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# PBJ PENN BIOETHICS JOURNAL

medical records

# Demand and Distribution: Paradigm Shifts in Healthcare

Autonomy in Informed Consent, Transplant Tourism, Pharmaceutical Prices, and a Conversation with Dr. Jonathan Moreno

# PENN BIOETHICS JOURNAL



The Penn Bioethics Journal (PBJ) is the premier peer-reviewed undergraduate bioethics journal. Established in 2004, the Journal provides a venue for undergraduates to make contributions to the field of bioethics. Embracing the interdisciplinarity of bioethics, PBJ reviews and publishes original work addressing debates in medicine, technology, philosophy, public policy, law, theology, and ethics, among other disciplines. The biannual issue also features news briefs summarizing current issues and interviews with eminent figures in the field. Authors and the editorial staff alike have a unique opportunity to experience the peer-review process through the collaborative, rigorous review and preparation of the Journal. With an audience ranging from undergraduates to scholars in the field to the broader public seeking unbiased information, the Penn Bioethics Journal occupies a unique niche in the field of bioethics.

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# Contents


## Letter from the Editor

Claire Fishman — 4
*Editor-in-Chief*

## Bioethics-in-Brief

Ethical Concerns Regarding Successful Creation of Human-Pig Chimera Embryos — 5

National Academy of Sciences Paves Way for Research on Germ Line Genome Editing — 6

Changes to the FDA Approval Process — 7

Marathon Pharmaceutical and Deflazacort: Charity or Chicanery? — 8

## Interview

Dr. Jonathan D. Moreno, PhD — 9
*University of Pennsylvania; David and Lyn Silfen University Professor of Ethics*

## Articles

The Bioethics of Alzheimer's Care: A Story of Autonomy and Trust Gone Awry — 12
Andrew Carlson
*Luther College*

Transplanting the Problem: Israel's Solution to Low Organ Donation — 18
Hope Lu
*University of Pennsylvania*

Are High Pharmaceutical Prices Morally Justifiable? — 23
Alexander Ren
*New York University*

# Letter from the Editor

Claire Fishman
*Editor-in-Chief*

Dear Readers,

It is my pleasure to present you with Volume XIII, Issue i of the Penn Bioethics Journal, entitled "Demand and Distribution: Paradigm Shifts in Healthcare." The three articles in this issue explore the allocation of medical resources from unique perspectives, covering topics ranging from organ transplantation and pharmaceutical prices to appropriate informed consent procedures.

Our first article, entitled "The Bioethics of Alzheimer's Care: A Story of Autonomy and Trust Gone Awry," argues that current informed consent procedures are inadequate in both ensuring autonomy and promoting trust in the physician-patient relationship. Author Andrew Carlson of Luther College uses the example of progressive dementia to illustrate his claim.

In our second article, entitled "Transplanting the Problem: Israel's Solution to Low Organ Donation," author Hope Lu from the University of Pennsylvania explores the causes of Israel's low organ donation rate and the government's promotion of transplant tourism as a solution to this problem. She uses Israel as a case study to investigate the factors that impact organ trafficking globally.

Our final article, entitled "Are High Pharmaceutical Prices Morally Justifiable?" explores the themes of drug development and funding through the lens of Rawlsian distributive justice. Author Alexander Ren from New York University argues for the impermissibility of high pharmaceutical prices through an analysis of the moral obligations of pharmaceutical companies.

In this issue, the Penn Bioethics Journal also had the opportunity to interview Dr. Jonathan Moreno, the David and Lyn Silfen University Professor of Ethics and a Professor of Medical Ethics and Health Policy, of History and Sociology of Science, and of Philosophy at the University of Pennsylvania. Dr. Moreno's wide range of research interests, including healthcare policy, neuroethics, and the bioethics of national security, give him a unique insight into the issues of informed consent and autonomy.

Furthermore, our Bioethics-in-Brief section, which can be found on the following pages of this issue, includes news briefs that provide updates on recent developments in the field of bioethics. The first two briefs discuss new advancements in genome editing technology, including the successful creation of human-pig chimera embryos and germ line genome editing using CRISPR/Cas9. With these progressions in medical technology come ethical questions that were once considered only abstract in nature. The second two briefs cover topics relating to the United States' pharmaceutical industry. Both briefs explore the connection between the government and pharmaceutical industry, and the ethical consequences that can ensue due to the largely unregulated nature of this relationship.

Finally, I would like to thank Dr. Harald Schmidt, our faculty advisor, for his continued support and guidance throughout the entire publication process. I would also like to thank the entire editorial and publication staff for their hard work and dedication, which made this issue possible.

I now invite you to begin or continue your exploration into the field of bioethics by taking a look inside this issue. I hope that our content will peak your interest and enable you to explore and engage with a variety of intriguing bioethical questions.

Claire Fishman
*Editor-in-Chief*
University of Pennsylvania C'18

# Bioethics-in-Brief

## Ethical Concerns Regarding Successful Creation of Human-Pig Chimera Embryos


Photo courtesy of NPR

Dr. Jun Wu and a team of biologists at the Salk Institute for Biological Studies in La Jolla, California announced the successful creation of human-pig chimeric embryos in the January 2017 issue of *Cell* (Wu 2017). The team created these chimeras, organisms containing cells or genetic material from multiple species, by introducing human stem cells into an early stage pig embryo before implanting them into a gestating sow. Through a process of trial and error, Wu and colleagues discovered that naïve pluripotent stem cells were less effective for transplantation than developed stem cells (Blackmore 2017). Of the 186 chimeric embryos that survived, Wu estimates that each had about 1 in 100,000 human cells (Blackmore 2017).

The importance of this study lies in the potential ramifications for chimeric organ transplantation. Juan Carlos Izpisua Belmonte, the Primary Investigator of Wu's lab, stated, "The ultimate goal is to grow functional and transplantable tissue or organs, but we are far away from that. This is an important first step" (Symons 2017). However, this type of technology raises bioethical concerns. Dr. David King, director of the Human Genetics Alert, responded to the experiment with distaste. He said, "I find these experiments disturbing […] The concern about mixing species touches something deep in the human psyche and our culture that is hard to put into words. It is not about some 'wisdom of nature,' but about the unwisdom of scientists" (Symons 2017).

Professor Daniel Garry, a cardiologist at the University of Minnesota, also shared his concerns on the ethics surrounding chimera research (Devlin 2017). More specifically, Garry has wondered whether the viable progeny of chimeric fetuses would appear more human or more pig, would possess human thought, or if the human cells could cannibalize the pig embryo entirely. However, these long-term concerns were not applicable to Wu's research because the embryos were only allowed to develop for 28 days before termination. Hank Greely, Stanford University bioethicist, has been against the production of chimeras for more than a dozen years (Begley 2017). Greely thinks that the creation of intermediate forms of life "denigrates human dignity and blurs the line between what is human and what is not, especially if you believe that we were created in the image of God" (Begley 2017).

However, other researchers are less concerned with the bioethical implications of the experiments. Insoo Hyun, a medical ethicist at Case Western Reserve University, said, "There isn't a need to get into a debate about moral humanization if scientists target the organs where the human cells will go. Scientists are not making chimeras just for fun - it's to relieve the dire shortage of transplantable organs" (Symons 2017). Professor Bruce Whitelaw, interim director of the Roslin Institute, described the results of the study as exciting and paving the way for future biotech applications (Gallagher 2017).

In 2015, the National Institutes of Health (NIH) decided to stop funding experiments that would put human stem cells into embryos of other animals over ethical concerns (Begley 2017). The Salk Institute was able to conduct its research through private donors, sidestepping the concerns of the NIH (Blackmore 2017). The NIH has since proposed to increase regulations on chimera experiments in lieu of the funding ban. However, in 2016, a bill was introduced in the House that would end all chimera research (Begley 2017). Therefore, the future of chimera research is uncertain due to the conflicting views of the federal government and the NIH.

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# National Academy of Sciences Paves Way for Research on Germ Line Genome Editing

In February 2017, the National Academy of Sciences released a report stating that heritable human genome edits "must be approached with caution, but caution does not mean they must be prohibited" (National Academy of Sciences et al. 2017). The recommendation came as a surprise amidst the contention in the public and scientific communities about heritable genome changes. In the year prior, scientists from all over the world met in Washington at the International Summit for Gene Editing to advocate for a moratorium on human genome editing (Wade 2015). A halt on human genome editing was put in place along with a call for better understanding of the technology's potential.

Despite the ongoing debate, doors are opening for the use of genome editing technology in treating human disease. In June of 2016, the United States' National Institute of Health (NIH) approved the first clinical trial using human genome T-cells to treat cancer (Reardon 2016). However, the ethical questions surrounding editing somatic cells, like T-cells, have caused less concern than those surrounding edits to the genome of germline cells.

While somatic cells are not inherited by future generations, germline cells are passed onto offspring. This is where concerns of transgenerational effects arise and the ethics behind the procedure become more complex. Many argue that if the genome editing goes awry in the germline, the effects can impact future generations, thereby demanding significant ethical and scientific consideration. Junjiu Huang, a scientist at Sun Yat-sen University, performed the first germline human genome edit in zygotes that were grown only to eight cell morulae using CRISPR/Cas9. Few of the resulting embryos were successfully edited and unintended mutations were introduced across the genome (Cyranoski and Reardon 2015).

A study published in March of 2017 showed more promising results; no off-target effects were found in the edited embryos. However, the efficiency at fully fixing the disease-causing mutation in these embryos was low (Tang et al. 2017). Before clinical trials begin, the technology has a long way to go. Many have voiced concerns that the current risks of germline genome editing outweigh the benefits, making it unethical to move forward.

Practical viability aside, the ethics of introducing artificial inherited genomic changes remain controversial. Germline genome editing calls into question the existing notions of consent. The director of the NIH, Francis S. Collins, argues that future generations "can't give consent to having their genomes altered from what nature would have made possible" (Skerrett 2015).

Therefore, Collins maintains that consent must be thoroughly considered when an individual's decision to undergo genome editing affects future generations. George Church, a professor of genetics at Harvard Medical School, compares the case of purposeful genome editing to "parents' intentional exposure to mutagenic sources that alter the germ line, including chemotherapy, high altitude and alcohol" (Church 2015). In regards to mutagenic causes of changes to the germline, consent is not obtained.

In part, the hesitation surrounding implementation of technologies like CRISPR/Cas9 to alter the human genome revolves around questions of the "natural". Essentially, are mutations from mutagenic sources more natural than those caused by genome editing in a lab? Should the status of "natural" hold weight in bioethical debate?

Furthermore, these concerns raise claims that humans are "playing god" by controlling genetic information. However, Ronald Cole-Turner, a theologian and ethicist at Pittsburgh Theological Seminary, feels it is not a "legitimate argument that Christian theology shares this worry about 'playing God,' rather that it arises from a misunderstanding of theology" (Joseph 2015). Cole-Turner questions the idea that the human genome holds a certain sacredness. Rather, he views creation itself as a gift that requires the responsibility of humans, but no strict limitations on what that entails (genome editing or not). Common to all arguments is a need for an in-depth understanding on a scientific, ethical, and societal level of the implications of genome editing. For this reason, many, including Harvard geneticist Ting Wu, advocate for information and education on human genome editing accessible to the public (Joseph 2015).

Ultimately, ethical issues surrounding heritable genome editing have subtle complexities that may not be as salient with somatic genome editing— whether it is concerns about unintended effects, "playing God," or transgenerational consequences. The debate is ongoing, but the movement to advance human genome editing is growing.

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# Changes to the FDA Approval Process

In December 2016, the 21st Century Cures Act was signed into law, accelerating the approval of new drugs targeted to unmet clinical needs (Congress 2016). All new drugs and medical devices distributed in the United States must meet Food and Drug Administration (FDA) standards before use in clinical settings. The rigorous drug approval process ensures that pharmaceuticals reaching the market are effective and safe. However, a consequence of high standards is a low approval rate for new products, with the approval rating for Phase I (testing of drug on healthy volunteers for dose range) as low as 9.6% from 2006-2015 (Thomas 2016). Critics of the process believe that the low approval rate prevents many potentially life-saving drugs from reaching patients with limited treatment options.

The 21st Century Cures Act implements various measures intended to promote public health, including funding for opioid addiction treatment programs and for mental health research (Congress 2016). The controversy surrounding the law stems from its legalizing the involvement of industry representatives and patient advocacy groups in the regulatory process while relaxing approval standards for several major groups of drugs (Congress 2016). Patient advocacy groups promote the development of new drugs for certain diseases, especially rare diseases, which are often passed over by drug developers in favor of diseases with larger patient populations.

For example, the approval of a controversial drug for Duchenne Muscular Dystrophy (DMD), a rare disease affecting young boys, has been ushered through under the influence of patient advocacy groups. Exondys was approved based on the testing of only 12 pediatric patients. The rarity of DMD made it difficult to recruit a large sample size that met FDA standards. Despite experts advising against the drug's approval, the FDA yielded to intense lobbying from DMD advocacy groups, and Exondys was approved in September of 2016 (Klugman 2016).

The language of the law explicitly lists "patient advocacy groups" and "industry representatives" as acceptable expert advisors for the approval of novel drug development tools and allows clinical data as evidence in the FDA approval process (Congress 2016; Ramachandran 2016). A drug development tool is defined as any biomarker, pathological feature, or other biological parameter that is used to evaluate a drug's effectiveness (FDA 2014). In surrendering control of the drug development tools to pharmaceutical companies, the FDA can no longer regulate the endpoints or goals of the clinical trial, making the process of approval more ambiguous.

In the past, the FDA required randomized double-blind placebo-controlled clinical trials for official approval of new uses of an already FDA-approved drug. Accordingly, only the clinical trial organizers knew who was receiving placebo or experimental drugs, keeping the participating physicians and patients in the dark. This controls for many confounding factors found in clinical trial data, including the placebo effect. Such trials are expensive due to the large number of patients involved but are considered the "gold standard" for clinical research (Junod 2016). The 21st Century Cures Act would allow data from normal day-to-day clinical use of drugs to be submitted as evidence of a drug's effectiveness (Congress 2016). This has raised concerns that drug developers may dodge the expense and rigorous requirements of the double-blind clinical trial at the cost of data quality. Clinical use data usually lacks the blinding and placebo controls in clinical trials.

*Photo courtesy of Mendelspod*

Additionally, the 21st Century Cures Act relaxes the approval requirements for certain types of drugs, allowing for approval based on testing limited patient populations. New antibiotics and antifungal drugs are included in this clause. Evidence required for approval has also been expanded to include non-clinical pharmacokinetic data (to ascertain where certain drugs are consumed by the body) and pre-clinical data (data from animal or lab studies prior to human testing), in addition to traditional clinical endpoints (Congress 2016).

Relaxed approval standards are expected to shift the burden of uncertainty and the risks of drug failure away from pharmaceutical companies and onto patients and healthcare providers, and unacceptably hazardous or ineffective drugs that would have failed to gain FDA approval under prior standards are now likely to gain approval. As a result, drug developers would benefit from increased sales and a higher drug approval rate, while patients, healthcare providers, and insurance providers would be left to suffer the risks and consequences of failed drugs.

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Bioethics-in-Brief

# Marathon Pharmaceutical and Deflazacort: Charity or Chicanery?

Deflazacort, a drug used to treat Duchenne muscular dystrophy (DMD), will soon be available in the United States at a price of $89,000 a year. However, Deflazacort has existed for many years in the European market and has been imported by American DMD patients at an annual cost of about $1,200 (Johnson 2017).

Deflazacort has been available to DMD patients in the European Union and Canada since the 1970s (Johnson 2017). The rare genetic disorder targets mostly males and leads to progressive muscle deterioration. With the medication, patients experience a reduction in muscle inflammation and immune activity, alleviating significant pain (Walsh 2017).

Marathon Pharmaceuticals, the company behind Deflazacort's production in the U.S., recently obtained an "orphan-drug" designation for Deflazacort from the Food and Drug Administration (FDA), giving it seven years of exclusive rights to own and sell the drug (Tirrell and Mangan 2017). In addition, the company received fast-track designation, priority review, and a "rare pediatric disease priority review" voucher from the FDA, meaning it can bypass certain regulatory measures for development of future drugs (Walsh 2017). The voucher is also marketable, allowing Marathon Pharmaceuticals to sell it to another company for a potential profit of hundreds of millions of dollars (Tirrell and Mangan 2017).

Marathon has been accused of abusing the Orphan Drug Act, legislation passed in 1983 to encourage investment and research in the development of "orphan drugs," medications used to treat rare disorders like DMD (Tirrell and Mangan 2017). The bill is a means of incentivizing innovation in the pharmaceutical industry, specifically for the development of drugs to treat rare and uncommon diseases.

Patients, advocacy groups, and members of Congress are questioning why a drug like Deflazacort, which has existed for decades in other countries, gained "orphan drug" approval in the first place. Notably, Deflazacort does not treat DMD directly (Tribble and Lupkin 2017). It only mitigates some of the symptoms, such as muscle pain. Other orphan drugs used to treat muscular dystrophy diseases (e.g., eteplirsen and nusisinersen) are considered "breakthroughs" as they target the specific genes underlying the disorder (Tribble and Lupkin 2017).

Moreover, Deflazacort is just one drug in a much larger drug "cocktail" for DMD, according to Pat Furlong, founder of Parent Project Muscular Dystrophy, an advocacy group (Tribble and Lupkin 2017).

Critics within the United States Congress such as Senator Bernie Sanders and Representative Elijah Cummings also voiced their disapproval, writing a letter to Marathon. Sanders and Cummings called the price "unconscionable" in their letter, asking the company to "significantly lower" prices before the drug officially becomes available on the U.S. market (Tirrell and Mangan 2017).

In response to public protest, Marathon CEO Jeffrey Aronin announced that the company was "pausing" the rollout of Deflazacort for an unspecified amount of time. Marathon noted that it was working closely with caregivers of DMD patients to hear their concerns about pricing and potential reimbursement programs (Tirrell and Mangan 2017). Additionally, Marathon states, "We are focused on providing access to this important drug to every young patient who needs it" (Nocera 2017). The company also announced an expanded access program designed to provide the drug to 800 patients free of charge (Tirrell and Mangan 2017).

Marathon's exclusive control over Deflazacort and the drug's inflated cost raise ethical concerns outside of this specific case. Should disadvantaged populations be left without life-saving medications due to profiteering motives of pharmaceutical companies? Drug manufacturers claim that high R&D costs, manufacturing, FDA approval, as well as economic interests are responsible for the inflated drug prices. Most of these companies are publicly-owned entities, meaning that executives must respond to stockholders who want to see market growth and profitability (Patel 2017). Therefore, in such a capitalistic framework, the patient's best interests are sometimes subordinate to the advancement of the company.

Despite the opportunistic rhetoric commonly applied to the pharmaceutical industry, it is important to note that many companies pursue philanthropic causes and invest heavily in crucial treatments for deadly diseases. For instance, Merck agreed to supply free doses of its HPV vaccine for three years in Rwanda, helping to create the program for cervical cancer patients in 2013 (LaMattina 2013). Additionally, Merck, in conjunction with the World Health Organization, UNICEF, and the World Bank, also set out to eradicate river blindness in Africa. Thanks to their efforts, about 40,000 cases of river blindness are prevented each year (LaMattina 2013).

Merck's efforts in Africa demonstrate that, by considering the social and financial context of the targeted patient population, pharmaceutical companies have the potential to distribute vital drugs such as Deflazacort at almost zero cost.

Ultimately, Deflazacort's introduction into the United States has triggered a nation-wide discussion among executives, patients, and advocacy groups, bringing the debate over governmental regulation of pharmaceutical pricing into focus.

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# Interview

# A Conversation with Dr. Jonathan Moreno

Jonathan D. Moreno, PhD, is the David and Lyn Silfen University Professor of Ethics and a Professor of Medical Ethics and Health Policy, of History and Sociology of Science, and of Philosophy at the University of Pennsylvania. He is a Senior Fellow at the Center for American Progress and served on the Obama-Biden Transition Project in 2008 as the Director of the Department of Health and Human Services Agency Review for Bioethics. Moreno's research covers a wide range of topics, notably healthcare policy, neuroethics, and the bioethics of national security. He is also an elected member of the Institute of Medicine of the National Academy of Sciences and is the U.S. member of the UNESCO International Bioethics Committee.

*Photo courtesy of Dr. Moreno*

**Penn Bioethics Journal (PBJ): In your opinion, what is the definition of "autonomy" in terms of the patient's role in his/her medical care?**

Dr. Jonathan Moreno (JM): Autonomy is really borrowed from political philosophy. It means self-government, so the general idea of respect for autonomy is that people are moral agents whose agency should be respected, and they are capable, under normal circumstances, of deciding how they want to live according to rules and standards that should be respected, including for people who are patients in a medical setting. Then we get to the harder part, which is what happens when they aren't or don't have the ability to exercise their autonomy or even to articulate it, or even know what their preferences are.

> "The goal is supposed to be to respect the wishes of the patient, which requires that the patient understand what the options are, understand what his or her future would be under different scenarios that are possible."

**PBJ: At what point, if any, could a person with Alzheimer's or any sort of debilitating psychiatric disorder be said to no longer possess autonomy?**

JM: This varies according to at least two dimensions: one is what kind of disorder they have, and the extent to which it interferes with their ability to identify and express their values and preferences. So in early stages of dementia, people still know what they want and they're able to express it. In later stages, they may no longer feel that they are the same person that they were or even, in fact, be physically able to express their wishes. Here we get into very difficult territory about advanced decision-making, and a long-standing debate about whether there should be such a thing as a "Ulysses contract." A Ulysses contract is the idea that in *Ulysses,* he [Ulysses] told his men to tie him to the post of the ship as they were sailing past the sirens, who would seduce him, and he insisted that no matter what he said while they were sailing past that they should keep him latched to the bow of the ship. And for the forty years I've been in clinical ethics, hospital ethics, there have been arguments about whether people should make a Ulysses Contract as they descend into some kind of condition where they will lose their capacity. Say a spouse says to his or her spouse or partner, "If I get to this point, please shoot me, and just do it no matter what I say" or "Please give me the lethal drug" or "Please put the pillow over my head," whatever it is. That's one kind of situation in which a diminished autonomy might play out. But it very much depends on where in the disease and what kind of disease it is.

For example, somebody with schizophrenia who hears voices may nonetheless be able to make certain, particular kinds of decisions for him or herself. They may not be able to make financial decisions, for example, but they might be able to make a decision about whether they want to have a particular surgery. So that's why when people talk about "competence" in bioethics, they prefer to talk about capacity because capacity is more specific to a certain task. Even with people who have dementia, it may be a pretty advanced dementia, may be able to decide if they want one dessert or another. So the need to be task-specific is the general line of argument.

**PBJ: So specifically for Alzheimer's, at what point do you think the patient is considered to not possess autonomy?**

JM: You know, there's no test for that, it's a clinical judgment, and often a very difficult one. It's supposed to be made by the physician along with the family. Now, ideally, everybody has some kind of surrogate decision-maker who has legal status, and pretty much every state has a statute that enables people to identify an authorized person in advance of their losing capacity to speak for themself, and that person is supposed to, in theory at least, know what their values and preferences would be under certain

conditions. To show you how this gets to public policy, during the Obamacare debate, there was this debate about whether doctors should be reimbursed for the time they spend counseling patients about a legal decision-maker if they have a terminal illness and it's predictable that they will lose capacity. Those were dismissed as "death panels." In fact, our professor, Zeke Emmanuel, was called "Dr. Death" because he was notably an advocate for that kind of discussion. Since doctors are not generally compensated for talking to patients, they're compensated for time and for procedures, this is viewed by many in bioethics as a real problem.

It would be good if a doctor and a legal decision-maker and the patient could have an open conversation on a regular basis. So this system, unfortunately, very often breaks down at that point. Back to your question, there is no specific test that really determines when somebody has lost capacity. There is this sort of a cliché test that people will use called orientation tests: what year is it, what's your name, who is the president of the United States, and so forth. People often, particularly if they've come out of anesthesia, don't remember who the president is or what year it is, and indeed many of us may forget. Now and then we might forget who an important figure is in the world, so there's no very reliable way, short of a substantive conversation, often of knowing when somebody can make a decision or not.

> "In principle, the role of the doctor (though he is unfortunately not paid to do these things) should be to elicit the wishes of the patient under various circumstances."

**PBJ: Does the doctor-patient relationship represent an imbalance of power or is it fair given the greater experience and knowledge of the doctor? If so, is there a way to alleviate this or minimize its impact?**

JM: As the ability of medicine to intervene in a way that's pretty predictable and powerful has increased, the desire of patients, certainly in the U.S. and Europe, to have a say in their treatment has also increased. In the old days, almost all of history, the doctor's role has mainly been to predict the outcome and hold a hand and provide some comfort, but do very little in terms of intervention. As that's changed, patients have wanted more control. The standard view, which we can argue about, is that doctors know what doctors know, and patients know what patients know, and what patients know is what they would want under various circumstances. That's the way the ceasefire has been drawn between doctors and patients: "I know my values, I know my preferences, you know the way the medicine works, you know what happens with the surgery, you know what my chances are either way, but I know what I know." Sometimes that works and sometimes it doesn't. That's the peace treaty between doctors and patients.

**PBJ: In cases where you need to have informed consent, what is the underlying assumption or goal to be met, and are there cases where, by following the informed consent model, that goal was not met?**

JM: The goal is supposed to be to respect the wishes of the patient, which requires that the patient understand what the options are, understand what his or her future would be under different scenarios that are possible. I can give you my mother's case. She died last September. She was 99 when she died. She had everything in place, besides all the advanced directives, she was cognitively intact, and she had a son who was a professor at a medical school.

She was a very well informed person who lived her life with great command, and we thought we'd figured it out. She started having intractable bone pain from several hip procedures - she no longer had a right hip. In the nursing home, they started giving her Tylenol, which stopped working pretty fast, and then the hospice organization came and started giving her morphine, which also didn't work so well. She really wanted to die, and she woke up and would say, "I'm disappointed, I'm sorry I woke up, I really thought that this would be it." But everything with effect to informed consent was perfectly in place.

Then after the pain was just too horrible to describe, for I don't know how long, they upped her dosage to methadone. Now, that knocked her out; with her the methadone did it, and she was unconscious for fifteen months until she died. Now, this is a question: was that a failure of informed consent? We didn't really have a conversation about giving her an overdose, because it was impractical. But an overdose wasn't even a possibility in the nursing home; it would have been illegal in the state of Maryland, so there was nothing we could do about that.

Would she have consented to fifteen months in what was effectively a pharmacologically induced coma? I don't know, but that's what we did, and I think the pain at that point would've made it very difficult for her to give an informed decision. It was a case, which I'll write about someday, in which all the ducks are in a row, the consent has been fabulous, she's her own advocate for 98 years, and then something comes up--and this is why

I said to you before: you can never predict how you are going to go—something that we had not anticipated. So informed consent can fail, in particular, when there are unanticipated circumstances, and that's what we had.

**PBJ: What role can or should caregivers play in the informed consent model?**

JM: For a while in the '90s, when bioethicists had been all over the place in hospitals, I heard the attitude of, "Well, I have to respect your autonomy, I'm your doctor; therefore I'm not going to tell you what I think you should do." That went too far, because doctors should be counselors. On the other hand, what doctors often say is, "Look if you were my mom or my dad, this is what I would want for you." But that isn't exactly right either, because this patient is not your mom or your dad, and your mom or your dad may have different preferences than your patient Mrs. X or Mr. Y. In principle, the role of the doctor (though he is unfortunately not paid to do these things) should be to elicit the wishes of the patient under various circumstances. "Who is the person sitting in front of me, and how do I know how they've lived and want to live, and how they want to die, and don't want to die?"

That requires more contact than often happens in medicine these days. Now, doctors spend as much time looking at their screen filling out electronic records as they do looking at the patient. That does not facilitate having the conversations we are talking about. There are people who believe we might actually be able to have those kinds of conversations with Siri or some other kind of automated system. You've heard of the Turing test, where you're convinced there really is a human being and not just a software system that's interacting with you? There are some people who think we can elicit that kind of information--what kind of person you are, what your preferences are--through some kind of automated software, which is weird. But (a) I wouldn't rule it out, and (b) I think we may well be getting to that, because it's so expensive to have a lot of time with doctors. Many people would find this an absolutely horrible concept, having intimate conversations with a machine that would then guide your end of life care.

*Interview by Michael Fortunato and Alex Shi*

# Article

# The Bioethics of Alzheimer's Care: A Story of Autonomy and Trust Gone Awry

Andrew Carlson*

A focus on the relationship between doctor and patient as the foundation for ethical decision making in medicine has been overshadowed during recent decades by the prominence of informed consent documents in both therapeutic medicine and medical experimentation. Since progressive dementia acts to strip away the cognitive basis for using individualistic autonomy to build relationships, patients suffering from dementia are rendered particularly vulnerable in such an environment. A complex history of bioethical discourse led to the current prominence of informed consent in bioethics. An examination of this history reveals informed consent's key theoretical flaws, while engagement with caregivers of people suffering from dementia and the bioethicists who have considered their stories, reveals specific challenges to the moral conventions of health care. By relating their concerns, arguments, and stories to the theoretical flaws of an informed-consent heavy bioethics, this piece explores the inadequacy of informed consent as a vehicle for ensuring respect for autonomy and promoting trust in medicine, both for patients with Alzheimer's disease and all persons compromised by illness. Finally, it addresses why reforms to medical education are necessary to address the moral challenges presented by dementia patients and their caregivers.

**Introduction**

A person suffering from Alzheimer's disease goes through an often humiliating and demoralizing process of losing his or her authority to make decisions. Clinicians mediate this process by vigilantly evaluating a patient's competence for each important decision, based on measures of communicative function, ability to understand consequences, and proficiency in thinking through choices. However, the progressive nature of cognitive loss in Alzheimer's disease means that, eventually, Alzheimer's patients will become "globally incapacitated" (Kapp 2008). The power to make medical decisions on their behalf, including providing informed consent, will pass to a surrogate – often as some version of a "power of attorney" (Kapp 2008).

The current paradigm of caring for people with Alzheimer's disease (including legal authority, individual rights, and formal procedures) reflects how decision making is managed in the American medical-legal system, and results from a complex history of bioethical discourse. An early focus on the relationship between doctor and patient as the foundation for ethical decision making in clinical medicine has been overshadowed, during recent decades, by the prominence of informed consent documents in both therapeutic medicine and medical experimentation. When Paul Ramsey, for instance, first published *The Patient as Person* in 1970, he put forth a vision of a deeply relational bioethics – a bioethics that, rather than solely relying on individualistic principles such as respect for autonomy, is based in the loyalty essential to a proper relationship between doctor and patient. For Ramsey, a theologian who contributed heavily to the early development of American bioethics, it is loyalty that allows doctor and patient to strive cooperatively for common goods such as the relief of pain or eradication of disease (Ramsey 1970). While informed consent was intended to provide a legal framework in which to advance respect for persons and to repair bonds of trust with medical professionals, it has fallen short of its original promise – instead becoming one of the many impersonal control mechanisms acting in health care (O'Neill 2002).

The approach to medical decision making advocated by much of American bioethics, which employs voluntary and informed consent as an exclusive vehicle of securing respect for persons, has led to a marginalization of patients who lack individual autonomy and has proven inadequate for repairing the trust necessary to counteract ambivalence experienced by doctors toward non-autonomous patients (O'Neill 2002, Lysaught 2004). In light of this phenomenon, the obstacles to obtaining adequate support from physicians, expressed by the personal caregivers of patients with Alzheimer's disease, reflect the shortcomings of informed consent as a model for decision making. Since progressive dementia acts to strip away the cognitive basis for using individualistic autonomy to build relationships, an examination of dementia care reveals the concerning lack of trust present in medical encounters. This is a problem of urgent importance, as ethical conduct in clinical medicine requires some level of trust between doctor, patient, and surrogate decision-makers. Such a revelation should motivate physicians, bioethicists, and others involved in the well-being of patients to re-imagine how autonomy, trust, and networks of caring interact in the practice of medicine and in the training of medical professionals.

This piece specifically focuses on the clinical management of progressive dementia, even though some of the relevant bioethical concepts – such as autonomy, respect, and trust – were formally developed in the context of human subjects research. I will begin by presenting a historical argument derived primarily from the work of Onora O'Neill, David Rothman, and M. Therese Lysaught,

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which explores why informed consent has developed such prominence in bioethics. This account will also reveal the major theoretical flaws in the informed consent model and investigate how the connection between respect and autonomy has marginalized patients who are cognitively compromised. Then, I will engage with caregivers of people suffering from dementia and the bioethicists who have considered their challenges to the moral conventions of health care. By relating their concerns, arguments, and stories to the theoretical premise set forth in the previous section, I will illustrate the inadequacy of informed consent as a vehicle for ensuring respect for persons and promoting trust in medicine, both for patients with Alzheimer's disease and all persons who are compromised by illness. Finally, I will discuss why reforms to medical education are necessary to address these challenges.

**Informed Consent: Necessary but Not Sufficient**

The principle of "respect for autonomy" has become one of the most important and predominant forces within American bioethics over the past several decades. According to philosopher Onora O'Neill, the emphasis on individual autonomy developed as a response to some ethically troubling characteristics of the "traditional" doctor-patient relationship. This relationship was based not on genuine trust, but rather on an imbalance of power, which was deeply intertwined with the dependency of the patient on the physician – similar in many ways to the dependency of a child on a parent (O'Neill 2002).

This imbalance of power, while normative historically, was made more problematic by several key transformations in the relations between doctors and their patients, which were rooted in changes experienced by American society and specific innovations concerning the practice of medicine. David Rothman, a social historian of medicine, addresses the effects of two trends in medical practice during the decades following the Second World War: an emphasis on maximizing the efficiency of medical care and a new reliance on advanced medical technologies for diagnostic decision making. Combined with an increased severity of illness managed in hospitals, these changes limited the doctor's ability to "linger at the bedside" – meaning that even when patients and physicians were most likely to interact, their relationships failed to develop trust (Rothman 1991).[1]

The bioethics movement in the United States was unprecedented in the formality and legalism of its approaches to medical decision making, as well as the increased involvement of non-physicians in "protection of the patient." This phenomenon can be at least partially accounted for by the isolation of doctors from their patients, and the radical breakdown in trust associated with that trend. In addition, several highly publicized medical abuses arising from the doctor-patient power imbalance demanded a response aimed at empowering the patient, and the response issued by government commissions and hospitals featured informed consent prominently.[2] Ideally, requirements for informed consent were intended to set up "respect for autonomy" as a "precondition of genuine trust" by enhancing doctor-patient communication and establishing a system of formal checks on physician authority (O'Neill 2002).

However, this transformation has been less than ideal. While an increase in public trust would be expected in a society where individuals are empowered by respect for autonomy, this has not occurred (O'Neill 2002). In fact, a trend of steadily decreasing trust in medical providers and institutions has occurred in spite of notable attempts to increase trust, improve the regulation of medicine, and heighten public attention to environmental concerns related to health care (O'Neill 2002). Rather than an increase in trust between doctor and patient, O'Neill argues that we have witnessed a transition to an "audit society" based on impersonal systems of accountability (O'Neill 2002).[3] A theoretical tension between trust and individual autonomy, as well as the insufficient notion of autonomy in bioethics as simply the ability to consent to or refuse proposed treatments, both call for a new configuration of trust and autonomy. Because the individualistic autonomy in bioethics inherently conflicts with the development of the interconnectedness necessary for trust, O'Neill argues that we can have the benefits of both ideals only if they are the right manifestations of themselves (O'Neill 2002). In the context of the progressive dementia, this necessitates a shift to a focus on the relational networks of which the patient, personal caregivers, and physicians are unique members.

The understanding that the fundamental deficiency in bioethics over the past decades is a failure to address decreasing public trust in medicine invites those in the bioethics community to the task of increasing the trustworthiness of physicians and the institutions of which they are a part. Notably, the audit-based approach taken by government bodies as a way of increasing trustworthiness, which has featured informed consent procedures as an

[1] Moreover, the highly competitive nature of both pre-medical and medical education requires early commitment, intense focus on a narrow range of subjects, and vast allocation of time to career preparation – which decreases the ability of aspiring physicians to cultivate relationships with those outside the field. More physicians are destined for a career as a specialist than in the decades before World War II – meaning that they will be more likely to encounter patients for a short course of intense treatment when they are seriously ill than to develop trust with them over a lifetime of illness prevention. Once they are established in their careers, modern physicians are likely to be overworked and less ethnically or professionally relatable than their historical counterparts (Rothman 1991).

[2] Many of the abuses of power most prominent in changing public attitudes toward medicine were outlined in Henry Beecher's 1966 article in the *New England Journal of Medicine* entitled "Ethics and Clinical Research" (Rothman 1991).

[3] In addressing the reasons for ever-decreasing public trust in medicine, O'Neill points out that it is conventionally thought that either the goodwill of others or evaluation of others' reliability is required for a person to place trust. Given that few objective means of evaluating reliability are available in modern society, she asserts that it is rather the *perception* of unreliability that produces distrust – allowing the commonplace procedures surrounding autonomy to enter in as candidates for the cause of decreasing public trust (O'Neill 2002).

essential control mechanism, has largely failed to produce genuine trust. This is due to the impersonal monitoring of health care systems, which has made medical institutions more complex and obscure. Such a trend toward unfamiliarity means that the informal relationships of trust, traditionally relied upon for accountability, became insufficient – increasing the need for more systemic control of health care. While compliance with auditing procedures increased *trustworthiness* as assessed by objective reliability, *trust* became less achievable because regular people have been unable to evaluate the "trustworthiness" that is objectively present (O'Neill 2002). Setting up informed consent as an organizational requirement fulfilled by the use of a complicated legal document has been unsatisfying chiefly because it serves to reinforce one of the basic causes of mistrust in medicine – a perception of the doctor as a stranger in the strange land of the modern hospital.

Theologian M. Therese Lysaught makes a different, but not entirely unrelated, claim about the problems related to modern bioethics' reliance on respect for autonomy as envisioned by informed consent. She asserts that the importance of patients who are not fully autonomous is overlooked in a system predicated on respect for autonomy. She examines the changing use of the term "respect" – first in the context of "respect for persons" and then later in the context of "respect for autonomy." Describing the notion of respect early in the bioethics movement as synonymous with "protection," Lysaught notes that, at the time of the Belmont Report in 1979, respect applied equally to all persons. The protection afforded by "respect" against abuse or unwanted manipulation was extended to the whole person – not just his or her usefulness to society or abstractions such as rationality (Lysaught 2004). Paul Ramsey evoked a similar conception of respect in *The Patient as Person* as he weaved an ethical analysis predicated on a reverence for human life, requiring canons of loyalty with both autonomous and non-autonomous persons (Ramsey 1970). Autonomy was not a condition for equal consideration as a person under this model. Other publications, including the National Commission's *Report and Recommendations: Research on the Fetus*, insisted that consideration as a person was based on human genetic identity, and that respect applied to all human persons.

However, Lysaught argues that the publication of *The Principles of Biomedical Ethics* by Beauchamp and Childress in 1979 changed the narrative of respect by classifying respect for persons as a type of respect for autonomy – meaning that respect became a term reserved for only those able to choose freely. This shift, along with publication of *Research on In Vitro Fertilization* by the Ethical Advisory Board of the Department of Health, Education, and Welfare, constituted a recasting of respect as a rhetorical tool only, rather than a source of protection to persons (Lysaught 2004).[4]

A bioethics with informed consent at its core is problematic for Alzheimer's patients and their families. The procedures involved with informed consent have formed a key aspect of the medical decision-making process. While these procedures characterize much of the dialogue that occurs in medical settings, the viewpoints explored above suggest that informed consent as a model of communication privileges the rational and fails to build sufficient trust between doctors and their patients. To enhance protection of progressive dementia patients and the empowerment of their family caregivers, physicians must challenge the predominant notions of respect for autonomy and seek new ways of engaging both patients and caregivers in respectful dialogue.

**Expressions of Caring: Physician Obligations and Communication with Caregivers**

Late-life progressive dementia, specifically dementia caused by Alzheimer's disease, has increasingly presented a public health challenge as global lifespans have increased. According to one projection, one in eighty-five people will be living with Alzheimer's disease by 2050 – a threefold increase in the prevalence of the disease from 26.6 million people globally in 2006. Approximately 156 billion dollars every year are spent on caring for Alzheimer's patients worldwide, with patients suffering from the disease often requiring intensive medical care and daily support (Rocca et al. 2011). The disease requires increased consideration by physicians and other healthcare professionals, given the mounting burden it places on human well-being. Alzheimer's disease, among other types of progressive dementia, also presents challenges to widely held notions about the obligations of the physician, in addition to her role in a patient's network of caring relations.

Perhaps, the most important role physicians can take in caring for patients with Alzheimer's disease is that of empowering and supporting the personal caregivers of those patients. In his book, *The Moral Challenge of Alzheimer Disease*, bioethicist Stephen G. Post argues that family caregivers are irreplaceable members of society because they contribute uniquely to the well-being of their loved-ones who are living with dementia. Namely, caregivers enable patients with dementia to be seen as whole persons who are part of essential relations with family members and friends, instead of merely as individuals who have experienced a radical decline in their cognitive abilities (Post 2000). In doing so, they protect their loved ones from harms inflicted by a society oriented toward rationality and productivity – a society that often fails to appreciate the unique needs of people who have dementia. The caregivers of people with dementia can, according to Post, be seen as actively resisting the tendency of modern Western culture to exclude the weak and unproductive. They encourage the

[4] O'Neill also recognizes the marginalizing effect an emphasis on autonomy can have for non-autonomous patients and their voices. According to O'Neill, ". . . .where options are few, where cognitive and decision making capacities are limited, procedures of informed consent may become a burden. . . ." She insists that a system in which patients are normatively presented with options for medical treatment and then simply told to independently choose between them fails to accommodate the needs of patients who have an impaired ability to make choices for themselves (O'Neill 2002).

rest of society, through their consistent demonstration of unconditional love for people with dementia, to re-envision the predominant conceptions of human worth (Post 2000). Personal caregivers are people who have, at least, accepted responsibility for those to whom care is given, even though the demands of providing care sometimes prevent Post's notion of unconditional love from being actualized. For these reasons, physicians bear specific obligations to support the persons who serve as personal caregivers – and in doing so, to answer claims of loyalty issued by patients who cannot, as of now, be cured of progressive dementia.[5]

However noble the provision of correct support to caregiving family members might be, the relationships between doctors and their patients' families often fail to allow medically empowered caregiving. In a brief discussion of communication between caregivers and doctors, dementia caregiver and patient advocate Sue Matthews Petrovski reports:

The effective Alzheimer's doctor must deal with the family as well as the patient. But at times, although they can diagnose and prescribe, medical staff often seem to deny responsibility for helping a family with suggestions for day-to-day care. A survey by the Alzheimer's Association found that only thirty-one percent of caregivers believe that their doctors were of help in finding services, while ninety-seven percent of doctors said they had given such advice. (Petrovski 2003)

Certainly, a marked disparity in the perception of needs related to Alzheimer's care indicates something is amiss in the doctor-patient-caregiver relationship. The study to which Petrovski refers, in addition to providing evidence for this disparity, also indicates that physicians tend to inadequately communicate the possibility for stabilizing the symptoms of Alzheimer's disease – even if they acknowledge this possibility based on their medical expertise (2001).[6] Moreover, themes of distrust of physicians and barriers to doctor-patient-caregiver communication were noted in a qualitative study conducted by the Alzheimer's Association in 2008 with family members and patients living with dementia (2008). Information from these studies indicates that while the level of support for caregiving provided by physicians varies, there is generally a concerning lack of support – a problem closely tied to a lack of trust.

[5] Post also warns against the tendency to provide inadequate support to caregivers because doing so has unjust impacts on women. Women make up a larger portion of the caregiving population than men, often because daughters and daughters-in-law are more likely to assist in caregiving than sons and sons-in-law. This reality reflects gendered family expectations that are problematic in themselves, but also means women disproportionately shoulder the burden of caregiver exhaustion (Post 2000). Post demonstrates that supporting caregivers is a question of justice for caregivers, as well as for those who are recipients of care.

[6] Poor communication regarding care services appears to be a problem in a variety of health care systems, as noted in a more recent qualitative study of Alzheimer's care in the National Health Service (NHS) of the United Kingdom. Caregivers who participated in the study reported confusion about where to learn about caring for a loved one with dementia, and specifically that general practitioners often provided inadequate support. Moreover, the information that was shared was not presented in a sensitive manner and often caused anxiety on the part of caregivers (Sutcliffe 2015).

Given the inadequacy of support for caregiving evident in testimonies from dementia patients and their families, it seems appropriate to investigate its causes. A qualitative study by public health researchers Ester Carolina Apesoa-Varano, Judith Barker, and Landson Hinton found that physicians tend to experience intense ambivalence over the their role in treatment of Alzheimer's patients. Doctors often respond to this tension by failing to acknowledge responsibility for "care related activities" – activities required for the affective and relational well-being of patients regardless of their contribution to the eradication of a patient's disease. Such an approach indicates that primary care physicians consistently revert to a "cure orientation" when stressed by a lack of education on how to "care for" patients, or by organizational constraints such as lack of time.

Ambivalence, in this context, refers to uncertainty by physicians about whether their responsibilities are limited to merely providing pharmacologic and behavioral therapy for treatable Alzheimer's symptoms, or whether attending to the non-curative well-being of patients is also required. In order to attend to patients' needs in the case of a disease such as progressive dementia, the model conventionally used by physicians in relating to patients – identification and normalization of pathologic states ("curing") – often becomes insufficient (Apesoa-Varano et al 2011). While it might be imprudent for physicians to be tasked with directly attending to the emotional and daily care needs of dementia patients, it seems reasonable to acknowledge Stephen Post's insistence on the importance of personal caregivers. Physicians should be able to perceive their obligations to inform and support personal caregivers about care-related services (home care equipment, care professionals, caring skills education, and eventually referral to quality memory care centers) even though they lack the time or education required to care for the daily needs of patients directly.

Even though a variety of causes might be proposed for the uncertainty and lack of confidence by doctors in providing access to "care-related activities" described by Apesoa-Varano and her colleagues, the trends related to autonomy and trust addressed separately by O'Neill, Rothman, and Lysaught, taken together, open the possibility for a startling conclusion. Perhaps, those who might be most in need of the protection afforded by a healthy bond of trust with a physician (including, especially, patients with progressive dementia) are placed at unique risk of being treated ambivalently because an emphasis on "respect for autonomy" through informed consent has failed to repair bonds of trust between doctors and patients that have been severed by modern life. The informed consent process, as a model for communication with patients and their families, is insufficient to cultivate the trust required to empower personal caregivers of people struggling with dementia.

While a notion of autonomy as an individual's ability to provide voluntary and informed consent is prominent in mainstream bioethical thought, other models for autonomy might better serve Alzheimer's patients and their families. Bioethicist Bruce Jennings points out that competing notions of what autonomy is and what it means

for professional practice increasingly offer compelling alternatives to the conception of autonomy that has been traditionally adopted in bioethics. He argues that while bioethics has historically utilized a conception of autonomy based on lack of interference in decision making ("negative autonomy"), many contemporary scholars, including bioethicists Jennifer Nedelsky and Rachel Halliburton, are shedding this view for one in which flourishing social relations are essential. Nedelsky, a legal scholar by training, asserts that a network of connections with others is not only a precondition for the ability of persons to make choices; it is actually a part of this ability.

As a philosopher, Halliburton has advocated the idea that autonomy does not have inherent value, but rather has value only when it contributes to human flourishing. These two views, assessed in conversation with each other, lead to a re-configuration of what it means to make a free choice, and thus have implications for informed consent among other issues (Jennings 2016).

Moreover, they offer models for the relationship between doctors and patients that might better serve patients suffering from Alzheimer's disease – models emphasizing support for the personal caregivers who are their most important sources of strength and wellbeing.

**Reforming the Bioethics of Autonomy Through Medical Education**

To work on building trust in medicine and to better serve patients who lack claims to "bioethical" autonomy, the medical community should strive to cultivate a more meaningful way of approaching respect for *persons* that emphasizes a patient's networks of relations.

Doing so requires a transformation in daily medical practice that could be accomplished through two distinct strategies – organizational reform of health care systems and a modified approach to physician training. For example, modifying legal standards surrounding surrogate decision making, and equipping doctors to more effectively navigate intra-family communication, are two essentially different ways to promote a greater role for caregivers in decisional processes – thereby ensuring that the people providing personal care for incapacitated adults are also involved in making medical decisions on their behalf.

While aspects of both approaches are worthy contributors to any trajectory of meaningful reform, medical education promises to be a more fruitful target, in light of the history of bioethics and the failure of informed consent's legal formalism to advance relationships of trust.

By choosing a path of change that includes a focus on cultivation of virtue, it is possible to leverage existing features of medicine – namely the importance of medical education in ensuring patients are respected and cherished. Paul Ramsey, among others in the early history of American bioethics, recognized the unique importance of professional education to the moral life of physicians.

In his seminal text, *The Patient as Person,* Ramsey observes, "there is no profession that comes close to medicine in its concern to inculcate, transmit, and keep in constant repair its standards governing the conduct of its members" (Ramsey 1970). This propensity toward the communication of professional values, already fixed in the traditions of medicine, ought to be capitalized on as part of the process of reforming medical decision making to better serve the crucial work done by caregiving networks on behalf of patients with conditions such as progressive dementia.

Specific transformations ought to emphasize the importance of active listening skills as tools that allow doctors to view their patients as whole persons. While attentive listening is undoubtedly a central aspect to taking a good medical history or noticing subtle changes in a patient's medical condition, more work could be done to form bridges between training in ethics and the dialectics so revered in medical education. Effective reforms will likely not involve adding requirements to an already dense course load, but rather will more effectively integrate ethics training throughout the medical curriculum.

Some approaches in pursuit of this goal might involve the integration of reflective writing into medical curricula, which might increase students' comfort with their own vulnerability and mindfulness of the suffering of others (Shapiro et al 2006). Playback Theatre (PT), a form of theatrical improvisation that engages with the real-life stories of participants, also might offer benefits due to its emphasis on listening and expression as ways of appreciating others as whole persons integrated in networks of relations. PT has already been in use by Baylor Medical School to help medical students deal with the stress of medical education while also cultivating sensitivity to the stories of patients (Salas et al 2013).

Training that will help doctors relate more constructively to the caregivers of patients suffering from illness, while balancing this focus with an appreciation of patients' privacy needs, is of paramount importance. Expecting medical students to engage with ethnography or narrative medicine might be one path to this goal, as these disciplines emphasize the position of patients within the context of their relational networks and might encourage doctors to skillfully invite the participation of caregivers without ignoring the needs of patients to have their privacy respected. The delicate balance between including the caregivers of patients who are aged or disabled in medical decisions while also preserving trust with patients as individuals requires a subtle cultivation of professional habits, rather than the introduction of new forms of impersonal legalism.

As we confront the challenge of empowering caregivers of patients suffering from Alzheimer's disease and other diseases that impair claims to the protection of informed consent, medical education will certainly play a major role. Instead of hollow insistence upon new procedures, the focus should be on giving future doctors new moral capabilities, which encourage them to view patients holistically and in the context of rich human relations, of which personal caregivers are a crucial part.

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# Article

# Transplanting the Problem: Israel's Solution to Low-Organ Donation

Hope Lu*

"When the dream of the regenerative body cannot be fulfilled on home ground, the gaze turns towards global bodies." (Lundin 2008)

**Introduction**

Organ trafficking—one of the most widespread medical crimes of the world—involves international sellers, brokers, and buyers of organs. From kidneys and hearts to lungs and intestines, harvested organs are traded like commodities. Due to the many associated human rights violations of targeting vulnerable populations and performing unsafe operations, trafficking is illegal. For example, in the Middle East, Egypt's organ rings are notoriously connected to sex trafficking rings. The Egyptian organ market has grappled with its underground trade for years and has drawn a lot of public attention. Recently, headlines featuring Egypt's organ market have been replaced with headlines featuring Israel's trans-national organ market.

This study focuses on the transformation of the Israeli kidney and organ trade in the past decade. Among the developed world, Israel maintains one of the lowest kidney donation rates and one of the highest rates of kidney purchase. For years, organ transplants abroad, also known as "transplant tourism," was subsidized by the Israeli government. Every year, more patients resorted to transplant tourism. In 2008, the Ministry of Health enacted a law that not only stopped reimbursement of foreign transplants, but also criminalized the act. Several questions particular to Israel arise: Why does Israel have such low organ donation rates? How do these lower rates of donation impact the nature of the kidney trade? Why was there a strong pivot in Israeli policy?

I argue that Jewish attitudes towards healing and death contribute to low organ donation rates in Israel. Responding to low donation rates and patient pressure, the Israeli government promoted transplant tourism as a solution. International media attention was the key factor in reversing the government's support and led to new policies, but the implemented policies do not address how to accommodate for Jewish views on respect for the body and brain-death. While the policies have successfully reduced transplantations abroad, they have failed to increase domestic donation considerably.

It is necessary to note that Israeli-Jews are not alone in the issue of organ-trade involvement. Most rabbinic authorities in other countries will also disapprove of transplantation and share similar perspectives. However, because Israel is demographically 75% Jewish, they face a particularly severe situation of low donation. It is also important to note that Jewish authorities do not exercise great impact on the culture towards transplantation world-wide. Most countries advocate organ donation whenever possible (Shimazono 2006). Israel serves as a useful case study for the factors that impact organ trafficking. Valuable insights on implementable regulations can be applied to other countries facing similar issues.

**Context of the International Kidney Trade**

Organ trafficking is as widespread as human trafficking. In Asif Efrat's progressive study of legislative prohibition in Israel's organ trade, the formal definition of organ trafficking is the "...sale and purchase of human organs for transplantation" (2013). However, organ trafficking is only one form of organ trade and legal forms do exist. First, viable organs for transplantation may come from people who die naturally from accident, age or disease. Second, other transplantations involve donors who are close family members of the recipient. A third type, altruistic donations, involve living individuals who donate with no relation with the patient with no monetary reward. In these three cases, organ trade is not criminalized. In commercial transplantation, patients obtain kidneys from financially vulnerable citizens who are expecting monetary compensation for their kidney (Flechner 2015). There are about 10,000 commercial organ transplantations annually in the world and they make up about 10% of all transplantations (Efrat 2013). Commercial organ transplantations are generally illegal because they are connected to organ trafficking. The human violations associated with organ trafficking will be discussed later on. As noted in Alexis Aronowitz' *Human Trafficking, Human Misery*, there are "...about 6,000 international kidney transactions in one year" and the most common case is the donor and the recipient agreeing to the sale (2009). Unique to commercial transplantation is the presence of a broker. Brokers seek poorer provinces in various countries, looking for individuals who are willing to trade their kidney for cash. Brokers not only recruit donors, but also recruit medical directors, travel agents, surgical teams and insurance agents.

In conjunction, these actors make up the illegal industry of transplant tourism. Transplant tourism "... involves the travel of both the donor and recipient to the place where the transplant will occur" (Aronowitz 2009). Willingness to travel expands the market for any individual

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seeking an organ, especially if domestic donation is low. In a 2007 study commissioned by the World Health Organization, researchers identified India, Philippines, Egypt, Pakistan, Turkey, South Africa, Azerbaijan, Iran and Colombia as major exporting countries. Major organ-importing countries included Japan, South Korea, Singapore, Saudi Arabia, Kuwait, Oman, Israel, and the US (Shimazono 2006).

As shown in Eytan Mor and Hagai Boas' analysis of non-related compensated donation, even policymakers of the countries that import the most kidneys condemn and outlaw organ commerce and trafficking (2005). Policymakers are concerned that vendors are under-compensated for their kidneys. In *Bodies for Sale*, Stephen Wilkinson asserts that transactions will often exploit vendors by offering them an inadequate fee and ignoring safety precautions before and after surgery (2003). Organ trafficking rings are also closely tied to sex-trafficking rings and drug rings (Scheper-Hughes 2005). Furthermore, commercially-transplanted patients and donors are at a higher risk of surgical infections like HIV and hepatitis because of substandard care (Efrat 2013). Most donors have poor health after the operation, and can only work limitedly (Aronowitz 2009).

Transplant tourism is still widespread despite rampant opposition for a few reasons. Patients who undergo kidney transplantation have higher rates of survival than patients who are on dialysis, and it is less costly in the long-run (Mor and Boas 2005). Additionally, the market is highly profitable for the brokers, doctors, and medical teams involved because the demand for kidneys is so high. To illustrate the severity of the demand, according to the 2014 Milliman Research Report on organ and tissue transplants, the average cost of a kidney is $1.2 million. The worldwide demand for organs is never met by the supply. For patients who are facing imminent death and an enduring waitlist, the last available option may be to obtain an organ through commercial transplantation. For donors, selling a kidney may be the only course of action to pay off debt or escape poverty. With cadaveric death contributing to less than 2% of kidney donations and ineffective strategies in changing the number of altruistic donations, the world's kidney supply fails to satisfy the world's kidney demand (Amsel 1994).

In the Middle East, wealthy patients from Israel, Kuwai, Oman, and Saudi Arabia have traveled to India, Turkey, Iran, Iraq, and several other countries for kidney transplants. Later, Moldova, Georgia, and Romania became popular destinations and most recently Israeli patients have been traveling to Brazil and South Africa (Scheper-Hughes 2005).

More than one thousand citizens are listed for transplants in Israel and over 600 are waiting for a kidney. Each year, some resort to illegal kidney rings like the one led by Dr. Zaki Shapira of Tel Aviv. Dr. Shapira was released several times from charges because of insufficient evidence that he was selling kidneys. He continued to recruit organ sellers from Gaza and the West Bank for 7 years and profited immensely until he was indicted in 2015 (Ashkenazi et. al 2015). Another notorious case involved a woman named Aisha from Nazareth, Israel. She was paid about half the original amount for her kidney, and Aisha could only work part-time after the operation. Later, the members of the ring that bought from Aisha were arrested. Dr. Hiss, the head of the operation, sold over 125 kidneys in a decade (Ashkenazi et. al 2015). Organ traffickers like Shapira and Hiss are able to profit from trade for many years without getting caught because people who buy themselves health keep quiet, and donors fear the consequences of partaking in illegal activity. Prior to the outlawing of transplant tourism in 2008, citizens did not see the need to pressure the Ministry of Health since kidney trafficking was saving the lives of sick people they knew. Israeli transplant tourism was unique because for a period of time, Health Maintenance Organizations (HMOs) could legally reimburse patients for kidney transplantations performed abroad. Patients faced low organ donation rates and heavily pressured the government to use transplant tourism as an efficient solution.

**Jewish Attitudes towards Organ Donation**

As mentioned before, Israel has extremely low donation rates of kidneys despite having advanced medical centers and doctors. Simultaneously, Israeli patients constitute a large number of kidney transplantations that occur across the globe. Low donation and high numbers of transplantation can be accredited to religious demographics and how religious values impact the medical community. About three quarters of the Israeli population is Jewish. An additional one-fifth of the population is Arab, with which other religious barriers to organ donation are present.

Representative members of the Arabic-speaking community are skeptical about the donation process. Similar to Jewish attitudes, decisions about organ donation would require solving tensions between family, community, and religious values. The primary ruling of Islam about a Muslim's corpse is that it should be disposed of through washing, shrouding, and burial. Thus, different religious leaders (Ayatullahs) of the Islamic community will rule differently about major organs. For example, Ayatullah Tabrizi would not allow the donation of a kidney during a life time, but Ayatullah Sistani would; both are prominent Ayatullahs with these rulings on their official websites (Padela 2015).

*Jewish Value of Appreciation of Human Life*

While there are diverse branches within Judaism, central to Jewish ethics is an appreciation for the value of human life. The medical community is respected because Judaism promotes the mandate to heal. Healing also plays a crucial role in explaining why Israeli patients are willing to undergo transplantation, and elucidates why so many patients go abroad to receive the operation.

As described in Aaron Mackler's study of transplantation ethics, the Jewish faith views life as a gift from God (2002). Provisions of Jewish law require that saving a life when possible is not only permitted but required. In the Book of Leviticus (19:16), the statement "You shall not stand idly by the blood of your neighbor" is what most refer to as the teaching of 'saving life'. The weight associated with saving life in traditional Jewish law encouraged Jewish authorities to accept organ transplantation. In Nachum Amsel's *Jewish Encyclopedia of Moral and Ethical Issues*, authorities also

promote prioritizing an individual's need for medication or lifesaving equipment over forgoing the treatment to help someone else (1994). Combining the two ideas leads to the conclusion that with a failing lung, heart, or kidney, a patient is nearly required to look for ways to save his or her life. Aside from personal will, Jewish patients seek to protect and extend life because it should not be taken for granted.

From a Jewish perspective, one also favors the definite saving of a life over the possible saving of a life. The Talmud, which is the body of Jewish civil and ceremonial law, rules that one "...may not put himself at risk to save a person in danger of dying, if it qualifies that the person will risk dying instead" (Nachum 1994). In response to this law, a number of rabbinic authorities advance arguments that those who practice Judaism should not risk their life by donating a viable organ, especially if it increases the risk of death for them. On the other hand, more progressive religious authorities affirm that healing and the life saved from a transplantation overrides this ruling.

*Kevod Hameit and Bodily Desecration*

The definition and association of death from the Jewish perspective also contributes to low kidney donation. Religious authorities debate two aspects of kidney donation: respect for the body and brain death. *Kevod hameit* or respect for the body supports a degree of caution toward kidney donation, especially in the popular opinion of the community. Respecting the body by not disturbing its integrity is interpreted as a way to respect someone who has passed (Mackler 2001). Therefore, removing parts like organs before or during burial may be considered mutilation (known as *nivul ha-met* by scriptural law). Because *nivuh ha-met* is deeply offensive to the dead and to God, some forgo donation. One study using focus groups in Nazareth found that non-donors "...felt it was important to go to the grave whole" (Mackler 2001). Additionally, formal burial is important in Jewish law, and those who choose not to donate may see removing a kidney as undermining a respectful burial.

Furthermore, the Jewish perspective asserts that the body is not a disposable possession. In relation to transplantation, the removal or disposal of body parts may be inappropriate. Other perspectives emphasize that kidneys cannot be removed in the vague hope that they will potentially save lives, which means kidneys cannot be removed for storage in an organ bank. This viewpoint further eliminates some potential donors after death. In general, orthodox rabbis will assert that the body should be buried rather than used for medicinal purposes if it means that the body will remain intact after death.

*Controversy Towards Brain Death*

More progressive religious authorities will forgo the violation of bodily desecration. Rabbi David Bleich notes in *Judaism and Healing* that in *halakhah* (laws of Judaism), the prevailing view is that cutting open the body can only be performed if "...the information gained will contribute to the immediate preservation of life." Additionally, the ban on desecration of the body is permitted in the face of danger (Bleich 2002). An even more liberal interpretation suggests that transplants are permitted if the removal of the kidney is not performed while the donor is yet in *gesisah*: the state when death is anticipated within seventy-two hours (Bleich 2002). With the lack of cohesion on respect to the body with regards to kidney removal, parts of the Jewish community will err on the side of caution. In recent years, however, groups of individuals in the Jewish community have been advocating for organ donation and more liberal approaches to transplantation (Mackler 2001). NGOs like Halachic Organ Donation Society have even been reaching out to individuals to change their perception of organ donation and have recruited rabbinic authorities to carry donor cards (Flechner 2015).

For the religious authorities that forgo the prohibition of removing organs and value saving life over *nivul ha-met*, there is still the issue of brain death. Most kidney transplants involve donors whose breathing and circulation are maintained artificially through medical devices and machines, even though brain activity has stopped. This phenomenon of the ceasing of mental function or consciousness is known as brain death. Jewish law recognizes no heart beat as the criterion for death, and so, brain death may not count in some interpretations. Ultra-orthodox Jews who strictly interpret *halakhah* also require respiratory function to cease. 25% of the Jewish population who identified as religious or religious-traditionals favor this orthodox interpretation of death criteria and therefore cannot donate as living donors (Mor, Eytan, and Boas 2005). For them, the body is still alive, and artificially killing the patient for the purpose of kidney harvesting would be unacceptable. This reduces the number of domestically donated organs and increases the need for trans-national kidneys. Organs from live donors are also more likely to be accepted into the new body, which encourages patients to consider transplantations abroad rather than receiving a cadaveric kidney. In recent years, there has been an effort to modify traditionally accepted criteria of death in order to make more kidneys available for transplantation. Some religious authorities are suggesting that beneficence might mandate donation in some instances, superseding the importance of maintaining an intact body (Bleich 2002). Conflicts between basic principles on views of healing and death are inevitable, but they reduce the number of domestic donations leading to an increasing need for transplant tourism.

**International Media Exposure and Policy Reversal**

Internationally, the most common kidney buyer is identified as 40-50 years old, male, and from Israel (Shimazono 2006). Recipients are treated similarly to the way a tourist on a guided trip is treated. They are provided with airfare, accommodation, and some operations even include sightseeing tours. Israeli kidney brokers could even advertise on radios and newspapers, much like other travel agencies. Lacking legal obstacles, brokers were formal agents on the kidney transplant scene. In contrast, patients who identified a willing Israeli seller were prohibited from undergoing the surgery in Israel. The original policy stemmed from unfavorable logic. The government interpreted HMOs' refusal to pay for kidney transplants abroad as exploitation of suffering patients who paid enormous out-of-pocket fees. The Ministry of Health ascertained that requiring HMOs to cover

transplant tourism was cost-effective and beneficial to the health of citizens. Dialysis, the clinical purification of blood, is the only alternative and costs about 160,000 shekels ($50,000) annually. Added costs of long-term hospitalization involving dialysis accentuated transplant tourism an attractive solution (Efrat 2013).

Above all, the State adopted a no-questions-asked approach: patients obtain reimbursement without needing to identify the donor or how the kidney was obtained. Reimbursement funded by health insurance tax and the government budget removed the financial barrier and eliminated the need for continued waiting or asking a loved-one to donate. For years, financial incentives and the absence of monitoring relieved the Israeli medical system of its problem. The number of kidney transplants hit a peak of 155 in 2006 until two years later when the Organ Transplantation Law immediately illegalized transplants abroad (Padilla et. al, 2013). International media attention caused the stark reversal from reimbursement to illegalization. More Israelis have been mentioned in reports involving international organ trafficking, whether in Ukraine, Turkey, Costa Rica, or Kosovo. There was a flux of media produced starting in 2000. In 2001, readers pored over the series of articles that revealed Israeli recipients paying $250,000 to brokers in the South African kidney ring. Non-Jewish advocates of the international community did not condemn the religious viewpoint. Rather they condemned the solution that the authorities and government resorted to. In 2003, newspapers condemned brokers who preyed on Russian immigrants in Israel who were forced to comply with the brokers (Efrat 2013). Outlets like CNN, NPR, and NBC have featured stories on kidney transplantation periodically. In 2004, when the WHO declared to take action against transplant tourism, reports consistently scrutinized Israeli transplantation policy. Local Israeli physicians and the international medical community eventually joined in on pressuring for change. Extensive media coverage initiated this build-up of intertwining local and international pressures.

Concerned for their country's international image, Israeli officials caved under the heavy criticism on international forums, and Parliament adopted new policies. The Brain-Respiratory Death Law defined brain death as an indication of death for all purposes, including religious ones. The Transplantation Law declared organ trafficking punishable by three years in jail and explicitly outlawed reimbursement for foreign transplantations. In an attempt to increase domestic donation, another provision prioritized transplant candidates who signed to donate their organs after death. The policies have been effective in reducing transplantations abroad to 43 in 2013 (Efrat 2013). However, the implemented policies do not solve all the relevant issues. Although policies have significantly decreased transplantations abroad, there has not been a significant increase in the consent rate for decreased organ donation, merely a 2% increase from 2004-2006 (Ashkenazi, Lavee, and Mor 2015). In 2014, a New York Times article exposed that Israeli patients were still traveling to Costa Rica to undergo illegal transplantations. Because of the clandestine nature of the transactions, the number of foreign transplantations could still be substantive, especially if media outlets are still pinpointing kidney rings. Additionally, ending transplant tourism adversely affected patients waiting for a kidney. From 2008 to 2011 the kidney waitlist increased from 540 to 733; the number of patients who died while waiting for a kidney rose from 22 to 39 from 2008 to 2010 (Padilla, Danovitch, and Lavee 2013). Many patients are willing to risk a few years in prison and fines if it means saving their life.

Patients are justifiably frustrated and have been calling for revision of the Organ Transplantation Law. Foremost, punishments for transplantation abroad need to be enforced. It unfair to those who avoid transplantation abroad when some patients successfully do not get caught. Also, the law fails to address the values that Israelis hold and does not solve the core of the issue: low donation rates. The reforms that targeted increasing living donations, such as prioritizing patients who signed a donor card, were insignificant in terms of meeting the demand for kidneys (Stoler 2016).

Most choose to forgo organ donation in hopes that others will increase the number of available kidneys and the mindset inhibits increasing domestic donation. Among rabbinical leaders, the Brain-Death provision has not received the anticipated response, and most religious leaders shy away from advocating organ donation.[6] Free-riding and lack of advocacy from the religious community are failures of the new policies. The Organ Transplantation Law needs to focus on domestic donation to satiate the increasing demand.

**Moving Forward with Possible Solutions**

To incentivize deceased organ donation, the provisions should not only grant priority on waiting lists to candidates who are registered donors, but further prioritize candidates who have a first degree relative who is an organ donor. This will encourage citizens to donate for the future well-being of their family members. Currently, donor cards can be applied for at the Ministry of Heath website. Another way to increase donors is to include it on driver's license applications. Additionally, the current clause cites that donors must be registered for at least three years before priority can be applied. If someone needs a kidney within the next few years, they will be less likely to donate. By allowing immediate priority to those who agree to become donors, more people will revise their status. Furthermore, the concept of brain-death also needs to be accepted by religious leaders. Training courses in organ donation for Jewish and Muslim leaders may guide the religious community towards acceptance (Rumsey et. al. 2013). The programs should aim to remove religious and cultural impediments for organ donation. Influencing rabbinic leaders to emphasize the "saving-life" aspect of transplantation, will encourage more donation in the Jewish community (Mackler 2001). Educating and promoting donation publicly through advocacy groups increases donation as well.

A more radical approach to solving the shortage of organs is creating a regulated market. A regulated market would ensure that donor health would be prioritized and procedures would be standardized. Most approaches suggest

that a fair market price of about $40,000 to donors would guarantee financial security for most donors. A third party organization, like the United Network for Organ Sharing, would manage marketing and partnering with appropriate hospitals around the world (Friedman 2006). But a regulated market does not solve the issue of financially vulnerable donors underestimating the costs of giving away an organ. Even with a regulated market price, black markets may still flourish if international law does not prevent it from offering lower prices. Logistically, a regulated market would also be too difficult to stream-line, assuming that donors are international. Different health regulations and procedures of countries would make an efficient market difficult to create.

In the meantime, patients can engage in kidney exchange programs within European countries. These programs offer a transplant option where candidates who have a living donor with an incompatible kidney for them can donate their kidney to a different patient, and the original recipient receives a kidney from elsewhere (Flechner 2015). This increases the pool of successful kidney transplants without needing to exploit poorer neighborhoods or increase domestic donation right away. Responding to pressure from the media and the medical community, the Israeli government has proved its commitment. It must continue to make changes that are fluid and address all the values of the patients, religious leaders, medical doctors, and donors. Other countries with large religious populations like Romania, Bulgaria, Turkey, Saudi Arabia, and Kuwait, should consider adopting strict out-lawing of transplants abroad if low-donation is an issue. They may also consider adopting the effective strategies that the Israeli government has adopted, such as donor cards and prioritization.

**Summary**

The trafficking of human organs and transplant tourism is not unique to Israel. Patients from Japan, Taiwan, and Saudi Arabia have also undergone commercial transplantations abroad. Once those suffering from kidney failure learned they could buy a kidney, transplant tourism transformed into an industry. Israel is identified as an initiator of transplant tourism because for years, its policy encouraged patients to seek abroad. Opposing interpretations of how religious values apply to transplantation explain the low donation rates and high rates of purchase. Values of healing and death counter-balance the Jewish community's perception of donation. Most feel desecration of the body is a form of disrespect, and brain-death does not count as death. To solve this issue of low donation, the government decided to financially reimburse patients and externalize the issue of bodily desecration. However, when media coverage fully exposed this trend of transplant tourism, advocacy groups and the medical community also started to pressure the Ministry of Health to reverse its policies. While exploitation of poorer donors and transplant tourism has since decreased, the current system still fails to prolong the lives of those waiting for a kidney.

Waitlists are growing, and each year, citizens die because of the shortage of kidneys. The current Organ Transplantation Law fails to address low donation rates and does not account for the Jewish character of the State. If the Ministry of Health does not adjust their laws, patients will grow more desperate and frustrated. Some will risk criminalization if it means avoiding death and transplant tourism will thrive underground. Israeli government was viewed as an early institutor of transplant tourism, and is now recognized as a leader in enacting policies that target it. But the state cannot be satisfied with its work. While outlawing transplantations abroad was a significant first step, the State should focus on providing options for patients and increasing kidney donation within Israel. Granting broader priority, increasing access to donor cards, engaging in exchange program, communicating with religious leaders, and supporting advocacy groups are viable methods to improve their current policies.

From a broader standpoint, organ-trafficking and transplant tourism are paralyzing nations around the world. Medical associations and governments are slow to adapt to changing realities, and unscrupulous brokers are profiting from an unregulated market. Studying Israel's successes and failures in tackling the issue can provide possible solutions on how to solve ubiquitous human rights violations in organ-trafficking.

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# Article

# Are high pharmaceutical prices morally justifiable?

Alexander Ren*

Several pharmaceutical companies have undergone intense criticism for selling drug products at exorbitant prices. Patent and market exclusivity laws allow these companies to engage in such extreme price gouging. If pharmaceutical companies are legally permitted to set high prices, the next question is whether said prices are morally justifiable. This problem can be addressed from multiple perspectives. This paper will begin with a discussion of the costs underlying drug development, move to the funding for drug research, and then explore more formal philosophical principles, namely the doctrine of *justum pretium* and Rawlsian distributive justice. Finally, I summarize some possible, commonly accepted solutions proposed by other authors. Ultimately, we will see that high pharmaceutical prices are not morally justifiable, for drug companies essentially prioritize profit over the public good.

**Background**

In 2015, spending on prescription drugs in the United States rose to $425 billion—a 12.2% increase from 2014 (Loftus 2016). This rapid increase in spending can be attributed primarily to the high prices of potentially life-saving drugs. Recently, many cases of pharmaceutical price gouging have surfaced in the news. Highly-publicized cases—such as Turing Pharmaceuticals' price increase from $13.50 to $750 per tablet for the drug Daraprim (used to treat toxoplasmosis) (Pollack 2015) or Mylan Pharmaceuticals' over 500% price hike for a pack of EpiPens (Pollack 2016)—demonstrate the tremendous power of these large companies to alter the price of a drug however they choose. The two aforementioned cases also represent examples of precipitous rises in the prices of their respective drugs: in Turing's case, the hike occurred overnight in September 2015, while in Mylan's case, the price rose from $265 to $609 over the last three years (Pollack 2016). On the other hand, disease-modifying therapies for multiple sclerosis (MS DMT) have seen prices escalate from between $8,000 and $11,000 per year in 1993 to over $60,000 per year in 2013, an increase spanning twenty years (Hartung et al. 2015). New drugs for hepatitis C were set at prices exceeding $40,000 from the outset (Conti, Gee, and Sharfstein 2016). Regardless of the time it took for companies to raise the prices of their drugs, it is clear that the average prices for specialty drugs today are exceedingly high.

How are pharmaceutical companies able to set the high prices for their drugs in the first place? To answer this question, we look to the United States Constitution. Patent law was initially included in the Constitution to encourage innovation (Kesselheim, Avorn, and Sarpatwari 2016). If citizens could be assured that they will reap the financial benefits of their useful ideas, this would encourage the development of novel inventions. Patents can last for up to 20 years, and FDA approval also sets a lower bound by guaranteeing new drug products protection from competition for 5 to 12 years (Kesselheim, Avorn, and Sarpatwari 2016). These legal protections thereby endow drug companies with monopolistic rights in the pharmaceutical market (Kesselheim, Avorn, and Sarpatwari 2016).

**Pharmaceutical Costs and Social Responsibility**

Since they are legally permitted to charge people as much as they wish for their products, pharmaceutical companies attempt to justify their high prices by arguing that the research and development (R&D) that goes into creating important drugs has created extensive costs that require substantial revenue in order to see a return on investment. In an interview on CNBC's "Closing Bell," Yumanity Therapeutics CEO Tony Coles noted that "Finding new cures and innovating for diseases that we've not been able to treat is hard business," adding, "We've got a commitment and responsibility to find these cures, but they don't come cheap and the research certainly doesn't come cheap." A 2014 study by the Tufts Center for the Study of Drug Development suggests that the cost to develop a new drug amounts to approximately $2.6 billion (Tufts CSDD 2014). There are, however, two important issues with this figure: (1) several drug companies have been shown to spend more on marketing than on R&D and (2) present research suggests that R&D costs are over-exaggerated. These points are important to acknowledge, for they suggest that these pharmaceutical companies are not optimizing their spending to benefit society, but rather to increase their profit margin.

First, we must address the role of marketing costs in determining drug prices. In 2015, Pfizer spent almost $15 billion (or 30.3% of their annual revenue) on selling, informational, and administrative expenses while spending about $7.7 billion (or 15.7% of their annual revenue) on R&D (Pfizer Inc. 2015). Although Pfizer and other pharmaceutical companies are, at their core, profitable businesses––which explains why a great deal of importance is placed on advertising and marketing expenses––these companies

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are also in the healthcare sector. Given the enormous role that pharmaceutical companies play in the distribution of healthcare, I argue that they serve an obligation to the community first and foremost.

An opponent to this assertion might suggest that a business and its employees need not prioritize the health of consumers over their own profit (i.e. businesses do not have any social responsibilities). However, bioethicist David B. Resnik argues that, "corporations are like moral agents in that they make decisions that have important effects on human beings. In making these decisions, corporations can decide to either accept or ignore social values, such as respect for the environment, public safety, and so on. If corporations are like moral agents, then they have some of the same duties that apply to other moral agents. In particular, corporations have obligations to avoid causing harm and to promote social welfare and justice" (Resnik 2001). In other words, businesses are part of a social ecosystem in which their decisions affect the entire environment in which they exist. This is not to say that companies like Pfizer have not attempted to make progress in reducing drug prices. Pfizer acknowledges in its 2015 Financial Report the "increasing pressure on U.S. providers to deliver healthcare at a lower cost and to ensure that those expenditures deliver demonstrated value in terms of health outcomes," and stresses that they are "continuing to work with health authorities, health technology assessment and quality measurement bodies and major U.S. payers throughout the product-development process to better understand how these entities value our compounds and products" (Pfizer Inc. 2015). Though these companies have not yet achieved satisfactory drug pricing levels, many are making concerted efforts to include affordable pricing in their corporate social responsibilities.

Pharmaceutical businesses are particularly crucial to the social environment, for they represent public access to life-saving treatments. There is a moral obligation for pharmaceutical companies to benefit the community, yet this obligation lies primarily in self-interest—in the hope of larger profit gains. Pharmaceutical companies' responsibility to their shareholders can be satisfied by the improvement of market conditions. However, shareholders will have to expect long-term returns on their investment, rather than immediate compensation, as a result of implementing more responsible budget allocation and consumer-friendly pricing. Although businesses' social responsibility hinges on the prospect of future profits and better business conditions, the optimal course of action would still be to pursue responsible corporate behavior, such as devoting more funding to R&D rather than marketing and appropriately pricing drug products with respect to the true cost for R&D. It is also important to note that the pharmaceutical industry rolls out a wide variety of drug products, with some requiring more marketing and/or development costs. For example, drugs for respiratory disorders like asthma or chronic obstructive pulmonary disorder (COPD) tend to have higher-than-average development costs compared to drugs treating genitourinary disorders (e.g. Viagra), which have lower-than-average development costs—this variation may be due to the disparity in success rates between drug therapies for different ailments (Adams and Brantner 2006). Thus, we cannot expect all drug manufacturers to conform to an absolute median cost for marketing and R&D.

If we look solely at the cost of R&D with regards to high drug prices, we again see an issue. One 2006 study in the journal *Health Affairs* replicated the methodology of a former Tufts Center study (which concluded that the cost of developing a new drug, at the time, amounted to approximately $802 million (Adams and Brantner 2006). It was found that the cost actually varied between $479 million and $2,119 million (Adams and Brantner 2006) depending on the type of drug produced and the size of the company, and we can likely expect similar uncertainty in today's $2.6 billion estimate. Again, this $2.6 billion mark represents a median, and so the R&D costs for individual companies may vary substantially from this estimate. Another 2006 *Health Affairs* study found that, "Longer clinical trial periods have been offered as a justification for increasing drug prices; our analysis demonstrates that these periods have not been increasing and might in fact be decreasing. This finding, in turn, suggests that development times are not a factor in rising drug prices" (Keyhani, Diener-West, and Powe 2006).

In addition, the justification that high prices are necessary to encourage domestic innovation also appears to be faulty (Kesselheim, Avorn, and Sarpatwari 2016): A 2012 *British Medical Journal* article noted that "neither policies considered to be obstacles to innovation […] nor those regarded as promoting innovation […] have made much difference [in the difficulty of getting drugs approved]" (Light and Lexchin 2012). The same authors even go further as to argue that pharmaceutical companies find it most financially optimal to develop large numbers of new drugs with fewer additional benefits over their older models––they are essentially emphasizing the rollout of new drugs over the innovation of new therapies (Light and Lexchin 2012).

Light and Warburton refer to a 2003 survey by the National Science Foundation to further illustrate how "little company R&D is devoted to basic research," in other words how much R&D is not allocated towards therapeutic innovation (Light and Warburton 2011). Notably, "pharmaceutical firms invest 12.4 per cent of gross domestic sales on R&D. Of this, 18 per cent, or 2.4 per cent of sales, went to basic research. More detailed reports from the industry indicate the percentage of R&D going to basic research is even smaller, about 9.3 per cent (or 1.2 per cent of sales)" (Light and Warburton 2011, Light 2006). The authors go on to add that "Most pharmaceutical R&D (11.2 per cent of sales) is spent on new drugs of little therapeutic benefit rather than for breakthrough drugs," highlighting the deprioritization of innovative basic research (Light and Warburton 2011). By inaccurately representing the amount of money spent on research and focusing on maximizing revenue rather than encouraging innovation, these pharmaceutical corporations are breaking the trust between consumer and company. Not only does this shatter the aforementioned social responsibilities

that pharmaceutical companies are morally obligated to uphold, but it also destroys the reputation and customer loyalty of the companies themselves: "consumers' perception of a corporation's efforts to be transparent about production and labor conditions and to be socially responsible by giving back to the local community plays a critical role in building consumers' trust and positive attitude toward the corporation" (Kang and Hustvedt 2013). Therefore, exaggerating R&D costs is not only morally reprehensible, but also financially reprehensible, particularly for shareholders and other investors in these pharmaceutical companies. By encouraging financial transparency and accountability through accurately detailing R&D costs, pharmaceutical companies will affirm their social responsibility of providing improved drug products and protecting their shareholders' finances.

Another important point regarding pharmaceutical R&D is that much of the research is actually "conducted by scientists at academic medical centers, often supported by government funds including the US National Institutes of Health and similar bodies in other countries" (Kesselheim, Tan, and Avorn 2015). Stevens et al. conclude that "PSRIs [public-sector research institutions] have contributed to the discovery of 9.3 to 21.2% of all drugs involved in new-drug applications approved during the period from 1990 through 2007" (Stevens et al. 2011). Often times, academic scientists will perform the initial basic research to identify the primary treatment approach before allowing pharmaceutical companies to perform clinical testing and begin production (Kesselheim, Tan, and Avorn 2015). Essentially, taxpayers are investing money in the government as part of a social contract, with the expectation that the government will use this money to ensure the future security for its citizens.

By funding basic research that is then further developed by pharmaceutical companies, the government expects that the drug products of these companies will be distributed to the taxpayers. However, if the prices of these drugs are simply unaffordable for the majority of the population, then there is clearly a violation of this contract. Taxpayers expect to see a return on their investment in the form of accessible, life-saving drugs, but current lofty prices (Figure 1) clearly restrict this.

Unfortunately, because of the essential nature of many of these medicines, many consumers are still forced to purchase these products, giving pharmaceutical companies an almost guaranteed consumer base. Reisel and Sama write that, "Life-saving medicines contribute to exchanges that are fundamentally different because the problems they address are chronic rather than temporary, such as hunger. Therefore, exchanges are not subject to voluntary participation espoused by market-based theory" (Reisel and Sama 2003). Again, we see that although pharmaceutical companies operate in a competitive industry, the fact that they are involved in the distribution of life-saving drugs means that these companies cannot be held to the same standards of social responsibility as other types of businesses.

### *Justum pretium* and Distributive Justice

Aside from research and development costs, there is another reason that drug prices ought to be lower which lies in more formal moral theory. Aristotle first developed the concept of *justum pretium* doctrine, which argues that price must reflect worth (Kantarjian et al. 2013). Accordingly, if a drug product has a particularly profound impact on the health and life expectancy of a population, the price should decrease to allow for such a product to be easily accessible. This doctrine also suggests that human life ought to be valued over money: a right to life takes precedence over an opportunity for profit.

Currently, pharmaceutical companies operate by setting prices that they know the market can just barely bear. In that sense, they set their prices at a point where they know they can maximize revenue without turning away consumers. As we mentioned before, because of the life-saving implications of these drugs, consumers are forced to tolerate a higher price standard for pharmaceutical products. This behavior of course reflects the free-market economy in which these companies operate. Yet given the competitive nature of the free-market, how are drug prices rising rather than lowering (Figure 2)?

The behavior of drug prices suggests the existence of "collusive behavior [which] can tacitly maintain high prices over extended periods of time, despite competitive markets" (Experts in Chronic Myeloid Leukemia 2013). The pharmaceutical industry behaves similar to an oligopoly, since companies appear to have a tacit understanding that several large producers of a certain drug product will not undercut the prices of one another and instead maximize profitability for all parties.

So why should we respect the moral doctrine of *justum pretium* over the natural behavior of the free-market? A 2013 study in the journal *Blood* makes the case that cancer drugs ought to abide by the doctrine of *justum pretium* over free market economics since commodities like drugs are essential to extending life and relieving suffering. The authors specifically argue that cancer drug prices should objectively reflect the benefits (e.g. prolonged survival time, improved quality of life) of these treatments and not exceed prices that would harm patients' health (Experts in Chronic Myeloid Leukemia 2013). When one's natural rights are hindered by disease and suffering, pharmaceutical companies have a moral obligation to make their products affordable and accessible. Furthermore, a system of tacit collusion represents a clear power imbalance between consumer and company. Since prices determined through tacit collusion are higher than the prices assigned by worth—the *justum pretium* principle—there is moral egregiousness in the high prices set by these companies.

An equally applicable moral theory—distributive justice—should also be considered in the discussion of the moral permissibility of high pharmaceutical prices. The theory of distributive justice suggests that different economic frameworks will result in an uneven distribution of social benefits and burdens, such as wealth or the lack thereof (Lamont 1996). Within the subject of distributive

justice is a principle called strict egalitarianism, which argues "for the allocation of equal material goods to all members of society" (Lamont 1996). Although this theory is quite idealistic—we know our reality is by no means a utopian, fully-egalitarian society—the moral principles are important in considering ethical pharmaceutical pricing.

In this paper, we will look specifically at distributive justice as described by the philosopher John Rawls (1921-2002). As Spinello writes in a 1992 paper for the *Journal of Business Ethics*, "Rawls' conception of justice, which is predicated on the Kantian idea of person hood, properly emphasizes the equal worth and universal dignity of all persons" (Spinello 1992). Rawls further argued that a just and fair society ought to secure the right to Kantian self-determination through the equal access to liberties and material necessities. Thus, Spinello concludes that "a certain extent of health care (including medicine) should be considered as one of the primary social goods since it is obviously necessary for the pursuit of one's rational life plan. Therefore, the distribution of health care should not be contingent upon ability and merit" (Spinello 1992). Healthcare constitutes one of the most basic human needs for citizens in our society, given its ability to allow us to access other freedoms through which we can ultimately find self-determination.

High pharmaceutical prices essentially represent a form of price discrimination, since pharmaceutical companies are unequally distributing life-saving drugs on the basis of one's socioeconomic standing. According to Rawls's interpretation of the theory of distributive justice, this violates the natural rights of citizens in a just society and can be condemned as immoral. That being said, if high drug prices represent a violation of strict egalitarianism, then why can't all price levels be considered immoral? At any price, there may always be those citizens who are unable to afford life-saving drug products, so wouldn't the socially optimal course of action be to demand that they be freely distributed? This is not correct in a practical sense, but there is also a moral reason as to why this should not be done. Although pharmaceutical companies aim to be successful businesses, they are responsible for a great deal of innovative medical research, which yields the hope for future cures and treatments. Therefore, pharmaceutical companies require reasonable profit margins in order to contribute to the long-term stability of the pharmaceutical industry (Spinello 1992). With financial stability, the industry can continue to perform important life-saving research. If we are to improve healthcare for citizens while also providing the necessary profits to stimulate pharmaceutical research, then our society must find an appropriate pricing system that agrees with both consumer and company.

It should be noted that these two theories are limited in scope, and should not be interpreted to be the only two theoretical frameworks on which one can base a definition of morality. This question of acceptable and fair pricing for essential goods is highly complex, and cannot be satisfactorily explained through a specific philosophical lens. Both Aristotle and Rawls were selected due to their extensive writings and novel ideas regarding the intersection of justice and the economy. Of course, other authors might ground their basis for moral permissibility in different theories, but in this case, *justum pretium* and distributive justice were deemed to be appropriate models for ideal moral standards in a society.

**Possible Solutions**

It is clear that the current pricing of pharmaceutical products is quite unjust. These prices have proven to be immoral for a number of reasons, from a lack of financial transparency on the part of the pharmaceutical companies to a violation of the principles of Rawlsian distributive justice. So is there anything feasible that can be done to lower prices to a reasonable point? Current market conditions make it difficult for the federal government to "set [prices] for the entire marketplace…in part because of the power of the pharmaceutical lobby in Washington, DC" (Kesselheim, Avorn, and Sarpatwari 2016). However, this does not mean that the market can be left to its own devices, as conservatives will often advocate. Existing legislation protecting patent exclusivity and restricting price negotiation between drug companies and employers has sparked a competitive atmosphere in the pharmaceutical industry, with companies compelled to engage in tacit collusion in order to achieve the highest prices for their products. Legislative reform could allow for more standards so that companies could not simply make small changes to the formulas for their drugs and then re-patent them. That way, pharmaceutical companies would have to devote more research into enhancing the safety or effectiveness of their drugs in order to file for a new patent. Perhaps market exclusivity through patent law could be limited by opposing the extension of current exclusivity periods on drugs other than generic or orphan drugs (Daniel 2016).

Another strategy is to have the government dedicate additional funding to reviewing generic drug applications in order to encourage healthier competition among brand-name drugs (Kesselheim, Avorn, and Sarpatwari 2016). Kesselheim, Avorn, and Sarpatwari suggest that "Congress could authorize Medicare to negotiate the prices of drugs paid for by Medicare Part D plans, as it does for nearly all other goods and services…Medicare price reductions are likely to have effects on drug pricing in private markets, which tend to follow Centers for Medicare & Medicaid Services–set prices in other health services." By negotiating the prices paid for through Medicare, the government can encourage companies to follow suit and set lower prices themselves.

Many prescription brands have generic versions that are much less expensive. Some might believe that generic brands are inferior in quality, and that this allows for lower prices. But this is not true. The Food and Drug Administration (FDA) assures consumers that "Generics have the same quality, safety, and strength as branded medicines" (Center for Drug Evaluation and Research 2003). It is essential that generic brands are not made to seem like second-tier drug products. This can be accomplished with

greater investment in awareness campaigns that stress the bioequivalence of generic drugs (i.e. their active ingredients work exactly the same as the brand-name drugs) on the part of both government and insurance companies alike (Center for Drug Evaluation and Research 2003). Consumer education about the efficacy of generic brands is crucial for promoting more cost-effective healthcare purchasing, and has the added effect of encouraging prescription drug brands to lower their prices to stay competitive. Investment in generic drug awareness campaigns can provide people with this essential knowledge about their drug options.

We could also look to physicians to take a more active role in monitoring the prices of the drugs they prescribe. By familiarizing themselves with the pricing of prescription drugs, doctors can inform patients of the costs for different medications and promote wiser decision-making (Kesselheim, Avorn, and Sarpatwari 2016). Rarely do we consider the fact that doctors are the people controlling which drugs are sold. Patients trust doctors' expertise, and will often accept that doctors are working with the patient's best interest in mind. If doctors are educated in the pricing of drugs and the availability of alternatives, they might be poised to provide cost-efficient recommendations for prescriptions. This method of physician intervention in patient treatment could prompt greater attention to generic brand options.

**Conclusion**

This paper raised the question of whether or not high pharmaceutical drug prices are morally justifiable. We examined several reasons for the immorality of such prices. Marketing costs are often used to justify pharmaceutical companies' costs, even though they do not contribute to research and innovation. Published estimates for the pharmaceutical industry's research and development costs have been shown to be highly exaggerated, and studies suggest that much of the research that contributes to drug development is done in government-funded academic centers. There are also more theoretically philosophical reasons as to the immorality of high drug prices. The *justum pretium* doctrine suggests that the price of drugs ought to reflect their worth, and due to the life-saving capabilities of these products, they must be priced reasonably to allow for public accessibility and to discourage the tacit collusion that often takes place in an oligopolistic pharmaceutical industry. Rawls's perspective on distributive justice advocates for the equal distribution of pharmaceutical products, since it can be considered a material necessity. A variety of possible solutions exist for counteracting the rise of pharmaceutical drug prices, from the level of federal legislation to the level of doctor-patient communication. Regardless of the solution, public awareness of the unethical nature of today's high prescription drug prices is perhaps most fundamentally crucial for instigating any change.

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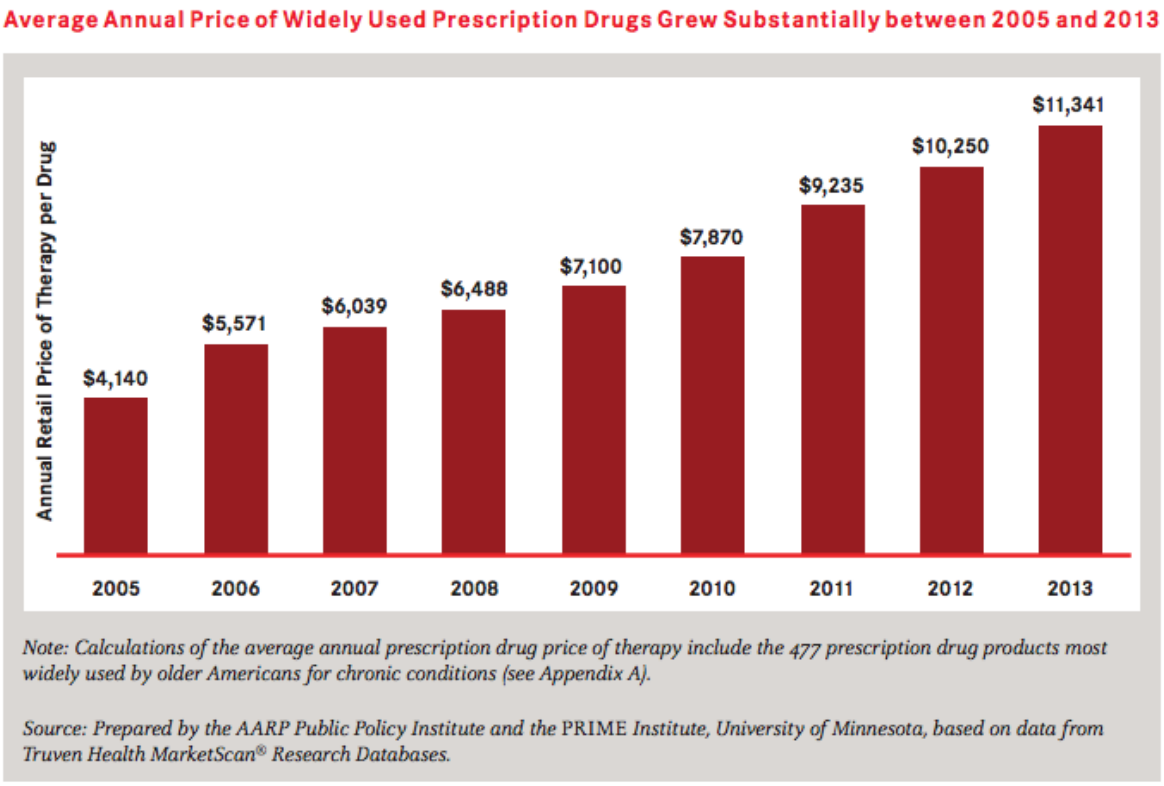


Figure 1. Graph from AARP's "Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006 to 2013"

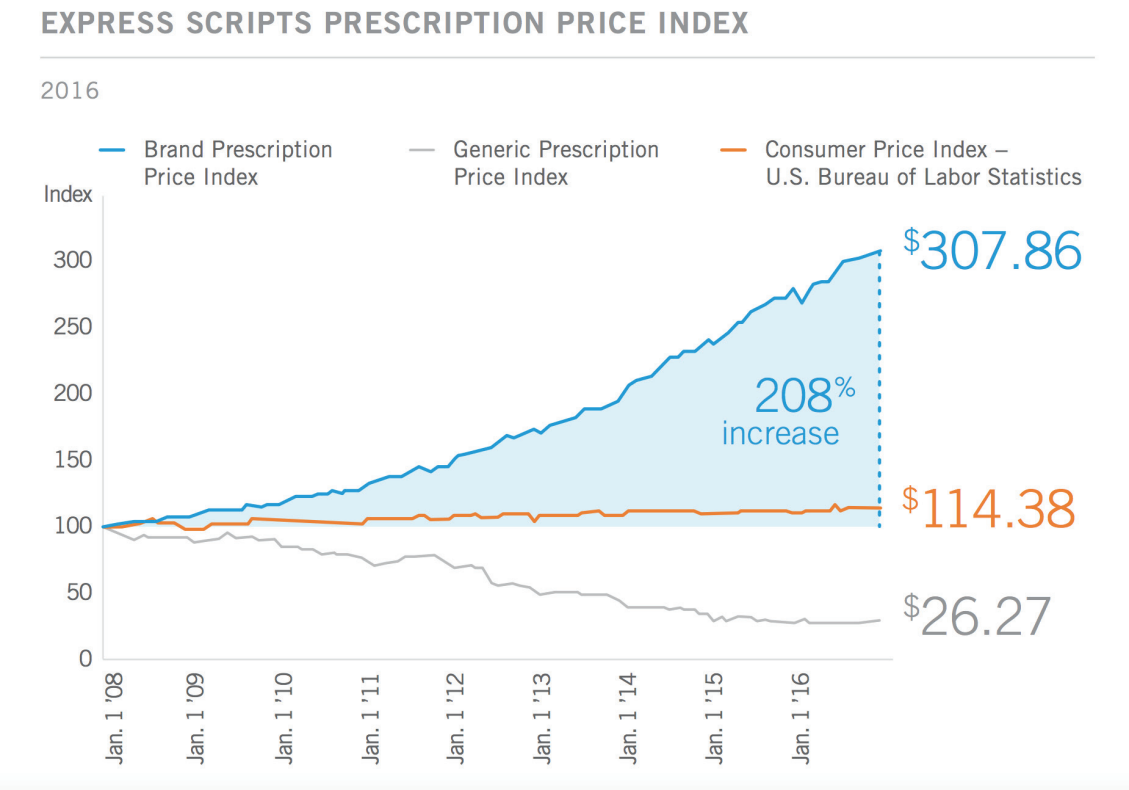


Figure 2. Graph from Express Scripts's "2016 Drug Trend Report"


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