbook*



Malawi: Controversy over Perinatal AZT Trials

A drug trial in 2001 regarding new HIV medication for pregnant women had drawn a lot of global media attention. In Malawi, a US sponsored drug trial was conducted in a manner contrary to prior bioethical guidelines that were set out in the Declaration of Helsinki. In 2001, even though zidovudine (AZT) was proven to be beneficial for patients with HIV, research protocols only gave patients nevirapine, a significantly less efficacious, more cost effective medication. There was a significant amount of mortality associated with this trial.

Claire L. Wendland. "Research, Therapy, and Bioethical Hegemony: The Controversy over Perinatal AZT Trials in Africa." African Studies Review 51.3 (2008): 1-23. Project MUSE. [Library name], [City], [State abbreviation]. 12 Jun. 2009 <http://muse.jhu.edu/>.

Ukraine: Swine Flu

In one week, 60 people have died due to respiratory problems, causing Ukraine to shut down schools, universities, limit public events and travel. Many politicians are criticizing the government for the way the outbreaks have been handled and many claim that politicians are trying to take advantage of the outbreaks to overshadow negative campaigning, and instead gain political points for the upcoming elections in January.

Dorosh, Svitlana. "Panic in Ukraine over swine flu." BBC News 3 Nov. 2009: n. pag. Web. 10 Nov 2009. <http://news.bbc.co.uk/2/hieurope/8338835.stm>.

Japan: Brain Death Controversy

Approximately 70% of transplanted kidneys and 80% of segmental liver procedures performed in Japan are live donor organs. While almost half of Japanese people accept brain death as consistent with death, organ procurement from brain-dead donors is not widely accepted in Japan. Many factors contribute to this regulation, including distrust of physicians, past inaccuracies in determining brain death, insufficient resources (ie, staff and technology) to adequately apply brain death criteria, and traditional cultural beliefs concerning life and death.

Wicks, Mona Newsome. "Brain death and transplantation: the Japanese". Medscape Transplantation. 25 April 2000. : n. pag. Web. 10 Nov 2009.< http://www.medscape.com/viewarticle/408769>

India: Female Infanticide

In India, gender disparity is still culturally acceptable. In traditional communities, the birth of a girl is often seen as a liability especially because of the banned, yet existing practice of dowry—in which the bride's family pays the groom with cash and goods. In the past 20 years, 10 million newborn girls have been killed in India by her own parents. New scientific developments have made sex-determination possible at an early stage of pregnancy, allowing parents the option of legally aborting their daughter. Is it a good idea to legalize abortion to prevent female infanticide?

Kumar, Palash. "India has Killed 10 Million Girls in 20 Years". ABC News Health. 15 Dec. 2006. : n. pag. Web. 10 Nov 2009. <http://abcnews.go.com/Health/story?id=2728976&page=1&page=1>

An Ethical Analysis of the Use of Individuals with Dwarfism in Entertainment

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The involvement of individuals with any of over 500 types of dwarfism in the entertainment industry is a controversial issue. Opponents will likely argue that their participation will be potentially harmful to both the individual dwarf and his or her community. However, the inclusion of persons with dwarfism in entertainment careers can be beneficial in numerous ways, including promoting positive self-images for all dwarfs and easing potential alienation by de-sensitizing the general public and erasing harmful false stereotypes. Even if there are legitimate concerns about the possible effects that dwarf entertainment may have on the dwarf community, we cannot accurately count the interests of the group against those of the individual because the interests of the group may not be common to all its members. While there may be forms of dwarf entertainment that could be damaging to persons with dwarfism, these do not ethically justify any attempts to keep dwarfs from participating in entertainment. The practice of prudential decision-making is the best way to determine the involvement of dwarfs in entertainment roles. These decisions can best be made, and certainly should be made, by the individual.

The use of persons with dwarfism in entertainment is a "centuries old" practice. Opponents of this will argue that the representation of the dwarf community through various forms of entertainment may cause more harm than good because it often leads to discrimination or false stereotypes. Others will argue that it is the right of each individual dwarf to do what he will with his body. In this essay, I will provide an ethical analysis of dwarf entertainment, and specifically dwarf comedy. I will utilize research in disability ethics as well as comparisons to other forms of entertainment to determine that dwarf entertainment can be used to the advantage of the dwarf community; I will also consider the ways in which it can be potentially detrimental to its social standing, and what is necessary to avoid this. As I will show, we must rely on an ethics of prudence to determine the morality of dwarf entertainment on a case by case basis.

There are known to be over 100 types of dwarfism, the majority of which are thought to be genetically linked and fall under the name Achonodroplasia.[1] There are generally two types of achonodroplasia: those persons with proportioned limbs, referred to as midgets, and those with disproportionate limbs, generally referred to as dwarfs.[2] In this paper I will be discussing issues related to persons who have both forms of dwarfism. The history of persons with dwarfism in entertainment goes back for thousands of years. In ancient Egypt, dwarfs held the positions of personal attendants, animal tenders, jewelers, and entertainers.[3] There is evidence that during this time period that dwarfs were seen as equals in society and their disorder was not seen as a disability; in some cases, they even held very high ranking positions.[4] In the middle ages, those with dwarfism maintained their roles as jewelers and jesters.[5] Now, people with dwarfism can be seen in forms of entertainment varying from leading roles in movies (i.e. Verne Troyer as Mini-Me in the film *Austin Powers*) to commercial spokesmen, entertainers at parties to those who hire themselves out for "dwarf tossing" events.[6] Also, persons with dwarfism have created an organization known as the Little People of America (LPA) whose mission is to improve the lives of dwarfs everywhere through social interaction, medical support, education and scholarships (see LPA).

The presence of individuals with dwarfism in entertainment is a unique opportunity for the dwarf community. It provides dwarfs with an opportunity to showcase their talents, their culture, and to dispel any misconceptions or false stereotypes about their appearances or personalities. While a dwarf's physical impairment may prevent them from performing some physical tasks required in the manual labor industry, they can instead utilize their characteristics (if they so choose) to fill another of society's needs: entertainment. For these reasons, it is essential that restrictions are not placed on the access of those who have dwarfism to entertainment roles.

Opponents of dwarf entertainment are likely to argue that it threatens the dignity of both the dwarf entertainer/comedian and the dwarf community as a whole. They will use the concept of dignity to defend their position that the involvement of dwarfs in entertainment will be somehow damaging to the dwarf's psychological or social well-being. However, as Ruth Macklin states, dignity is a concept that is basically synonymous with autonomy.[7] She concludes that the common use of dignity is equivalent to respect for persons; this entails voluntariness, informed consent,

and the absence of discrimination and abuse.[8] In its common use, dignity is often used in reference to persons in "end of life" care. In these cases, the dignity that is being described is the opportunity to make one's own choices about their own death, which is the equivalent of autonomy. Other times it is misused in place of terms such as abuse or degradation; this occurs most commonly in reference to sexual acts.[9] Because of this uncertainty in definition and usage, I believe we can conclude that Macklin's argument is strong; therefore autonomy is a better definition to use in this context. Thus, if we can determine that dwarf entertainment does not infringe on the autonomy of the comedian with dwarfism, then we can safely say that the dignity of that comedian is also not impacted. I believe that we can determine that the autonomy of the dwarf entertainer is not violated. Individuals with dwarfism who are interested in careers in entertainment are not prevented the opportunity to pursue this goal and they are free to go into any job opportunity with the knowledge of what their role will be; it is also important to note that the actor with dwarfism is not forced to participate in his role. The only possible concern could be that of undue inducement on the part of a media producer, in which the dwarf is paid unreasonably large amounts of money to perform his or her act. However, this is not a significant concern because I believe we are justified in the assumption that media producers are not paying extreme sums of money in order to coerce individuals with dwarfism into the entertainment industry. Therefore, we can dismiss the concern about the dignity of the dwarf entertainer.

If there are still lingering concerns about dwarf autonomy, let us consider if dwarf entertainment is deemed to be unethical. In this case, it would be the ethically reasonable decision for society to enact laws prohibiting persons with dwarfism from participating in entertainment careers. But limiting employment opportunities for a community of people with an already physically-limited range of possibilities is not what would be considerable for their best interests. Dwarf entertainment poses no physical threat to dwarfs, nor does it conflict with any societal laws. Thus, we can see that the prevention of dwarfs from entering entertainment careers would be unreasonable.

Another legitimate objection to dwarf entertainment may be that of the interests of the dwarf community. Dwarf entertainment that reflects the dwarf community in a negative or degrading way may cause unnecessary pain on the dwarf population. However, as McGee points out in his article on the practice of dwarf-tossing, the community does not have interests; there are only the interests of individuals.[10] Furthermore, society cannot have a common goal because each individual member has different goals.[11] Therefore, when trying to weigh the interests of the entertainer with dwarfism against those of his community, we cannot logically count the interests of the community as outweighing those of the individual because they are not necessarily shared by the entire community. It is more ethically responsible to concern ourselves with the individual interests of the dwarf entertainer than to argue on the grounds of group interests.

However, I will not claim that we can completely ignore the possible effects on the dwarf community. In his essay on the disabled in the media, Colin Barnes asserts that "disabled people have been a source of amusement for non-disabled people for centuries".[12] He claims that exploitative entertainment undermines opportunities for the disabled to be taken seriously and may harm their self-confidence.[13] Further he claims that, even if it is true that all facets of society take their share of criticism at the hand of comedy, it is not warranted for the disabled because there aren't any counteractive, positive images to offset the ridicule.[14] While this argument may seem to condemn dwarf entertainment, I believe that it gives too little credit to the dwarf community, and to the disabled in general. The idea that the disabled are merely objects of ridicule denies the fact that they have the potential to produce positive self-images about themselves. By denying them access to entertainment careers, we would be denying them the chance to represent both themselves and their community in a positive way so as to offset any possible negative image. While it is likely that some forms of entertainment will produce negative images of persons with dwarfism, it is unrealistic to believe that all entertainment will represent them in such a way. Furthermore, the presence of individuals with dwarfism in entertainment may actually be necessary. For roles designed for or best played by a person with dwarfism, I believe that it is absolutely essential that they are allowed to fill them. The portrayal of a dwarf by a normal sized person would be potentially even more insulting and demeaning to the dwarf community than any possible performance by a person who actually has dwarfism because, in this case, at least the dwarf will be able to make a judgment whether the role is appropriate or not.

Just as it is possible that dwarf entertainment could pose potential risks to the dwarf community, it also yields potential benefits. Stronach and Allen suggest that disabled people produce humor about themselves as a means of easing the alienation they would otherwise experience.[15] Robillard calls this mechanism "self-work". He describes this as "the implementation of socially known scripted talk, gestures, postures, grooming, clothing and ways of moving" used in relations with others.[16] Dwarf entertainment and comedy

in particular can be considered a likely extension of this concept. Those dwarfs capable of entertaining society or, in the eye of the media, can effectively "self-work" for both themselves and their community. Depending on the way in which the dwarf entertainer represents himself, dwarf entertainment has the potential to ease the alienation of the entire dwarf community. By familiarizing society with individuals with dwarfism, dwarf entertainment could remove the stigma on the dwarf community, and prevent them from conforming to possible stereotypes in order to avoid alienation. However, this is not to say that dwarf entertainers are to be martyrs for their community. The benefits for dwarf society are merely in addition to the benefits of employment, expression, and pursuing desires which the inclusion of dwarfs in entertainment brings to the dwarf entertainer, himself.

Robillard goes even further in his analysis of comedy involving the disabled. While he acknowledges that the proposal of Stronach and Allen is most likely present in disabled comedy, he denies "self-work" is the only mechanism present in humorous interaction between the able-bodied and the disabled. He asserts that analysis which identifies distinctions in the interactions of the disabled with society is teleological in that its goal is to look for differences.[17] He further asserts that, if proper scientific research were undertaken by actually observing the interactions of disabled with the able-bodied in comparison to the interaction of two able-bodied people, he believes that differences would be hard to find.[18] Essentially, Robillard's arguments can be extended to form the question: Is dwarf entertainment really that different from non-disabled forms of entertainment? I believe that it is more likely that society is looking for a difference between the use of persons with dwarfism in entertainment and the use of the able-bodied. As Alice Dreger puts it, the dwarf comedian, "uses his disadvantage to his advantage"[19] just as the obese comedian uses his weight to his advantage or the beautiful actress uses her good looks to her advantage. To disallow or somehow prevent persons with dwarfism from participating in entertainment denies them the opportunity to use their attributes in potentially positive ways.

As the self-proclaimed goal of the "Little People of America" is to promote the good life for its members, it may be helpful to look at its stance on dwarf entertainment. Martin Weinberg, in his analysis of the LPA, discusses the social challenges for dwarfs and midgets. He points out that while some choose to isolate themselves from society, others play into their situation and use their disability to their advantage. The most readily identifiable of these cases would be the entertainment industry, including dwarf comedians, and advertising.[20] While the LPA encourages its members to seek jobs outside of the entertainment industry, it does not discourage members in entertainment. The entertainment industry provides dwarfs with a means of earning a living, as well as perhaps "opening doors" to other opportunities for employment for others with dwarfism. The exposure of entertainment may desensitize the public to dwarfism and help to eliminate possibly harmful or degrading stereotypes. The LPA believes that employment for dwarfs is a substantial problem because employers expect that persons with dwarfism will not be socially accepted by customers or fellow employees.[21] By public exposure, it may be possible for dwarf comics to do away with common misconceptions and stereotypes about dwarfism or other "little people" that would prevent society from willingly interacting with them in positive ways.

Also, the media attention to comedians with dwarfism could force others with dwarfism that deny their identity to accept who they are.[22] Just as the LPA is used as a means of bringing dwarfs together, dwarfs in the entertainment industry could help others to realize that they are not alone. In this way, they could gain a sense of pride and respect for themselves, as well as the realization that they can pursue highly paying jobs. Thus, the publicity of dwarf entertainment could actually help those with dwarfism who doubt their abilities to realize that their life has potential. Furthermore, seeing a person with dwarfism attain popularity could have a net effect, inspiring dwarf society.

As previously discussed, most forms of dwarfism are genetically linked. However, as Alice Dreger points out, all degrees of body height are genetically linked.[23] The dwarf's impairment is a shortness of stature; we would not prevent an abnormally tall basketball player from competing. Rather, we celebrate that person's trait because of its usefulness in his or her sport. Perhaps a dwarf's short stature allows him to be humorous in ways that other people are not able

to be. Preventing him from using his or her uniqueness robs him or her of an opportunity to succeed in the way that the tall basketball player does. Since it appears that dwarfism is really just a difference in height to the eyes of society, we should consider whether or not the notion of a dwarf society is a reality or merely a social construct. Perhaps, as Robillard pointed out, society analyzes dwarf entertainment from a teleological perspective. Perhaps there is no difference until you start looking for one. If this is the case, it would be unreasonable to restrict what a dwarf entertainer can and cannot do.

Of course, one could argue that some forms of dwarf entertainment, and entertainment in general, may actually increase the stigma and play into social stereotypes. This is why the manner with which dwarf entertainment represents both the entertainer and the dwarf community must be considered carefully. It is the responsibility of the actor with dwarfism to make sure that he is representing himself and his peers in a way that he deems to be morally acceptable. If he feels that the role or performance he has been assigned to is demeaning, derogatory, or inappropriate, it is his duty to reject the job. An ethics of situational prudence is critical for analyzing the specific cases of dwarf entertainment. Undoubtedly, roles requiring entertainers who have dwarfism will vary in their degree of acceptability; arbitrary line drawing is seldom helpful. It is not morally acceptable for government or any other agency to restrict the ways in which dwarfs choose to employ or represent themselves. Therefore, we must rely on the judgment of those with dwarfism to determine those acts or performances which are unacceptable and those which will actually benefit both the actor and his community. As history shows us, individuals with dwarfism have been in entertainment for centuries. Their diminished social standing due to their impairment in today's society is regrettable. However, it is not grounds for discouraging them from participating in entertainment roles. As I have shown, entertainment can be used as a means of bettering the lives of persons with dwarfism through increased exposure as well as increased opportunities. The prevention of dwarfs from entertainment would not only be a strain on their autonomy, but also another step to push them further from society's consciousness.

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Posthumous Sperm Procurement: The Critical Condition of Autonomous Consent

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Even though during Posthumous Sperm Procurement (PSP) the patient has already passed away, the decedent still has an interest in informed consent. This informed consent must not just be the vague sentiment that the patient wanted children in the future, but that he would have consented to PSP with a particular partner and specific intended parent. Because the partner and intended parent(s) will so often be the patient's close family members, they are inadequate surrogate decision makers in the case of PSP. While close family may be the only consent available for the time-sensitive sperm procurement, an advanced directive or a neutral third party must be produced who can give credence to the autonomous consent of the decedent to PSP.

Posthumous Sperm Procurement ("PSP") has been possible for 28 years, but there are still many important questions regarding the ethics of its usage. Scholars often take a consequentialist approach to the ethics of PSP and focus on effects on the future child. Although the interests of the child may be an important factor in the decision of whether to proceed with insemination, this Article will go back a step and reemphasize the importance of the first question that must be asked: did the decedent consent to PSP and how do doctors and ethicists establish that consent? This Article will apply the basic concepts of informed consent and surrogate decision making to PSP, and make the case that before procured sperm is released for insemination, an advanced directive or a neutral third party must be produced who can give credence to the autonomous consent of the decedent to PSP.

PSP is the harvesting of sperm either from a moribund male or a deceased male within 24-36 hours of his passing. Methods of procuring sperm include "electroejaculation" before death, epididymal aspiration, a testicular biopsy, or removing the testes "en bloc" after death. Once the sperm is procured, it can be cryopreserved (frozen) for future in vitro fertilization and the resulting embryo may be implanted for gestation in a woman. PSP is not currently legally regulated in the United States.

Before discussing what consent to PSP entails, it is important to have a basic grasp of the concept. Beauchamp and Childress define "informed consent" as "an individual's *autonomous authorization* of a medical intervention or of participation in research." They break down the components of informed consent into: (i) a patient being competent to make the decision; (ii) the disclosure of all of the necessary information to him; (iii) his understanding of the situation; and (iv) his voluntary offering of consent.

Direct informed consent of the patient however, is not always possible because of a lack of competence or unconsciousness. In these situations a surrogate decision maker is sought to make medical decisions on the basis of: (i) the best interests of the patient, (ii) the substituted judgment of the patient; or (iii) the purely autonomous choice of the patient. The "best interests" standard is when the surrogate decides which option or options would result in the greatest net benefit for the patient and their "quality-of-life," which is not applicable to posthumous decision making. A surrogate can also "substitute" her judgment for the patient's in that she tries to make the decision that she believes that the patient would make if he were competent. Lastly, the purely autonomous choice standard can only be applied to a once-competent patient who "expressed a relevant autonomous preference" prior to his incompetence. Beauchamp and Childress encourage a "pure autonomy standard whenever explicit prior autonomous judgments are identifiable," however, issues with surrogate consent still include the surrogate "selectively choos[ing] from the patient's life…values that accord with the surrogate's own values . . . ."

Because a surrogate decision maker plays such an important role, Beauchamp and Childress suggest that her qualifications should include: (i) an ability to make reasoned judgments; (ii) adequate knowledge and information; (iii) emotional stability; and (iv) a commitment to the incompetent patient's interests that is free of conflicts of interest. Clearly, a family member may possess the most substantial knowledge of the patient's wishes and therefore would seem able to make the best informed "autonomous" decision, but a family member is also the most likely to lack reason, emotional stability, and unbiased analysis in a situation in which a loved one is rendered incompetent. Because of this, Beauchamp and Childress suggest an advanced directive as a "promising and valid way for

competent persons to exercise their autonomy."

Informed Consent and Posthumous Sperm Procurement

Legally speaking, a dead body has no rights. A spouse or next of kin may attempt to fulfill the decedent's wishes regarding how to be buried, etc., but the corpse would have no standing or claim if his requests were not honored. If a human is dead, he cannot suffer pain, shame, happiness or any other mental state society has an interest in protecting. It can be argued, however, that acts after someone's death can still either promote or harm the decedent's interests. For example, lawyer/client confidentiality extends past death to protect interests in reputation.

In terms of an interest in posthumous reproduction, John Robertson argues that "[p]osthumous conception affects the deceased's interests, because it redefines the content and outlines of the deceased's life." Other concerns surrounding posthumous reproduction include that of passing genetic material, effects on the decedent's estate and property, or how a child would affect loved ones left behind. These examples however, are really concerns of the living about what happens when they die. We wish to control posthumous reproduction because we wish to control our *own* reproduction, not because we think we will actually care when we are dead. Because the living have a substantial interest in informed consent to PSP, however, this interest is reflected and acknowledged in the deceased.

Another area in which the interests of the living and the dead become convoluted in PSP is in defining the act to which the decedent is actually consenting. It is of critical importance not to phrase the consent issue as whether the decedent wanted children or even whether the decedent would have wanted a child conceived after his death. Both of these questions leave out several vital components required by informed consent which requires "disclosure of all necessary information." All of the necessary information surrounding PSP includes the other half of the genetic makeup of the child and the intended parent. The correct question is whether the decedent would have consented to his sperm to being cryopreserved for the future insemination of a particular partner, and whether he would have consented to the intended parent raising the child without him.

Informed consent must also include the patient's "understanding of the situation." This means the decedent must have been aware of PSP. If he did not know that PSP existed, there is no way for a surrogate to say the decedent autonomously consented to it. If a decedent dies without expressing consent to PSP, the usual state of death which does not include creating children should be assumed because this is most likely what the decedent himself assumed. If the surrogate tries to make the case that *had the decedent known it existed* he would have wanted PSP, then the surrogate is creating an interest in controlling posthumous reproduction that did not exist when the decedent was living. Only if the decedent consented to PSP before death did the decedent have a vested interest in PSP. It is only through this living interest in controlling posthumous reproduction that the informed consent of the dead can be established.

Lastly, it is worth nothing that surrogate decision makers who are family members or partners will have a hard time making purely autonomous decisions for the decedent in the case of PSP. Qualifications for a surrogate decision maker include an "ability to make reasoned judgments, adequate knowledge and information, emotional stability, and a commitment to the incompetent patient's interests that is free of conflicts of interest . . . ." The "adequate knowledge and information" requirement must include specific consent to PSP, partner, and intended parent. However, reason, emotional stability, and freedom from conflicts would almost certainly be lacking in a family member or a partner within 24-36 hours after having lost a loved one.

It has been suggested that between the procurement of the sperm and the actual implantation of an embryo, a 6-12 month "bereavement" period pass where a partner can make the decision whether to become pregnant with more distance from her grief. However, is simply impossible that a partner could ever be conflict-free when it came to the decision of whether to inseminate *herself* with her deceased partner's sperm. Because she is physically part of the "procedure," there is no way to extricate herself mentally from her own interests in order to look objectively at the interests of the decedent.

Other personal interests that a partner/surrogate might (consciously or unconsciously) allow to influence her decision include anything from her own desire to have a child or her hope of honoring the memory of her partner, to less altruistic interests in death benefits and inheritances. Parents' ulterior interests might include trying to "replace" a son, or propagating a genetic line or name. Considering that a relative or partner requesting the PSP "expects to use and benefit directly from the anatomic donation," there cannot be any true expectation of bringing forth a totally autonomous decision of the decedent through his family members.

Proposed Solutions

PSP has two distinct time periods in which decisions need to be made. First, a decision of whether to

go through with the procurement must be made within 24-36 hours of death. Just because procurement needs to be made in such a small period of time, however, does not mean that the sperm must be used in insemination. Perhaps in that initial 24-36 hour period, the surrogate decision maker for procurement can be a family member or partner. A family member or partner will still have all of the difficulties of conflicted interests as discussed above, but in such a limited time period a thorough investigation of third parties is limited and the most likely surrogates available will be family members. The most profound concerns regarding PSP surround the decedent's consent to posthumous *reproduction* in any case, not the act of procuring the sperm itself.

Before the sperm is allowed to be used for insemination, professionals and the British Medical Association have called for advanced directives or disinterested third party concurrence that the decedent consented to PSP. An advanced directive in particular serves the goals of "spar[ing]" family members from having to make wrenching decisions and giving patients a "sense of control over their lives . . . ." It would also solve the issues of selectively choosing values that Beauchamp and Childress worry can influence autonomous surrogate decision making.

If an advanced directive does not exist, a neutral third party such as a doctor, friend, or family member that would not be involved in raising the child should be required to confirm the decedent's autonomous consent to PSP. Although it is true that a third party might still have a conflict of interest (such as wishing to promote the relationship with the living family), that conflict seems to be less profound than deciding whether to create a child or grandchild. A surrogate should also have a knowledge of the decedent that is "sufficiently deep and relevant that a judgment will reflect the patient's views and values," which admittedly is harder to obtain outside of the immediate family. However, a partner or immediate family members' values are so likely to convolute the decision that consent is still better procured by a neutral party. If the patient has no advanced directive, and if a neutral third party does believe that the decedent would have autonomously consented to PSP, the sperm cannot be released for insemination because too many deficiencies in consent exist.

Framing informed consent as requiring a specific partner clears up several other ethical issues as well. One such situation is when the parents of a single male request PSP for the insemination of a surrogate to create a child for whom the child's grandparents would be his intended parents. As Batzar points out, "[i]t is difficult to allow anyone to make a request for posthumous sperm procurement who would not have been in a position to contribute to the reproductive decision-making of the deceased." Since parents ordinarily would not be intimately involved in the creation of a grandchild, and because no specific partner has been chosen in this situation, allowing parents to request PSP for their son is not appropriate.

Another issue that true autonomous consent would clarify is whether an unmarried or gay couple should have access to PSP. Marital status cannot be the basis of the judgment that the decedent did or did not want children with his partner. The two are not inextricably linked, particularly if gay partners cannot legally be married in the state at issue. If a hospital requires that the decedent have an advanced directive or that a neutral third party attest to the autonomous consent of the decedent to PSP, then there is no need to base the implied desire of children on marital status. The decedent either consented to a particular partner to posthumously gestate or raise his child, or he did not—the test can be applied equally to all.

Lastly, if a hospital allowed surrogates to ask the question of whether the decedent would have consented to PSP had he known it existed, this brings up the question of whether medical professionals have the ethical duty to tell the family that PSP is possible in the first place. If medical professionals do not inform patients of the procedure, prerequisite of knowledge would leave an uneven pool of potential users. Requiring an advanced directive or actual autonomous consent of the decedent would still require that the decedent have knowledge of PSP, but it would no longer be up to the medical staff whether or not to inform the family that PSP exists so they may ponder it. The decedent either knew of and informed his loved ones that he was interested in PSP, or he did not. The possible biases involved in the decision whether or not to inform patients about PSP is out of the institution's hands.

Conclusions

Decedent consent to PSP matters when a man has an interest in PSP and then passes away. In order for this autonomous consent to be deferential, it must include the critical components of choice of a partner and intended parent and be free of the emotions and conflicts of interest that a partner or immediate family member would infuse into surrogate decision making. Only an advanced directive or a neutral third party can be trusted to impart autonomous informed consent of the decedent. This directive or third party does not need to be produced before the procurement of the sperm in the interest of time, but does need to be secured before the sperm can be released for insemination. This Article does not argue that just because the decedent autonomously consents to PSP that this

means it should be done. The partner plays their integral consent role when they decide whether they want to be impregnated by the decedent. There are also other important ethical considerations—such as the welfare of the child—that must take place before insemination. However, the autonomous consent of the decedent is the critical first step in the ethical framework surrounding PSP.

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27 Bahadur, *supra* note 21, at 2769-2775.
28 Batzer et al., *Postmortem Parenthood*, *supra* note 4, at 1265.
29 BEAUCHAMP & CHILDRESS, *supra* note 8, at 79.
30 There is, of course, only so far the "necessary information" requirement can go, however. Suffice to say that the decedent must have an understanding that the intended parent of his child created by PAS would make her own decisions about how to best raise the child.
31 BEAUCHAMP & CHILDRESS, *supra* note 8, at 79.
32Rebecca Collins counters that "lack of contemplation by the deceased" should not be the end of the PSP discussion. She points out situations where a substituted judgment can still be made "consistent with the likely wishes of the deceased," including a murder victim consenting to the prosecutor using blood samples during the trial. Rebecca Collins, *Posthumous reproduction and the Presumption Against Consent in cases of Death Caused by Sudden Trauma*, 30 Journal of Medicine and Philosophy 431, 437 (2005). One difference between PSP and Collins' example, however, is that in her thought experiment, the decedent is likely still familiar enough with the justice system that his surrogate would have a solid basis on which to make their decision. If the decedent does not know that PSP even *exists*, questions of posthumous reproduction are too myriad and profound for the surrogate to fill in the gaps.
33 BEAUCHAMP & CHILDRESS, *supra* note 8, at 154.
34 Batzer et al., *Postmortem Parenthood*, *supra* note 4, at 1268.
35 Nor should the partner attempt to take her own interests off the table, since her consent is in many ways more important than his. Without a female, PAS just creates frosty sperm.
36 Batzer et al., *Postmortem Parenthood*, *supra* note 4, at 1265.
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38 Batzer et al., *Postmortem Parenthood*, *supra* note 4, at 1266.
39 Bahadur, *supra* note 21, at 2769-2775; Batzer et al., *Postmortem Parenthood*, *supra* note 4, at 1268; Horner, *supra* note 24, 1477; R. D. Orr & M. Siegler, *Is Posthumous Semen Retrieval Ethically Permissible?* 28 Journal of Medical Ethics 299, 300 (2002).
40 Robertson, *supra* note 23, at 1032.
41 BEAUCHAMP & CHILDRESS, *supra* note 8, at 101. An objection to the requirement of an advanced directive is that because PSP is most often requested in cases involving trauma of a young adult male, they are the least likely types of patients to have written advanced directives. Collins, *supra* note 32, at 432. Although this is a good argument against *only* allowing advanced directives, it does not negate the fact that "reasonably informed consent is a legitimate approach in the presence of the catastrophic death of a mate F. Shenfield, Consent and intent in assisted reproduction. *Law and Medicine* 3 (2000), pp. 317–325.," BEAUCHAMP & CHILDRESS, *supra* note 8, at 101, and that autonomous consent must still be given.
42 BEAUCHAMP & CHILDRESS, *supra* note 8, at 101.
43 Batzer et al., *Postmortem Parenthood*, *supra* note 4, at 1265.
44 It is true that there would be more involved in the informed autonomous consent of a gay male to PSP (including where the oocyte was going to come from and who was going to gestate the embryo), but if these decisions had been made in advance there is no reason that a gay decedent could not be found to have consented to PSP with his partner.
45 For example, the American Society of Reproductive Medicine ("ASRM") suggests that the standard for cancer patients going into radiation should be that their oncologists inform them "about options for fertility preservation and future reproduction prior to treatment." The Ethics Committee of the ASRM, *Fertility Preservation and Reproduction in Cancer Patients*, 83 FERTILITY AND STERILITY 1622, 1622 (2005).

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Rutgers Students Speak Up

A recent report published in February 2009 in the New England Journal of Medicine has found that several clinical trials are now being performed by the United States outside of the US and in several countries globally. According to this report, "a third (157 of 509) of Phase 3 trials -- typically the largest and most significant trial in the development of a drug -- led by major U.S. pharmaceutical companies were being conducted entirely outside the United States." Should companies conduct human trials and administer drugs to individuals abroad (in countries in Eastern Europe and Asia) who do not receive healthcare in the first place? Is it immoral to test drugs on people abroad when those trials would not be allowed within the United States? Why? This issue raises several questions about ethics in medicine and drug trials as well the question of human rights and equal treatment in medicine.

"At first glance, it seems like a clear cut moral issue to me, but I think I can see both sides to the issue. While personally, I think that the standards set by law for companies to follow within the United States should remain the same even for their operations in other countries, I don't think that they could ever be practically enforced without issues of sovereignty and governance. There is a practical benefit where these trials may result in important developments that could not be achieved otherwise. However, if these trials are harmful to the human trial subjects, I don't see how any of the possible beneficial results can justify these companies' actions." (Robin Jones, 2012)

"In my opinion, I believe that this is a terrible thing for pharmaceutical companies to even think about. Yes, there are people in this world who may not be as fortunate as others to have health care. However, that does not give anyone the right to even suggest testing drugs and medicines on those individuals, let alone actually performing experiments and analysis on them." (Gary Matthews II, 2010)

"At first, I felt that it should be allowed because it is the person's responsibility and own personal choice when they comply with such trails. However, if these individuals do not receive healthcare, it is wrong for companies to allow those people to participate. By having people with no healthcare participate in such trails jeopardizes their health. Of course the companies are not going to accept any responsibility leaving with individuals stranded." (Abha Huckoo, 2012)

"It is wrong for American drug companies to exploit the hardships and disadvantages of countries without health care for the benefit of the United States drug companies' pockets. More than likely, these drugs and tests are important to health care companies not because they can help people, but because the drug companies can make a profit. No matter what, the intent is not to help those individuals abroad, but to help Americans, and it makes those abroad seem worthless or inhuman to treat them as test subjects for the US." (Amanda Gallear, 2012)

"I don't think it's immoral. It is a pragmatic solution. We don't allow testing in the United States because it would cost the government too much. Many of the people who volunteer for these drugs are of low income without health care. It is simpler and cheaper to outsource. When we outsource our jobs, the US minimum wage does not go along with it. We hardly give a second thought to the billions of lives that are made to be less than par due to our wants and needs for cheap products. Should we start paying the outsourced workers more so that their lives are better? I say no, and I say no to this too. Human rights are a subjective matter. The healthcare industry is not forcing anything on the people outside the United States. Just as, the foreign workers not being forced to work in the haphazard industries, these test subjects are not being forced to join the clinical trials. I say it is better that these people have an opportunity to contribute to the global economy and possibly better their lives than to not." (Lap Nguyen, 2013)

"Drug companies know that what they are doing is unethical. They do not care because their goal is to make money. Doctors, who have been historically silent on public policy issues, laws, and regulations (which is very clear now during healthcare reform), are the ones who should organize to expect more from companies that are crucial to their careers and their patients' lives." (Devangi Patel, 2011)

"I don't think there's really a simple answer to this issue. Surely heart disease deserves the funding it's receiving, as does oral health as the problems that result from it can be very dire. However, I think cancer research is definitely underfunded as it seems the rate of cancer deaths just keeps going up. I can understand why HIV/AIDS doesn't receive as much funding in the United States, as it is a more serious issue in other countries that lack the money to put research into it. This, however, is a shame and I believe it characterizes American medicine." (Robin Jones, 2012)

"Even though I believe cancer and HIV/AIDS should get more money, the money allocated to heart diseases should not be taken away. HIV and cancer are crucial issues but in US, heart disease has a more prevalent impact on our society." (Mark Inverso, 2012)

"I think that it is not more or less important to study heart disease than to study HIV/AIDS and cancer. All of these diseases have an impact on many people worldwide, so I think that the budget should be balanced. It may be "easier" to cure heart disease, but consider how much people with HIV/AIDS can be helped by modern medicines. Studies pertaining to cancer and HIVAIDS to find treatments, even if cures take longer to discover, are not less valuable than studies done to help those with heart problems, stroke, and oral diseases. I believe that greatest amount of people could be helped if programs for all of the diseases are supported, as they are all global concerns." (Lavina Jethani, 2012)

"Humans are not genetically predisposed to HIV/AIDS the way many are genetically predisposed to cancer and heart disease. HIV can be fully combated with regular testing, education, and safer sexual practices." (Devangi Patel, 2011)

The Preventive Health and Health Services Block Grant for 2008 outlines the allocation of funds from the states for particular programs in the CDC. While heart disease and stroke received $9,282,508 and oral Health received $3,248,689, cancer received $883,651 and HIV-AIDS only received $194,776. Cancer is responsible for 13% of all human deaths and HIV has killed 25 million people worldwide from 1986 to 2006. Should the CDC focus more on studying diseases such as cancer and HIV and balance their budget? Or is it more important to study heart disease, the number one killer of women in the United States? Why? This issue raises questions about how funds are allocated in medical programs.

"First and foremost, it is hard to compare these two matter when one of the statistics is given in a percentage and another in a number. Sure 13% may not seem like a big number, but cancer does affect a lot of people, and I agree with the way the money was allotted. Cancer is not something that can be prevented, it is something that develops within our bodies, so it is important for the CDC to find ways to cure it. HIV, though a serious problem, can be prevented; one gets HIV through sexual intercourse, sharing needles, etc (things one can easily protect oneself from). It is more important to raise awareness, through that, people can avoid being infected." (Abha Huckoo, 2012)

"Considering the fact that heart disease and stroke research have more of a possibility of turning out viable solutions and preventative medicine, I say the CDC is right. Heart diseases and stroke are a more global concern than HIV and cancer. It is simple logistics. Cancer and HIV are a harder cure. It is almost impossible, due to the nature of cancer to find an overall cure. Billions of dollars can be poured into research and the best that can be come up with is a cure for one strand that is so specific it may affect only 10,000 people. The same can be said about AIDS and HIV. Heart disease is common and there is very little variation. That makes it more efficient to pour money into heart disease." (Lap Nguyen, 2013)

" Consider a situation where Anthrax is responsible for about 90% of all human deaths in America and SARS is only responsible for 10%. Which type of research would you choose to fund? The point that I am getting at is that I believe the CDC should focus more on the disease that is the leading cause of death." (Gary Matthews II, 2010)

Case Study: Ethical Decisions for a Patient Born with Trisomy 18

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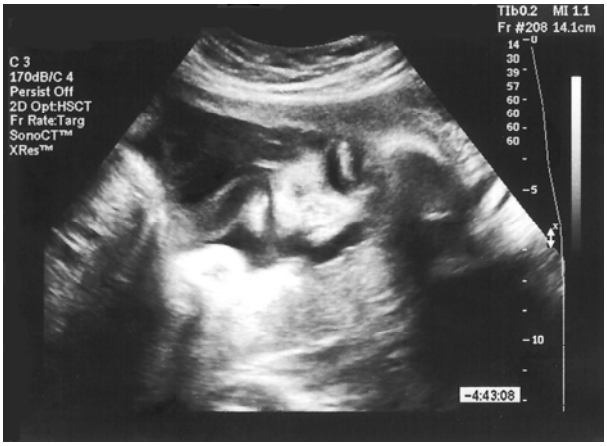
Baby M was a full term infant born to a forty-one year old mother. This was the mother's third pregnancy; her previous two children were born at term, and both were doing well. During this pregnancy, a chorionic villous sampling was performed at twelve weeks gestation due to advanced maternal age, revealing that the fetus had Trisomy 18. The parents' religious beliefs respectfully did not consider termination of the pregnancy as an option. The pregnancy continued until the mother went into labor, and was taken to a hospital where the pediatricians were unaware of the prenatal diagnosis of Trisomy 18.

Trisomy 18 is the second most common autosomal trisomy, with only Trisomy 21 (i.e. Down syndrome) being more frequent. Major abnormalities commonly associated with Trisomy 18 include growth and mental deficiency, cardiac defects, facial dysmorphia (malformed ears and micrognathia), clenched fists with overlapping digits, and multi-organ deformities in the renal, intestinal, genitourinary, and neurologic systems. Greater than 95% of concept uses are spontaneously aborted in the first trimester. Of those surviving to birth, 50% die within the first week; 90-95% die in the first year of life. Although 5-10% of infants conceived with Trisomy18 survive past their first birthday they have severe mental retardation and motor deficits.

Just prior to delivery of Baby M, the parents shared with the hospital pediatrician that the baby was diagnosed with Trisomy 18. When the pediatrician asked the parents what they understood about this diagnosis, they were able to describe the most commonly associated signs and symptoms of the syndrome. However, they did not fully understand the fatal nature of Trisomy 18. This confusion was, at least in part, due to the fact that the mother had a sister with Trisomy 21 who was a semi-independent adult; the family had erroneously assumed that Trisomy 18 was similar to Trisomy 21. After intensive discussions with the hospital pediatrician, the parents respectfully requested that the infant be given only comfort care; that is, if the vital signs were to become unstable with imminent natural death, then no resuscitative measures, such as intubation or chest compressions, would be performed.

Baby M was born with an extremely low heart rate and without effective respiratory effort. After being wrapped in a blanket, he was given to his parents to hold and was baptized shortly afterwards. His respiratory effort improved, and he was able to breathe on his own with a stabilized heart rate. When it was clear that death was not immediately imminent, the parents and the health care team agreed to provide him nutrition by using a feeding tube inserted through the nose into the stomach, as he did not have the neurologic ability to be breast-fed. The parents were taught how to provide tube feedings, but due to their discomfort with taking him home, Baby M remained in the hospital for several more days. During this time, a severe heart defect became evident. With assistance from social work services, home hospice was arranged to assist the family with the care of Baby M. The parents also received counseling at home to prepare their two other children for the eventual death of their brother.



Baby M was discharged home a few days later, and on his second day there, he died. The following Sunday, the family's twelve year old son gave the eulogy at his funeral, speaking of his little brother whom God gave to him to share for a brief time on earth.

After Baby M's hospital discharge, health care team members continued to discuss the medical and bioethical decisions involved in the care of Baby M. Since Baby M's imminent death had occurred over a prolonged period than as a sudden death, these discussions were much more complex. In today's age of

technologically advanced medicine where life support can prolong the cardiopulmonary status of patient for an indeterminate period of time, health care professionals often feel bound to doing as much as possible for their patients. However, how does one balance technology with values? If one has the capacity to artificially keep a heart beating, forcing air in and out of the lungs, is there a point at which this should no longer be the primary goal?

For Baby M, it was agreed by the team of physicians, nurses, social workers, and parents that no heroic interventions should be taken other than gavage feeds. However, consider the case of another baby born with Trisomy 18 to a family whose religious faith did not accept acts of omission as an option with natural death. This infant was given intensive medical care to prolong his life, including surgical repair of an esophageal-tracheal defect, central line placement for intravenous nutrition, tracheostomy placement, and gastrostomy tube placement[1]. When this infant went into cardiopulmonary failure, full resuscitative efforts, including chest compressions and epinephrine, were given before he finally succumbed to death. These two cases highlight how the same medical scenario can yield ethical dilemmas with two very different conclusions.

The American Academy of Pediatrics Committee on Bioethics supports individualized decision-making for all patients regarding life-sustaining medical treatment. In the case of the pediatric patient, informed parental decisions regarding the provision and/or omission of critical care for their child should be based on careful consideration of the benefits and burdens of such treatment as provided by the health care provider[2]. And herein lays the question: How does one ethically make a decision where the benefits and burdens of care involve life and death?

Ethics refers to the standards of right and wrong which prescribe humans' actions, usually in terms of rights, obligations, fairness, or specific virtues[3]. For example, the right to life, the right to freedom from injury, and the right to privacy are all ethical standards. Ethics is also the constant study and development of morals in light of the fact that although providing consistency, they must change to keep pace with contemporary viewpoints, technology, and cultural norms[4]. In 1979, James Childress PhD and Tom Beauchamp PhD authored the seminal work, *Principles of Bioethics.* With five editions currently in print in multiple languages, this text defines four basic principles of bioethics: Autonomy, Beneficence, Nonmaleficence, and Justice[5].

Autonomy is the right to self-determination in which the values and wishes of an individual are respected. In health care decisions, autonomy refers to respect for a person to act intentionally, with understanding, and without controlling influences upon a free and voluntary act. This principle is the basis for informed consent in the physician/patient interaction[6]. However, it requires that the patient have the capacity to deliberate a treatment plan; if a patient is comatose, is cognitively disabled, or is a child, the patient will need a surrogate to make a decision for them. In neonatology, the principle of autonomy is given to the parents who become the surrogate decision-makers for the infant.

Beneficence refers to the duty of a healthcare provider to act in a manner which provides the greatest benefit to the patient. This can be further categorized into "positive beneficence," where moral agents provide benefit and "utility" where moral agents weigh the benefits and risks to produce the best results[7]. These goals can be applied to individual patients and to society as a whole. For example, the good health of a particular patient is an appropriate goal of medicine, as is the prevention of disease through the employment of vaccines to the population at large[8]. However, this principle is often challenged by Autonomy, where the healthcare provider's and the patient's ideas of 'good' may differ (e.g. some of the population may not agree that vaccines are good for one's health).

Nonmaleficence, the opposite of beneficence, represents the duty to "do no harm," a phrase incorporated into the Hippocratic Oath which physicians take upon entering the medical profession. It is also the avoidance of negligence which would be enacted if one imposes a careless or unreasonable risk of harm upon a patient. Nonmaleficence seeks to avoid or minimize the risk of harm to a patient; it is a principle which is supported not only by societal moral convictions but by the laws of society as well[9].

Justice refers to the fairness of allocation of available resources. This is a key area in the controversy over whether or not the provision of health care in the United States should formally be universal. It asks the question, "How can access to health care be provided justly, resources apportioned fairly, and reasonably paid for equitably?" The answer, however, is not as obvious. The solution may lie in providing medical care without consideration of ability to pay in order to maximize the population with equal access to health care resources or rationing health care resources to have equitable distribution of limited resources to a greater population. As with many aspects of bioethics, implementing this principle is much more challenging than describing it.

Although the four principles of bioethics are clearly defined, they are interpreted and applied by people who, despite their attempts to remain objective and impartial, inevitably are influenced by internal

and external beliefs and morals when making ethical decisions. Internally, the health care provider must be aware of their own biases and emotions when assessing the bioethics of a situation. Externally, the provider must also be aware of the values of family and loved ones when considering the benefits and harms associated with a given ethical decision. The tension between the internal and external influences greatly complicates the "right-or-wrong" framework for decision making. End-of-life or beginning-of-life decisions, as occurs in neonatal intensive care medicine, are fraught with gray areas for which there may be no right or wrong answers, only "mostly right" or "mostly wrong" answers, at best[10]. These decisions must also consider the people who will remain after the patient has died because the decision affects them, too. Bioethical decisions at the end of life must consider this carefully, lest the end-of-life decision making processes leave the family and loved ones with life-long guilt and anger towards the health care team and themselves over a process in which they feel they have lost Autonomy, Nonmaleficence, Beneficence, or Justice.

To assist with the complex and challenging processes of bioethical decision making, five approaches have been developed to provide guidance in balancing the four bioethical principles. The *Utilitarian* approach considers ethical actions that provide the greatest balance of benefit over harm for the greatest number of people, although how "benefit" and "harm" are defined is often a matter of great debate. The *Rights* approach reflects the principle of Autonomy, stating that an individual has the right to choose his/her own medical course of action, including the right to be free from injury or harm[11]. The *Fairness* or *Justice* approach incorporates Aristotle's philosophy that "equals should be treated equally," reflecting the principle of Justice. This approach focuses the removal of favoritism and discrimination and aims to treat all stakeholders the same regardless of their differences[12]. The *Common Good* approach integrates theories from Aristotle, Plato, and Cicero, stating that both individuals and society should share a common good based on commonly held values, beliefs, and goals. It focuses on social policies, systems, institutions, and environments that are beneficial to all[13], such as public school systems, affordable health care, and a democratic voting system[14]. Finally, the *Virtue* approach is based on the concept of inherently ethical attitudes and traits, such as honesty, courage, compassion, generosity, integrity, and fairness[15]. It states that ethical decisions are those which promote the development of character and humanity of the society as well as of the individual.

Thus, reflecting on the principles and approaches to bioethical decision-making, the two ethical yet disparate set of health care decisions involving similar infants with Trisomy 18 can be appreciated. The medical decisions involved in their care incorporated bioethical principles and approaches which considered the benefits and harm associated with each action as well as the rights of the infant and of the family and loved ones. These decisions sought to reduce favoritism or discrimination in the allocation of health care resources and attempted to advance the common good, and support the individual and societal development of moral virtues. Although both infants had incurable genetic defects and died as infants, the bioethics involved in their care still resulted in different decisions. While the bioethical decisions made for an infant born with Trisomy 18, or any complicated medical condition, may be diametric, it is essential is that the decisions are systematically and exhaustively deliberated using the principles and approaches outlined above.

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2 MidAtlantic Neonatology Associates, Morristown, NJ

Bioethics Society of Rutgers University

Paper Submission

Bioethics Society Mission Statement: As members of the Bioethics Society of Rutgers University, we hope to raise general awareness of issues in bioethics within the Rutgers community by method of discussion and publication. Although the beliefs and opinions regarding bioethical issues of this group are not unanimous, we are united by our ardent belief that the student population at Rutgers should be made aware of the implications of biological research, medicine, and other topics of bioethical controversy.

Journal Purpose: In order to bring to light these issues, we are now accepting any papers that fall under the vast umbrella that is bioethics. All papers will be considered for possible publication. Some example subjects are abortion, animal rights, eugenics, gene therapy, human cloning, and medical malpractice, however you are not limited to these topics.

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