PBJ | PENN BIOETHICS JOURNAL

Spring 2023 Volume XIX, Issue i bioethicsjournal.com

Medical Decision Making: Bioethics in Action

Medical decisions are not straightforward by any means, and this issue delves into the important role bioethics plays in these discussions.

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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The cover artwork of this issue is derived from open-source images.

Philadelphia, PA. ISSN: 2150-5462

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Letter from the Editor

Dear Readers,

It is my distinct honor to present you with Volume XIX, Issue i of the Penn Bioethics Journal, entitled "Medical Decision Making: Bioethics in Action." For years, the magnitude of the autonomy certain patients have when making certain medical decisions has been increasingly debated with different arguments being made for various levels of involvement of other professionals such as physicians, lawyers, and ethicists. The pieces in this issue are some of the most tightly related of recent issues, all reflecting on the array of decisions patients can make in determining their future and the outside influences that could have an impact.

The first article, "Dementia and The Right to Die: Demoting the Advance Euthanasia Directive," discusses the complicated nature of Advance Euthanasia Directives held by patients with dementia. Author Juliette Copeland of Jepson School of Leadership Studies conveys the importance of tailoring the decisions regarding euthanasia towards the current state of a patient with dementia.

The second article, "Disability & Medical Decision Making: the State Interest in Preserving Life as a Source of Bias," investigates how patients with disabilities are often offered more opportunities to refuse treatment. Author Samuel Streicher of University of Rochester conducts case studies of prior court cases with patients with and without disabilities to support his detailed analysis.

Our Bioethics-in-Brief section covers current issues in the field of bioethics. In her brief, Lee discusses the potential ethical dilemmas of advance directives, further exploring a central topic in Copeland's article earlier in the issue. Lee argues that the benefits of advance directives hold more weight than the potential negatives, underscoring the importance of advocating for increased awareness regarding advance directives in vulnerable patient populations; she supports her analysis with a sample patient case from the intensive care unit.

PBJ also had the privilege of interviewing Dr. Holly Fernandez Lynch, JD, MBe, Assistant Professor of Medical Ethics in the Department of Medical Ethics and Health Policy at the Perelman School of Medicine (PSOM). In addition to teaching, Lynch has a secondary appointment as an Assistant Professor of Law at the Carey Law School. Before coming to Penn, Lynch worked on President Obama's Bioethics Commission and was the Executive Director for the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. Currently, her academic investigations center around USA FDA guidelines as well as the supervision of research by Institutional Review Boards (IRBs).

We would like to thank our publisher and amazing team of editors, without which this issue would not have been possible. Also, a special thanks to faculty advisor, Dr. Harald Schmidt, for his support during the editing and publication process.

We hope you enjoy this latest issue of the Penn Bioethics Journal and that it inspires you to engage with the field of bioethics. Please contact us with any questions, comments, or ideas for collaboration at pbjeditorinchief@gmail.com.

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Article

Dementia and The Right to Die: Demoting the Advance Euthanasia Directive

Juliette Copeland*

I. ASSISTED DEATH IN ITS CURRENT STATE

Over the past several decades, multiple countries and parts of the United States have increasingly legalized medical options that allow patients to end their own lives. Two common options for these so-called "assisted deaths" are physician assisted suicide (PAS) and euthanasia. In cases of PAS, the physician provides the means to perform suicide (i.e. the doctor gives the patient a life-ending medication upon request), but the patient carries out the final act. In cases of euthanasia, the physician administers the life ending medication directly to the patient (Picón-Jaimes et al., 2022). As of 2022, PAS is legal in 10 jurisdictions in the United States. Euthanasia, however, is not currently legal in the U.S. but is legal in eight countries across the globe –– the Netherlands, Belgium, Luxembourg, Colombia, Canada, Australia, New Zealand, and Spain (Worthington et al., 2022).

In the Netherlands in particular, the practice of writing advance euthanasia directives (AEDs) has been legal since 2002. An AED is a document that patients may craft in anticipation of losing their capacity to consent, requesting euthanasia to be administered at a certain point in the future after they have become impaired. Dutch law states that once a patient loses the ability to consent and a physician accepts the AED, "[the] advance directive has the same status as an oral request for euthanasia" (Miller et al., 2019).

Since 2002, there have been several documented cases of morally questionable implementations of AEDs within the Netherlands. However, one case in 2016 was the first to trigger a criminal investigation (Miller et al., 2019). To further explore the ethics of AEDs, specifically in cases of dementia, I will recount this patient's story.

II. THE CASE OF MRS. A

In 2016, a 74 year old woman with Alzheimer's (whom I will refer to as Mrs. A) was euthanized on the basis of her AED. Within the document, she specified, "Trusting that at the time when the quality of my life has become so poor, I would like for my request for euthanasia to be honored." As the patient's health declined, she was moved to a nursing home. Each day, she would become agitated and sometimes

physically assault her caregivers. She would communicate to staff that she often wanted to die, but when asked this question directly, she would repeat "But not just now, it's not so bad yet!" (Miller et al., 2019).

After one month upon arrival, Mrs. A's primary geriatrician decided that she was suffering unbearably for most of each day. The geriatrician with whom the two physicians consulted also agreed and approved of the motion to euthanize. The geriatrician first attempted to sedate the patient, then provide euthanasia, but Mrs. A struggled and resisted the process. The physicians and Mrs. A's family held her down to ensure that all of the drug could be administered. During the Euthanasia Review Committee hearing, the geriatrician explained that "the patient was not mentally competent, so her utterance [at the moment of euthanasia] was not relevant." The Euthanasia Review Committee eventually determined that the geriatrician had not acted ethically during the administration of euthanasia, due to the failure to ensure that the request was voluntary and that it was completed with due medical care (Miller et al., 2019). However, in 2019, she was acquitted of wrongdoing. This set the precedent in the Netherlands that physicians cannot be prosecuted for administering euthanasia if previous consent was given, even if the patient does not confirm their previous request (BBC News, 2020).

III. ETHICAL PROBLEMS WITH AEDS

Though Dutch law claims that pre-dementia requests have authority in granting AEDs, I believe that any overriding of dissent, even in cases of cognitive impairment (as was the case with Mrs. A), severely violates patient autonomy. This intuition leads me to my current argument, which is that advance directives should not be enforceable without current patient consent if consent is indeed possible. If consent is not possible, then healthcare workers should con-

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sider the overall quality of life when deciding whether to adhere to an AED.

My argument will be divided into three main sections. First, I suggest criteria of consent for patients with dementia and make a case for why current consent and dissent should be respected. Then, I argue that in cases where the patient is not able to consent, the AED should act as a suggestion that is taken into consideration with the patient's overall quality of life. Finally, I will discuss some of the implications of my argument and highlight any further questions that I have failed to address in my view.

IV. AUTONOMY OF THE DEMENTIA PATIENT

In this section, I will argue that if the patient with dementia has the capacity to consent, healthcare workers must obtain present consent before adhering to the AED. My argument follows the structure below:

> P1: The capacity to consent to euthanasia is determined by the ability to communicate choices consistently and to understand the facts of the situation.
>
> P2: Some patients with dementia meet the above criteria.
>
> P3: If the patient with dementia can consent, their consent is as valid as the consent of the pre-dementia patient.
>
> P4: Current consent overrides past consent.
>
> C1: If the patient has the capacity to consent, the patient must provide consent before physicians adhere to the AED.

1. Criteria for the Capacity to Consent

Clinically, the capacity to consent to a medical treatment is determined through the assessment of four criteria –– the ability to communicate a choice without significant variation, the demonstration of a factual understanding of the question at hand, comprehension of the possible consequences of the choice, and the display of logical reasoning in making the decision (Dahan and Eth, 2009). If the patient does not meet all criteria, they are below the threshold for the ability to consent. I would like to argue that regarding euthanasia, only two of the criteria mentioned must be met in order to provide consent –– the ability to communicate wishes clearly and consistently and the understanding of the facts of the situation.

In my view, the reason that the two conditions mentioned are necessary for the capacity to consent to euthanasia is so that 1) health workers can be sure that this is what the patient truly desires, and so that 2) the patient has the information needed and is able to process this information to make an informed decision. If the affirmation to die fluctuates, this could be indicative of a fluctuation in overall mood, rather than a consistent and genuine desire for death, and thus, the capacity to consent is not met. On the comprehension front, a patient may consent without understanding that death is irreversible, and what the process entails. If they are unable to process this information, they cannot reliably consent.

The reason I believe that consent requires the two criteria above and does not require the assessment of logic and consequences is due to the nature of decisions about death relative to decisions about medical treatment/care plans. While those types of decisions may require reasoning and future planning, the decision to die can be much more intuitive, and is often based on the patient's evaluation of their overall happiness and comfort. Such an evaluation can happen within an instant, as Mrs. A's consistent responses to inquiries about her death ––"It's not so bad yet!" –– reveal.

To see how these two criteria might apply to real patients, there is evidence that some individuals with dementia are able to 1) communicate choices consistently and clearly and 2) accurately answer questions when asked, showing a fair level of comprehension. In a study on the decision-making capacity of cognitively impaired individuals, it was found that patients with mild to moderate cognitive impairment were able to consistently respond to questions about their everyday living preferences in agreement with their caregivers' reports. They were also able to accurately answer questions about their own demographics (Feinberg & Whitlatch, 2001). Thus, some patients with dementia may be able to provide consent or dissent to euthanasia under the criteria I have put forth.

In laying out these criteria and in establishing a threshold for consent, the ability to consent is viewed as a "yes or no" question of capacity (i.e. either one is able or is unable to consent with no intermediary option). Thus, although someone may have cognitive impairments, if they are still deemed to have the ability to consent, this ability is equally valid as someone who is cognitively normal. I believe this is a valid assumption because if some sense of autonomy is still available, then any violation of their requests and their consent or dissent is a violation of their autonomy. Under this view, the validity of the consent of a patient with dementia is equal to the consent prior to their dementia diagnosis, or the version that created the AED.

In accepting this premise, one may then ask if the pre-dementia and the post-dementia preferences are equally valid, then how do you decide which preference to fulfill?

2. The Limits of Precedent Autonomy

In my view regarding euthanasia, I assume the Current Preference Thesis, which states that to respect the autonomy of another, one should respect the current preferences of that individual. To understand why this concept may have moral validity, let us use a hypothetical case regarding a couple, Rebecca and Jacob. Rebecca has never had sexual intercourse before, and she and Jacob are planning to do so for the first time. Rebecca and Jacob discuss the idea prior, and Rebecca says she is 100% confident in her decision. However, when the time comes, Rebecca says she no longer wishes to have sexual intercourse, communicating that she is not as ready as she previously thought, and that she needs more time to feel comfortable with the idea. Most would have the intuition that Rebecca's wishes should be respected, and that if Jacob continued with the act and disregarded her current communication, he would be violating her bodily autonomy and thus would be committing an act of rape.

Though the example above shows the scenario in a case of dissent, the same could be said for a case where there is no attempt to obtain present consent. Let's say Rebecca told Jacob that she would like to have sexual intercourse for the first time within a few months. When a few months have passed, Jacob initiates sexual intercourse and follows through without first confirming or checking in with Rebecca whatsoever. Though this is not as egregious as the dissent example, our intuition still tells us there is something morally wrong with this scenario as well. This is because when Jacob fails to obtain current consent, he runs the risk that Rebecca could have changed her mind, and without first confirming, he has no idea whether he is violating her bodily autonomy.

Most people are understanding of the fact that others change their minds, and that this type of change should be respected, especially with very meaningful and personal decisions. When the time to set a previous choice in motion comes, other factors that were not previously considered could arise. Emotions that were not accounted for could begin to dominate the situation, or the reality of the previously communicated choice could become more apparent, causing them to rescind what they had previously decided. Morally, we have an obligation to respect the current wishes of another because humans are inherently inconsistent creatures with the ability to fluctuate in our thinking as new information becomes available. If the patient with dementia has the capacity to consent, there is no reason they should be excluded from this principle.

One may object to the Current Preference Thesis altogether, arguing that previous requests can sometimes have priority over current preferences. This is what John Davis argues in his discussion of precedent autonomy. In his argument, he advocates for the prioritization of a resolution preference, a third preference that is stated to resolve issues when two preferences conflict. In cases of precedent autonomy, the resolution preference is stated before a decline in competency, with a patient ultimately overriding future choices and choosing the pre-decline preference. He gives an example to illustrate the concept –– the contented dementia case. In this case, a woman makes an advance directive to die with dignity, knowing that later with dementia, she might simply want to experience simple pleasures, and thus stay alive. In making the advance directive, she creates a resolution preference, specifying that she prefers death over these experiences (Davis, 2004).

Davis also gives the example of the late sleeper in cases of present dissent. Here, someone asks to be woken up in the morning so that they can be on time for a meeting. They anticipate that they will be groggy when they wake up and will dissent to getting up early. However, their previous resolution preference dictates that the roommate should override this dissent, as they overall value making it to the meeting on time (Davis, 2004).

Looking at both cases, we can see that Davis might believe that due to the AED, even when the patient with dementia dissents, health workers should override this dissent because of the earlier resolution preference stating their desires to die. However, I would like to reject this notion using Dan Moller's concept of "moral risk." Moller argues that if there is ambiguity of whether an act is deeply immoral or not, the mere risk of making a moral mistake dictates that we should not commit the act at all (Moller, 2011).

Let's return to Rebecca and Jacob to illustrate this concept. As before, Rebecca has never had sexual intercourse, and she is planning to do so with Jacob. She communicates prior that she is indeed ready to have sexual intercourse, and that if she dissents during the act, Jacob should override this dissent because she anticipates that this request is only out of fear. The scenario she describes does indeed occur, and Jacob overrides her dissent. In this scenario, there is a risk that Jacob is unjustified in continuing the act, and therefore there is a risk he is violating her autonomy and committing an act of rape. This moral wrong can be avoided if he respects her present dissent.

The situation is analogous to patients with dementia and AEDs. If the patient with dementia dissents to euthanasia presently, and the health worker overrides this dissent, they could be committing an act of murder, as they could be violating their autonomy to choose when or how to die. This is a large moral risk that could be avoided by respecting the patient's dissent.

The same can be said for failing to obtain consent. Without first affirming the request to euthanize the patient, the health worker runs the risk of violating the patient's autonomy in the case that this is no longer what they desire. Thus, because a dementia patient that can consent has equally valid requests to the pr form of themselves, and because respecting their current preferences should generally

be prioritized and is less morally risky, we can say that current dissent can override AEDs.

V. CRITICAL AND EXPERIENTIAL INTERESTS

In this section, I argue that even in cases where the patient cannot consent or dissent, an experiential interest standard should be followed. To define this idea more clearly, I will draw from the philosopher who coined the phrase "experiential interest" –– Ronald Dworkin. Dworkin has written extensively on respecting the autonomy of patients with dementia, framing the issue of advance directives as a balance between experiential and critical interests. Dworkin defines critical interests as those that concern what makes a life successful or unsuccessful. In his view, fulfilling these interests makes life better lived. These critical interests can also be viewed as someone's overall values and life goals. Some examples of such interests would include contributing to society or making strong relationships with others. Experiential interests, on the other hand, concern in-the-moment sensations and feelings. He argues that these feelings do not as a whole make life worse or better, even though we do tend to seek out pleasurable experiences and avoid negative ones (Dworkin, 1994). For further example, eating a hamburger may play toward someone's experiential interests, as it brings momentary pleasure, but it may not fulfill their critical interests. On the other hand, pursuing a college degree may not fulfill their experiential interests at times (considering stress and sleeplessness), but it will play into their critical interest of pursuing higher education.

Dworkin explains that critical and experiential interests can sometimes conflict in cases of dementia, with the dementia patient no longer maintaining critical interests, as they have no concept of themselves in relation to the continuum of their life. Thus, Dworkin suggests that when a patient has espoused their values and critical interests (or overall vision for their life lived) prior to cognitive decline, we should adhere to these previous wishes, even over experiential interests (or moment to moment feelings). In taking this view, he assumes that when an advance directive is in place, we should adhere to its conditions, as we must default to the critical interests of that person (Jaworska, 1999). His view suggests that even if the dementia patient is content with their life, health workers should still respect the AED. However, I'd like to first reject his argument, then propose another way to fulfill the pressing interests of the patient with dementia. I outline my argument below:

P1: AEDs sometimes care only for a patient's experiential interests.

P2: During the creation of an AED, there are epistemic issues, or issues regarding a lack of knowledge, present in relation to the future patient's experiential interests.

P3: The experiential interests of the dementia patient may be fully or partially fulfilled post-dementia.

C2: An experiential interest standard should be followed and should have priority over an AED.

1. The Purpose of AEDs

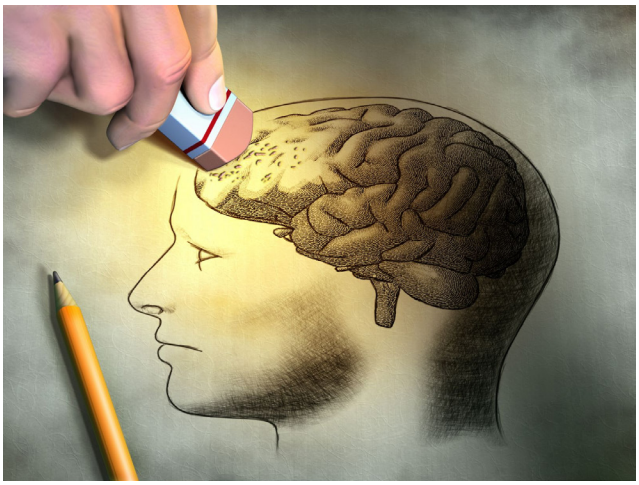
In rejecting Dworkin's argument, I believe that he fails to consider many common reasons for creating AEDs. While Dworkin presumes that patients solely create advance directives to ensure that the person with dementia maintains personhood and their overall goals, thus their critical interests, I assume that advance directives instead sometimes solely care for the experiential interests of the patient.

There may be a multitude of specific reasons for patients to create AEDs when anticipating a decline in competence, but many of these documents are created with the symptoms of dementia in mind –– agitation, confusion, memory loss, and mood swings. Patients requesting an AED will often make the request so that their future self does not have to live through an experience filled with the suffering and discomfort that accompany these symptoms. Because the discomfort associated with the symptoms of dementia is primarily due to in-the-moment sensations, the purpose of death would be to eliminate these sensations, thus fulfilling the experiential interests of the patient. Though critical interests still carry weight, they are not as prevalent as Dworkin claims when some patients create AEDs.

One may point out that in cases where the creation of an AED is out of a purely critical interest, Dworkin's argument still stands, and AEDs should be adhered to in these cases. An example of this would be a scenario in which the patient requests an AED because they anticipate that they will place a burden on their family. Another example would be that the individual anticipates the medical bill to be high at the end of life and would rather die than accrue debt needlessly. Experiential interests are not relevant to either of these requests, as the sensations of the future self are not the motivating factor. However, in response to Dworkin's argument regarding the need for AEDs because of lost critical interests, accounts of people with dementia show that they often do retain critical interests. These interests are just different or are altered versions of the critical interests prior to their dementia diagnosis. For example, patients with dementia have been known to still stay active in social causes, or to profess values that they had prior to dementia (Jaworska, 1999). Thus, to say that a person with dementia has completely lost their personhood and life interests due to their cognitive decline seems inaccurate and serves to

actively remove humanity from the patient with dementia.

In restructuring my own argument regarding autonomy to apply to critical interests, if the patient with dementia is deemed to have critical interests, these interests are just as important as the critical interests expressed prior to their dementia diagnosis. However, because the critical interests of the patient with dementia are current, we should respect these over those of the critical interests of the previous self. If the dementia patient no longer retains the critical interests that their pre-dementia self-professed, specifically the ones professed in the AED, we can disregard them, and thus the driving force of the AED is no longer relevant.



2. Epistemic Issues

To say that the AED would successfully fulfill the experiential interests of the post-dementia self through dictating death, we would also have to claim that the AED has strong predictive power regarding the future state of their illness. With this, the AED assumes that it is highly likely that there will be a gap between the experiential interests of the dementia patient and their condition. However, this brings up epistemic concerns, or concerns related to the knowledge of the facts of the situation, as prior to their dementia diagnosis they cannot predict this occurrence with any certainty. More specifically, they are not able to 1) predict with certainty that dementia will lead to suffering, and that 2) even if it does lead to suffering, that their experiential interests will be unfulfilled overall.

1) The Experience of Dementia

In proving the first point, we can rely on the actual lived experiences of patients with dementia to show that dementia does not always lead to suffering, and thus does not always undermine their experiential interests. Let us consider the case of Margo. In 1991, medical student Andrew Firlik recounted his experiences with an Alzheimer's patient in an article he titled "Margo's Logo." He described her daily life in intimate detail, explaining her love for mystery books, music, and peanut butter and jelly sandwiches. Margo did not remember Andrew's name each visit, but she did tell him that she knew who he was. In his time with her, he accompanied her to art class, where Margo painted the same picture every day. He wrote that, "despite her illness, or maybe somehow because of it, Margo is undeniably one of the happiest people I have known" (Firlik, 1991).

Now let us imagine a hypothetical –– before Margo developed dementia, she created an AED that specified that she wanted to be euthanized when her dementia reached a level deemed moderate to severe. Let us assume that she made her specific request out of concern for her experiential interests, rather than for a concern for her family or another critical interest. Though her request specified a specific cut off point in the progression of her dementia, what she truly desired was to be euthanized when her experiential interests were no longer fulfilled. Within her AED, she predicted that a certain level of the dementia itself would automatically lead to this disparity. This type of prediction may be inherent within many AEDs. If Margo had truly made such a request, she would have been incorrect in her prediction that a certain level of dementia would lead to suffering, causing healthcare workers to violate her overarching desires by administering euthanasia.

To further support this argument, we can turn toward an analogy to bodily disabilities. In her book, "The Minority Body: A Theory of Disability," Elizabeth Barnes makes the claim that disability is a "neutral simpliciter," or an item in life that does not inherently confer a positive or negative contribution to life if it is present. She explains that in this view, knowing that someone has a disability and having no other information tells us nothing about the welfare of that person. But, if we learn facts about the environment and the psychology of that individual, we may be able to deduce how disability would affect them (Hawkins, 2018). One might think that because AEDs are self-created, one would know their own psychology very well, and thus know how dementia might affect their welfare. However, one key aspect of dementia is that the disease itself often changes the patient's psychology. With this new psychology, and possibly with an unforeseen future environment, it would be incredibly difficult to predict the future welfare of the post-dementia self. Dementia also does not manifest identically in each patient, creating further uncertainty to how an individual may fare with the illness.

2) Dementia as a Package

To support the claim that dementia may not completely undermine experiential interests, even if accompanied by suffering, we can turn to Barnes once again. In her view, disability can be thought of as a package, or an experience that may provide an overall good or harm (global effect),

but with some negative or positive features respectively (local effect) (Hawkins, 2018). Therefore, the experiences that some people have with dementia may cause them to view dementia as a positive package, as overall their experiential interests are cared for, whereas the same experience given to someone else may result in the view that dementia is a negative package.

Though experiences with dementia vary between individuals, it seems that the view that dementia always confers overall harm and that the disease no longer makes life worth living dominates. However, on Barnes' view of disability, stigma could be motivating such views (Hawkins, 2018). Just as society views disability as a harm due to circulating negative conceptions, the same could be applied to dementia. This is not to say that dementia never results in harm, but with Barnes' view, whether one is harmed depends on the individual.

3) The Standard of Care and Objections

In proving that it is incredibly difficult to predict the level of suffering that may come with dementia, as well as how an individual might respond to this suffering, it seems difficult to justify the adherence to AEDs under all circumstances. This is why I propose that in cases where a patient cannot consent or dissent, healthcare workers should follow a care plan in which they prioritize the current experiential interests of the dementia patient. This means that if the patient has an AED, but they seem to be overall enjoying life, the AED should not be respected. However, if the patient is constantly suffering, then healthcare workers should consider adhering to the AED.

One could object to both premises that justify the standard of care I am proposing, claiming that individuals are entirely justified in predicting that dementia will lead to harm overall, and their experiential interests would most likely become unfulfilled. Therefore, it is morally risky to restrict adherence to AEDs, as this could cause great suffering. However, I believe that it is more morally risky to end someone's life if this is not what they would truly desire. Additionally, the standard of care I propose would minimize suffering due to dementia, as adherence to AEDs are still permitted in cases that suffering does seem unbearable.

VI. IMPLICATIONS

Some may worry that my view would allow for the ban of AEDs, or that AEDs would become obsolete with cases of dementia. However, I am not arguing to do away with these contracts. Instead, I am arguing that AEDs should not be as binding as they currently are, and that they should instead act as guidelines that health workers should supplement with other conditional information such as consent and overall welfare of the dementia patient. On my view, AEDs will have less power, but there are still cases in which they can provide important information – especially if the patient is unbearably suffering. Additionally, I believe that AEDs should have priority in cases of minimal or no consciousness due to the fact the patient no longer is able to consent, nor are they able to have experiential interests to which health workers should tend. Therefore, the creation and adherence of AEDs in some cases would still be permitted.

One further question that remains unanswered is where the line should be drawn for when a patient that is unable to consent is suffering so much that the AED should be followed. I believe that if healthcare providers were to put my view into practice, then this is a question that they would be required to deliberate and answer to ensure a fair threshold could be created.

VII. CONCLUSION

I have argued that in cases where patients with dementia can still consent, their affirmation or dissent should have priority over an AED. In cases where a patient cannot consent, healthcare workers should provide an experiential interest standard, and they should consider whether the overall lack of welfare grants the respect of the patient's AED. If the practice I have proposed were followed in the case of Mrs. A, her dissent would have been respected, and there would be no questions as to whether her healthcare providers violated her autonomy. Thus, I believe that my view respects the humanity of the dementia patient, refusing to view them as less than those who have full cognitive abilities. Inherent in this view is the desire to provide the best possible life and minimize the suffering of the patient in their current state, while also allowing them to have dignity and maintain some say in their own fate –– all of which should be granted to anyone regardless of cognitive status.

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Disability & Medical Decision Making: the State Interest in Preserving Life as a Source of Bias

Samuel Streicher* and Dr. Marjorie Shaw

ABSTRACT

Individuals with capacity to make medical decisions can legally refuse life-saving treatment even if they are not terminally ill. However, this right to refuse treatment is not absolute and may be balanced against multiple state interests. A review of past cases in which state interests were found to outweigh a capacitated patient's right to refuse treatment calls attention to issues relevant today. In the cases reviewed, courts heavily emphasized a particular state interest - the state interest in preserving life - when patients were not disabled, but did not place the same emphasis on this state interest when disabled patients sought to refuse treatment. Although ableist judicial treatment toward disabled individuals is not a novel idea, the literature does not seem to consider the state interest in preserving life as a specific source of this bias. If the state interest in preserving life is not acknowledged as a potential source of ableism, any legal controversies citing this state interest are more likely to involve bias.

PART I: INTRODUCTION

Navigating hospital departments and clinic floors, physicians are well-versed in aiding patients who seek to prolong life. On their journeys from bedside to bedside, physicians are also obligated to serve another demographic: those who wish to refuse life-saving treatment. Individuals who have medical decision-making capacity can legally refuse life-saving treatment even if they are not terminally ill (Quill, Lo, and Brock 1997, 2100; Kamisar 1996, 129-30). Indeed, the right to refuse treatment can be viewed as an extension of numerous critical rights, including the right to religious freedom (*Wons v. Public Health Trust*), protection from battery (Urofsky 1998, 384-387), informed consent (Herr, Bostrom, and Barton 1992, 5), privacy (*McKay v. Bergstedt*; Bourke 1990, 77), and others (Urofsky 1998, 354-356; Derish and Heuvel 2000, 122).

Notwithstanding this web of legal support for the right to refuse treatment, "states have interests that sometimes allow the infringement of individual rights" (Shaw, Quill, and Sussman 2020, 181). Related to the judicial systems' strict scrutiny test, state interests can be understood as governmental concerns regarding potential social harm and disorder (Steiner n.d.). In an effort to prevent harm and preserve order, state interests can vary in content and legal weight depending on the specifics of the case at hand (Harvard Law Review 2016; Britannica). In the context of treatment refus-

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al, withdrawal, or similar controversies, the four generally referenced state interests include the following: preserving life, protecting third parties, preventing suicide, and protecting medicine's standard of ethics (*Matter of Fosmire v. Nicoleau; In Re Gardner*).[1] Consider the focus of this paper: the state interest in preserving life. As plainly suggested by its name, the government has an interest in preserving the lives of its people and will take certain measures to protect its people from potentially life-threatening harms.

A review of specific past cases in which courts determined that state interests outweighed a capacitated patient's right to refuse treatment calls attention to issues relevant today. In the cases reviewed, the state interest in preserving life appears to have been less frequently cited when patients were disabled as compared to when patients were not disabled. In other words, in the cases to follow, courts appeared to support disabled patients' right to refuse treatment but more forcefully employed arguments relating to the state interest in preserving life when patients were not disabled.

Although ableist judicial treatment toward disabled individuals is not a novel idea (Herr, Bostrom, and Barton 1992, 3; Coleman and Drake 2002, 240-242; Coleman 1992, 68-79), the literature does not seem to consider the state interest in preserving life as one potential source of this bias. We address this analytical gap in the following manner. We first review the right to refuse treatment; common state interests weighed against this right; and the various conceptions of the state interest in preserving life. In two subsequent sections, we consider cases involving non-disabled patients' refusal of treatment, followed by cases involving disabled patients' refusal of treatment. The unique cases selected for comparison portray the vaguely defined state interest in preserving life as a possible source of legal ableism.

While some scholars note that there have been no "recent" cases whereby the state interest balancing process has resulted in an overpowering of a capacitated patient's right to refuse treatment (quote from Coleman 2020, 172; Standler 2012, 39; Feinberg 1998, 850), an analysis of past applications of state interests still offers important information for the present.[2]

Without acknowledging the state interest in preserving life as a potential source of medical ableism, any current controversy involving this state interest is more likely to involve such a bias. Indeed, the legal debates surrounding physician-assisted suicide frequently involve the state interest in preserving life (Feinberg 1998, 863-864, 873). As well, given the outcome of the recent Dobbs v. Jackson Women's Health Organization decision, it is especially important for scholars to study and critique components of state interest balancing procedures.

Although interests of the state may vary based on the details of the controversy at hand (Harvard Law Review 2016; Britannica), courts ought to reach an equilibrium between flexibility and specificity. If the state interest in preserving life can result in biased decisions largely due to unclear parameters, we suggest that courts define the interest with further precision in order to ensure that its use in current controversies does not inherently introduce bias.

PART II: A BRIEF NOTE ON COMPETENCY

Unless specified otherwise, patients in the scenarios below are presumed to possess competency. This may, on the surface, be perceived as a dismissal of an important issue. However, the following should be noted:

> The adult's right to execute an advance directive is derived from the legal presumption that adults are competent to make their own decisions about activities that affect themselves, including decisions to consent to or refuse [life-sustaining medical treatment]. Those who would force an adult patient to receive unwanted medical treatment have the burden of proving that a patient is incompetent rather than the patient having to prove that he is competent (quote from Derish and Heuvel 2000, 112).[3]

Additionally, "a physician's good faith determination of decision making capacity is presumed to be correct" (Derish and Heuvel 2000, 113-114). There exists a great deal of controversy as to how one can robustly evaluate patient

[1] Although these four state interests are among the most commonly cited, courts do not consistently reference the same state interests across cases. In 1977, *Superintendent of Belchertown v. Saikewicz* described the four general state interests: preservation of life, protection of third parties, suicide prevention, and protection of professional medicine's integrity (Gordon 1990, 67). However, two years later, the Massachusetts Supreme Judicial Court identified another state interest, being "the maintenance of orderly and secure prisons" (quote from Gordon 1990, 67; Urofsky 1998, 354-356). Moreover, *Compassion in Dying v. Washington* identifies notably different interests: that doctors should not kill patients; that the elderly and weak should not be pressured to agree to death; that groups particularly vulnerable to exploitation, such as minority groups or those of lower socioeconomic status, should be protected; that disabled individuals should be protected from negative social attitudes; and that abuses occurring in the Netherlands should be avoided (*Superintendent of Belchertown State School v. Saikewicz*; Gordon 1990, 67).

[2] We thank Dr. William FitzPatrick for his review of previous versions of this manuscript and his suggestion that we acknowledge that modern balancing processes would likely favor the patient's right to refuse treatment when public health or other matters, such as the wellbeing of third parties, are not at risk (*Jacobson v. Massachusetts; Cruzan v. Director, Missouri Department of Health; Commonwealth v. Pugh; In re A.C.*).

[3] Here, Derish and Heuvel cited the following sources: Meisel 1995; In the Matter of Karen Quinlan; Cruzan v. Director; Missouri Department of Health; and Berger 1993, 97.

competency in different contexts. To dissect these issues here beyond what is stated above would distract from the central claim: the state interest in preserving life as a source of bias.

PART III: HISTORY OF THE RIGHT TO REFUSE TREATMENT, STATE INTERESTS, AND THE STATE INTEREST IN PRESERVING LIFE

In 1891, the United States Supreme Court held that it could not order individuals to undergo medical examination without their consent, claiming that "[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law" (*Union Pacific Railway Co. v. Botsford*).

The 1914 opinion of *Schloendorff v. Society of New York Hospital* is frequently cited as legal precedent supporting one's right to refuse medical treatment, where the court acknowledged that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body." *Schloendorff v. Society of New York Hospital* further held that an assault is committed when surgeons operate without the consent of their patients. Not only does ample legal precedent support this right to refuse treatment, but scholars and courts have also associated this right with a diverse range of other important (though sometimes contested) rights, including, but not limited to, the right to die (Urofsky 1998, 354-356; Derish and Heuvel 2000, 122), the right against battery (Urofsky 1998, 386-387), the right to informed consent (Herr, Bostrom, and Barton 1992, 5), the right to religious freedom (*Wons v. Public Health Trust*), the right to liberty (*McKay v. Bergstedt*; Bourke 1990, 77), the right to privacy (*McKay v. Bergstedt*; Bourke 1990, 77), the right to control one's body (Derish and Heuvel 2000, 122), and the right to make personally intimate decisions (Urofsky 1998, 386-388; *Washington v. Glucksberg*).[4]

As noted earlier, however, the right to refuse life-saving treatment is not absolute; courts have historically balanced this right against multiple different state interests, even when patients had decisional capacity (Standler 2012; Coleman 2020, 171-182; Dangelantonia 1991, 351-354; Leeman 1999; Bourke 1990, 77). Although state interests - especially those like the state interest in preserving life - might appear to be rational and straightforward, the frameworks of these state interests are considerably unclear (Gordon 1990, 67). The historical application of the state interest in preserving life in particular demonstrates the high degree of ambiguity embedded within the legal term. Numerous court systems attempted to craft their own mechanisms for appropriately navigating this unclear state interest.

In *Satz v. Perlmutter*, for example, the court claimed that the weight of the state interest in preserving life was not equal for all patients. That court maintained that the interest diminished in weight when the relevant individual suffered from an incurable disease (Gordon 1990, 51-52, 67).

The Massachusetts courts also differentiated between treatment for curable disease and treatment for incurable disease to better evaluate the weight of the state interest in preserving life (Gordon 1990, 69-71; *Matter of Hier; Brophy v. New England Sinai*). However, Massachusetts courts relied on multiple other dichotomies as well, including whether treatment was determined to be life-saving or life-prolonging and whether treatment constituted ordinary versus extraordinary care (Gordon 1990, 69-71; *Matter of Hier; Brophy v. New England Sinai*). Daniel Gordon observes that the use of dichotomies failed to sufficiently clarify the weight of the state interest in preserving life and that the Massachusetts courts later changed their method by implementing a sliding scale to evaluate the strength of the state interest (Gordon 1990, 69-71; *Matter of Hier; Brophy v. New England Sinai*). With this latter approach, courts concluded that the state interest decreased when prognoses worsened, when patients were "nearing the end of a normal life span with incapacitating afflictions," and when treatments became more invasive and prolonged suffering (quote from Gordon 1990, 71 citing *Matter of Hier; Brophy v. New England Sinai)*.

Although this sliding scale approach seems to incorporate multiple factors previously considered by the courts, the scholarship and case law surrounding this sliding scale are curious as well. For instance, it has been noted that the sliding scale method did not consider quality of life in its calculations, at least in some respects (Gordon 1990, 71 citing *Brophy v. New England Sinai; Matter of Hier*). However, it seems contradictory to suggest that quality of life was disregarded when prognoses and disease details - elements that certainly affect quality of life - were included in case

[4] Especially concerning the latter three rights, the recently issued Dobbs v. Jackson Women's Health Organization decision has called into question the scope of the right to privacy, the right to control one's body, and the right to make personally intimate decisions as they relate to abortion. Given the controversial nature of this decision, as well as the debates surrounding physician-assisted death, the arguments to follow do not rely on any one particular support of the right to refuse treatment.

evaluations.[5]

Overall, the complex history of state interests, particularly the state interest in preserving life, demonstrates the high degree of uneasiness within this area of medical law. In the following[6] two sections, the complexity of the state interest in preserving life will be exemplified by our exploration of past judicial discrepancies between case outcomes for disabled and non-disabled patients.

PART IV: CASE EXAMPLES OF NON-DISABLED PATIENTS REFUSING TREATMENT

Denise Nicoleau, a Jehovah's Witness, refused blood transfusions after her cesarean section (*Matter of Fosmire v. Nicoleau*). Mrs. Nicoleau completed a consent form one month prior to the cesarean section, where she consented to certain birth-related procedures, excluding blood transfusions. After Mrs. Nicoleau underwent the cesarean section, her hemoglobin count dropped significantly due to blood loss from her uterus, but Mrs. Nicoleau continued to refuse blood transfusions. Brookhaven Memorial Hospital sought permission from a judge of the Supreme Court in Suffolk County to provide the blood transfusions over the patient's objection. Alongside this request, a physician completed an affidavit in which he wrote the following: "unless [Mrs. Nicoleau's] medical condition improves (which I consider unlikely) she must have a blood transfusion in order to preserve her life" (*Matter of Fosmire v. Nicoleau*). The court signed an ex parte order allowing for the provision of blood transfusions, perhaps because the court was sympathetic to the physician's appeal to the preservation of life.

The court's prioritization of the state interest in preserving Mrs. Nicoleau's life may have been heightened due to Mrs. Nicoleau being a mother to a newborn. Consequently, some might question whether this case shows the court's bias toward the state interest in preserving life (when the patient is not disabled) or instead shows a desire to save the lives of parents with minor children. The concurring opinion of Judge Simons in *Matter of Fosmire v. Nicoleau*, however, suggests a strong disposition toward the state interest in preserving life, independent of parental status. Indeed, Judge Simons specified that Mrs. Nicoleau was "neither aged nor grievously infirm" and that the blood transfusions could save her life with very low risk. The judge additionally wrote that "most courts, before approving a patient's decision to forgo life-sustaining treatment, would consider the nature of the patient's condition. . . " and the judge provides multiple factors to consider, including whether "the patient's condition is terminal, has lessened life expectancy or has drastically reduced the quality of life." While respecting this patient's religious reasoning for her decisions, he argues that if "competent adults . . . may reject lifesaving treatment without reason the rule condones a method of suicide." It should be noted that Judge Simons nevertheless concurred with the decision to vacate the blood transfusion order; Mrs. Nicoleau's status as a Jehovah's Witness, in his view, transformed the act of forced blood transfusion into a treatment that would violate Mrs. Nicoleau's constitutional right to religious practice. Regardless of the religious exception, the concurring opinion illustrates the disposition toward the state interest in preserving life (for patients who are not disabled) when treatment is available.

Some readers might theorize that the bias toward the state interest in preserving life could be isolated to religious controversies surrounding blood transfusions. However, *Ian Shine, administrator v. Jose Vega* suggests otherwise. In 1990, Dr. Jose Vega at Massachusetts General Hospital (MGH) restrained and intubated 29-year-old Catherine Shine over her strenuous objections. Ms. Shine, a life-long asthmatic, presented to the hospital during a serious asthma attack and agreed only to the administration of oxygen. MGH treated Ms. Shine with a nebulizer, administering both oxygen and medication. As MGH staff expressed increasing concern over Ms. Shine's refusal to continue the medication and accept more aggressive treatment, Ms. Shine's sister contacted their father, Dr. Ian Shine, to support Ms. Shine's authority to make her own medical decisions. Dr. Shine encouraged the attending physician at MGH to listen to Ms. Shine and respect her decisions. Later, after Ms. Shine's condition improved slightly, she and her sister attempted to leave through an emergency exit but were stopped by security and a doctor. Following this attempt to leave the hospital, Dr. Vega ordered restraints for Ms. Shine and intubated her against her wishes.

Ms. Shine's relatives testified that this incident traumatized her: it affected her sleep, her ability to work, and instilled in her a deep distrust of hospitals and healthcare providers. She "repeatedly 'swore' she would never go to a

[5] Even assuming quality of life was omitted from the sliding scale approach, it is unclear whether the sliding scale disregarded the patient's consideration of their own quality of life, the court's consideration of the patient's quality of life, or both. Further, the alleged omission of quality of life considerations in the Massachusetts sliding scale approach is particularly curious in light of claims made by California courts. For example, in *Bouvia v. Superior Court,* the California Appellate court noted that the trial court had erred by "failing to give quality of life equal weight with quantity of future life" (Gordon 1990, 84).

[6] It should be noted that the right to refuse treatment encompasses treatment refusal and treatment withdrawal (Luce and Alpers 2000, 2029). While the cases in the next sections might suggest that the courts more readily accept withdrawals as compared to refusals, this greater hesitancy toward treatment refusal seems to be an artifact of selecting disability-related cases. Indeed, the proceedings suggest that disability status is the primary factor motivating the differential ability to exercise the right to refuse treatment, at least in the examples we discuss. This is not to say that the cases to follow are devoid of other biases. Biases against the decisional authority of women appear to influence court decisions as well, though this discussion is explored in a separate work by Streicher and Shaw.

hospital again" (*Ian Shine, administrator v. Jose Vega*). In 1992, Ms. Shine suffered another severe asthma attack, refused to go to the hospital, and died. Dr. Ian Shine filed a wrongful death case against MGH and Dr. Vega, alleging that the trauma of the previous hospitalization - including the forced restraints and intubation - directly contributed to Ms. Shine's death. Dr. Vega maintained that consent for Catherine's intubation was not necessary. A Superior Court judge agreed, claiming that the right to refuse treatment is limited by "the right of the state or the obligation of the state to preserve the lives of its citizens . . . a right that exists in an emergency room setting to perform treatment without the consent of the patient." The judge also explained "that a doctor and/or a hospital does not commit an assault and battery when they treat a patient without her consent if the treatment is necessary to save her life or to prevent serious bodily harm." Dr. Shine appealed these findings, claiming that the legal information the judge provided to the jury was incorrect. The Massachusetts Supreme Judicial Court voided the previous judgment and ordered a retrial for the case.[7]

While the above cases are extreme examples of flawed decisions, as demonstrated by the fact that the original judgments preventing a patient's refusal of treatment were vacated or overturned by an appellate court, these cases illustrate the willingness of judges to override a capacitated patient's right to refuse treatment by relying on the state interest in preserving life or related logic. However, other courts give this same state interest different weight when disabled patients request discontinuation or withdrawal of medical treatments.

PART V: CASE EXAMPLES OF DISABLED PATIENTS DISCONTINUING TREATMENT

Consider the case of *McKay v. Bergstedt*, which illustrates the willingness of the respective court to comply with a disabled patient's wish to withdraw treatment (Dangelantonio 1991, 351-354). Quadriplegic due to a swimming injury at the age of ten, Kenneth Bergstedt required a respirator to live. Although Mr. Bergstedt's condition was irreversible, he remained competent, had capacity to make medical decisions, and was not terminally ill. Mr. Bergstedt was cared for by his parents for over twenty years. After the death of his mother and when his father became terminally ill, Mr. Bergstedt sought a district court order for aid in removing his own respirator, which would result in death, alongside the provision of sedatives necessary to treat pain following the respirator's removal. In addition, Mr. Bergstedt requested liability immunity for those helping him in this plan. The district court authorized Mr. Bergstedt's order, citing the right to privacy and the right to self-determination. The office of the state attorney general appealed the decision. The Nevada Supreme Court affirmed the district court's decision, even though Mr. Bergstedt had died prior to the issuance of the Nevada Supreme Court decision.

The Nevada Supreme Court noted at the outset "that the State . . . essentially agreed with Kenneth's petition and has accordingly assumed only a token adversarial stance on appeal" (*McKay v. Bergstedt*). It was noted that Mr. Bergstedt's condition was a primary factor that relieved the state of its interest in preserving life:

> [T]he [district] court also ruled *that given Kenneth's condition*, judicial recognition of the primacy of his individual rights posed no threat to the state's interest in preserving life, adversely affected no third parties, and presented no threat to the integrity of the medical profession (*McKay v. Bergstedt*, emphasis added).

In other words, in the eyes of the court, Kenneth's life was so overcome by medical conditions that his death did not contradict the state interest in preserving life. In this way, the court implies that the state is less than interested in preserving the lives of those who are as physically disabled as Kenneth.

The Nevada Supreme Court made similar suggestions. In describing the weight of the state interest in preserving life, the court suggested that "as the quality of life diminishes because of physical deterioration, the state's interest in preserving life may correspondingly decrease" (*McKay v. Bergstedt*). Circumscribing the state interest in this way might not have been as problematic if the court relied on the patient's evaluation of life quality. However, adding insult to injury, it seems the court instead relied on its own evaluation of life quality, as illustrated by the following claim made by the court:

> It is equally clear that if Kenneth had enjoyed sound physical health, but had viewed life as unbearably miserable because of his mental state, his liberty interest would provide no basis for asserting a right to terminate his life. . . . Our societal regard for the value of an individual life, as reflected in our Federal and state

[7] The Massachusetts Supreme Judicial Court writes further on the emergency exception to the requirement of informed consent, citing *Canterbury v. Spence*. The following are the criteria for the emergency exception to hold: when a patient is unable to provide consent (perhaps if the patient is unconscious, for instance), and time prevents the provider from obtaining consent, and the impending consequences from lack of treatment outweigh the consequences of the suggested treatment. The exception to the requirement of informed consent does not apply when the patient is, in fact, capable of providing consent, even if the patient seeks to refuse life-saving treatment (Leeman 1999 citing *Cruzan v. Director, Missouri Dept. of Health and Matter of Conroy* and *Vacco v. Quill and Washington v. Glucksberg and In the Matter of Karen Quinlan*).

> constitutions, would never countenance an assertion of liberty over life under such circumstances (*McKay v. Bergstedt*).

Here, the court writes that mental struggles would have been an insufficient justification for treatment refusal. Notice, however, that some patients might consider intolerable mental struggles to be reason enough to refuse treatment. By blocking this avenue for patient choice, the court demonstrated that its own assessment of quality of life might, in some instances, take precedence over the patient's assessment of quality of life.[8] In Mr. Bergstedt's case, the court's determination of sufficiently low life quality merely coincided with the views of the plaintiff, and the court was not shy to acknowledge this shared perception of low life quality:

> In Kenneth's situation it is not difficult to understand why fear had such an overriding grasp on his view of the quality of his future life. Given the circumstances under which he labored to survive, [we] could not substitute our own judgment for Kenneth's when assessing the quality of his life. We therefore conclude that Kenneth's liberty interest in controlling the extent to which medical measures were used to continue to sustain his life and forestall his death outweighed the state's interest in preserving his life (*McKay v. Bergstedt*).

Based on this analysis, it appears the state interest in preserving life was a vector the court used to inject its own evaluation of life quality into decisions, modifying people's ability to exercise the right to refuse treatment. In other words, individuals are free to exercise their right to refuse treatment when the court similarly perceives a low quality of life. The perception of low quality of life here seems to have rested on Mr. Bergstedt's physical condition. The peculiar justification for allowing Mr. Bergstedt's refusal of treatment - a justification that relies on Mr. Bergstedt's disability status - is in fact noted in a dissenting opinion: "I register now my strong disapproval of our courts' putting their 'judicial stamp of approval' on allowing 'the state to assist an individual to die only because he . . . has a disability'" (*McKay v. Bergstedt*).

Not all cases demonstrate such explicit dependence on the patient's physical condition. However, a comparison between court decisions for patients who are disabled with those who are not disabled still raises concerns about potential bias. For instance, a comparison of *State of Ga. v. McAfee* to Section IV's cases again suggests differential legal treatment toward disabled individuals. Larry James McAfee suffered a motorcycle injury in 1985, causing irreversible quadriplegia. Mr. McAfee, as a result, required a ventilator for respiration. In 1989, Mr. McAfee submitted a petition to the Fulton County Superior Court for permission to refuse further ventilation, which would bring about death. The trial court approved, basing its decision on the constitutional rights to liberty and privacy (*State of Ga. v. McAfee*; Bourke 1990, 77). The Georgia Supreme Court upheld the decision, explaining that the state interest in preserving life here could not dissolve Mr. McAfee's right to refuse treatment (Bourke 1990, 77 citing *State of Ga. v. McAfee*). If Mr. McAfee's right to refuse treatment remained intact because of his physical condition, the concerns regarding *McKay v. Bergstedt* would similarly apply here. Additionally, alongside the right to refuse treatment, the trial court cited Mr. McAfee's "constitutional rights of privacy and liberty" (*State of Ga. v. McAfee*). It would be odd to suggest that such rights could be justifiably modified based on one's physical condition or a court's subjective evaluation of life quality.[9]

When one recalls the details of the previous section - where the state interest in preserving life was emphasized - it is unsettling to find that, in this section, when patients are disabled, the state interest in preserving life is quickly overpowered by patient wishes.[10] Based on the differing levels of difficulty encountered by patients seeking to refuse or withdraw treatment, it appears that physical condition played a role in the above court decisions: non-disabled individuals are questioned when refusing treatment, yet disabled individuals are more readily permitted to discontinue treatment.

PART VI: CONCLUDING REMARKS & FUTURE WORK

Through an analysis of both non-disabled and disabled patients, it appears that the cases described above more often referenced the state interest in preserving life or similar notions when patients were not disabled, resulting in disabled patients having a greater ability to exercise the right to refuse life-saving treatment. Because the state interest in preserving life seems to have wavered on physi-

[8] Because the assessment of quality of life is something so intimate, it might be most appropriate for the matter to be primarily judged by the patient. In fact, in keeping with this idea, Dr. Leeman writes that *Bouvia v. Superior Court* previously found that "the quality of life as viewed by the person who must endure it must determine what is done" (Leeman 1999, 114 citing *Bouvia v. Superior Court*).

[9] Earlier, we specified that our arguments do not rely on any one particular interpretation of the basis of the right to refuse treatment. Indeed, regardless of the underlying source of the right to refuse treatment, it is unclear why the right could justifiably be modified based on one's disability status or the court's own determination of life quality.

[10] Similar issues are raised by Mr. David Rivlin's case. Mr. Rivlin was a quadriplegic patient who requested to cease the use of his ventilator. His request was unchallenged and successful (Herr, Bostrom, and Barton 1992, 13-15). In fact, "[t]he Oakland County circuit judge refused to grant a declaratory judgment because the pleadings failed to show that an actual 'controversy' existed" (Herr, Bostrom, and Barton 1992, 14).

cal condition and subjective elements, such as the court's perception of life quality, there was an implicit bias affecting disabled individuals.

We are not suggesting that the state interest in preserving life is without merit. The cases we bring forward merely highlight that the state interest is inconsistently applied, with subjectivity bleeding into its interpretation.[11] It seems that even legal authorities highly trained to render just decisions fall prey to the biased misconception that disabled individuals lead low-quality lives, and this bias creates life-altering differences. Crucially, the specific parameters of the state interest, to our knowledge, have yet to be robustly updated or defined in a way that limits the likelihood of bias. In this sense, this broad and malleable state interest poses a present concern by potentially precipitating bias in legal proceedings today.

To at least partially remedy the ableist issue noted in this discussion, the state interest in preserving life could be narrowed to represent a focus on preventing inauthentic medical decisions. In other words, states would have an interest in reducing the number of deaths as a result of impulsive decisions to refuse care, and this interest would manifest itself through procedures that ensure capacity, provision of robust medical care (including mental health services), and communication of non-lethal alternatives. This theoretical conception of the state interest in preserving life is quite similar to a conception of the state interest in preventing suicide provided by a Washington University Law Review, citing *Belchertown v. Saikewicz*, the *Quinlan* court, and multiple other authorities (Davis 1980, 109-110).

To meaningfully reduce bias with respect to the state interest in preserving life, it is likely that multiple rounds of definition refining will be necessary. Importantly, when these parameters are being remodeled, it is not merely the legal experts who should be included in the discussion. Diverse community members - especially those members intimately affected by the issues at hand - should be involved in this remodeling. In this way, legal doctrines reflect multi-faceted inputs and more meaningfully protect patients.

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[11] While the state interest in preserving life serves as a focal point in this discussion, other state interests appear to be problematically ambiguous as well. For instance, because the defining components of suicide are somewhat fluid, the state interest in preventing suicide also presents interpretive and bias-prone challenges (Herr, Bostrom, and Barton 1992, 13-20; Gill 1992).

Bioethics-in-Brief

Potential Ethical Dilemmas of Advance Directives

Albertina Lee

It is one of the core ethical tenets of medicine that patients' autonomy and fidelity be respected. Advance directives, in their various forms, preemptively serve this key principle in the event of the patient being physically or mentally incapable of coherently making their own medical decisions. Most commonly, advance directives in the medical field feature a living will and or durable power of attorney for healthcare (US Department of Health and Human Services). A living will allows patients to identify treatment preferences, goals for care, and under which conditions these choices apply. Appointing a healthcare proxy, on the other hand, places medical decision making into the hands of a trusted individual to communicate an incapacitated patients' health care decisions.

Advance directives have found a place in advancing patient's directions for their matter of treatment for a wide variety of afflictions, ranging from dementia's slow loss of mental faculty to more physical and immediately debilitating injuries such as those from vehicular incidents. However, despite advance directive's ability to prepare for future medical emergencies, they are not without their controversies. For example, in one aspect of advance directives, proper surrogate decision making may be impeded by conflicting interests or ideals with the patient. On the other hand, living wills may not be updated properly, may not clearly outline the patient's plan of action due to unforeseen advancement of medical technologies, or may even impede the patient's true treatment goal due to the patient's lack of medical understanding ("Advance Directives and Surrogate Decision Making").

A patient's lack of understanding of a proposed treatment can have significant ethical ramifications for both their surrogate decision maker as well as the actual medical team that is in charge of selecting and implementing treatment, often in time-sensitive situations. Take, for example, such an ethical dilemma set directly in the Intensive Care Unit (ICU). An elderly male patient has been admitted with fatigue, shortness of breath, and other cardiac-related symptoms (Yu, Kodner, and Ray). Prior to diagnostication, the patient's wish to refuse cardiopulmonary resuscitation (CPR) "under any circumstance", due to a perceived subsequent need of life support, is recorded in the electronic medical record.

After this advance directive, the patient is formally diagnosed with new-onset congestive failure, which is followed by the treatment of valvular replacement and coronary artery bypass graft. The patient agrees to the procedure after being briefed on its risks and benefits, but his previous Do Not Resuscitate (DNR) advance directive fails to be followed up on or modified in light of the new information.

A period of time following the surgical procedure, the patient exhibits continued signs of ventricular tachycardia that requires CPR. However, the physician now faces the ethical dilemma of either respecting the patient's outdated advance directive or proceeding with CPR to save the patient's life with a strong probability that life support won't be needed. The first option would respect patient autonomy, but present a detriment to the physician's duty to administer the best outcome to preserve life. But this begs the much-debated question: to what extent

should patient autonomy be protected? Key philosophical arguments point towards the autonomy's intrinsic value in an honor system, or whether autonomy may only be restricted over the rare situations in which harm may be done to others or to the patients themselves (Varelius). Thus, in this situation that physicians most commonly face on the field, the medical team must make conflicting decisions under a short time frame due to the conflicting nature of vague advance directives and their own medical understanding.

Unless more explicit policies are established to provide clearer guidelines for physicians in the event of conflicting advance directives as described previously, physicians will continue to struggle with these decisions. However, controversies in advance directives can also be found in an earlier part of the process: simply making one.

Yet, despite these ethical conflicts, it has to be said that the numerous benefits of advance directives outweigh the sparse negatives. Not only do advance directives provide an ethical route of respecting patient autonomy and allow

peace of mind for the patient's loved ones and the medical team, advance directives have also been shown to significantly correlate with a reduced cost of end-of-life care (Zhu). Completion of advance directives was found to have a significant correlation with lower hospital out-of-pocket costs, with a greater amount of saving in younger patients. This allows patients the bodily autonomy to choose in which ways to spend their money at the end of their lives, such as with terminally ill patients who may choose to spend their money in alternative ways to a high cost, low benefit medical plan.

Establishing advance directives is seeing an increase in prevalence in the medical field, but advance directive completion is still lacking in vulnerable patient populations. There is a significant need to increase the percentage of advance directives in more diverse age groups and underrepresented demographics such as men, younger patients, and Hispanics (Yadav). With nurse-directed palliative care planning, successful increases in advanced care planning have been seen in elderly patients (Solomon). Such strategies may be imperative in the future to establish increases in advance directives in minority patient populations.

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Interview

A Conversation with Holly Fernandez Lynch

Holly Fernandez Lynch, JD, MBE is an Assistant Professor of Medical Ethics and Health Policy at the University of Pennsylvania with a primary appointment at the Perelman School of Medicine and a secondary appointment as an Assistant Professor at the Penn Carey School of Law. Lynch formerly worked on President Obama's Bioethics Commission and was the Executive Director for the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School prior to joining Penn as a faculty member. Her research at Penn has focused on clinical research ethics and regulation, FDA policy, and IRB oversight of research.

This interview was conducted by Caitlyn Chen and Beatrice Han.

What got you interested in bioethics and law?

I came to Penn as an undergraduate not having any idea of what I wanted to do. I thought I might want to do science but not looking to go to medical school, so really a blank slate. I was in an "Introduction to Biomedical Ethics" class my freshman year and I found it very interesting, so I pursued that interest in bioethics throughout college and as you know, no one is just a bioethicist. They're bioethics and law, or medicine, or sociology, or anthropology, or whatever their discipline is. So I spent a lot of time in college thinking about what my other discipline was going to be, the angle I was going to take on bioethics.

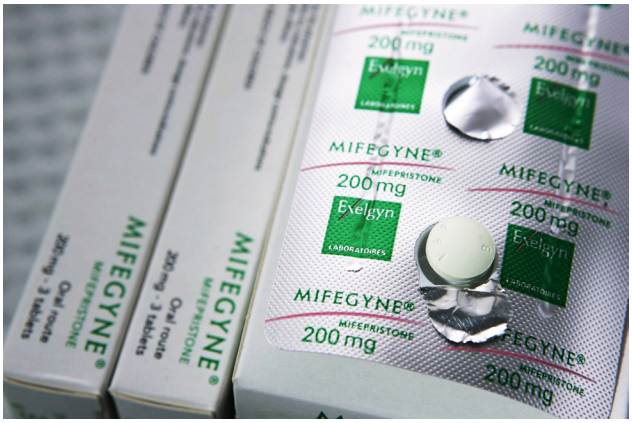
Because I was interested in policy, I thought going to law school would be a good backdrop for the bioethics work I was interested in doing. After law school, I worked in private practice in a D.C. law firm in their FDA (Food and Drug Administration) practice group for a couple of years. I became interested in clinical trials and the ethics of clinical research and how those studies are regulated, and that allowed me to move into a position at the Division of AIDS, where I worked as a bioethicist. I worked in a group called the Human Subjects Protection branch, and we were involved in ethical oversight of the domestic and international research that the Division of AIDS was funding. I left that job to go staff President Obama's Bioethics Commission where I contributed to two reports on research ethics issues. Then I went to Harvard Law School, where I was the execu-

tive director of the Petrie-Flom Center, which is a bioethics and health policy research program. I did that for five years, and I came to Penn in 2017 as an Assistant Professor in the Department of Medical Ethics and Health Policy.

In a recent NPR interview on the Mifepristone case, you mentioned how the approval undermined the FDA's authority, so what are your thoughts on how the FDA, drug developers, and other legal authorities should communicate in the approval process?

Mifepristone is one drug in a two-drug regimen for medical abortion. It was initially approved by the FDA several years ago. The FDA's standard for drug approval is that the drug must be safe for its labeled use, and that there has to be substantial evidence that the drug will be effective for its labeled use. In order to evaluate effectiveness, the FDA looks at adequate and well-controlled investigations: clinical trials. They look at how the product is working, its adverse events, and the patient population for appropriate use. The FDA did its usual process and approved Mifepristone, I believe, in 2000. At the time, the FDA incorporated safety provisions to monitor safe use of the product, as well as some special safeguards. For instance, you had to go physically get it in the office with an in-person doctor's visit. There were some additional layers put on for safety. Over the next several years, the drug was in widespread use. Additional information was gathered, because there's typical standard adverse event reporting that has to happen for all FDA approved drugs, and there was some added adverse event reporting that was specifically requested for Mifepristone. As you can imagine, this was a drug approval that was under a lot of attention, so the FDA was extremely careful in its approval and added safeguards. There was a generic allowed on the market, and the FDA over two application cycles reduced some of the initially imposed safety requirements because it decided they were no longer necessary for safe use. The drug had been used widely and safely and it didn't need to have those obstacles on it anymore.

It's very important to recognize that the safeguards around Mifepristone were far higher than what is typical for an FDA approved drug, including drugs that have more substantial safety concerns than there are for Mifepristone. During COVID, they also reduced the safeguards around in-person visits, and the FDA said that it was okay to prescribe the drug through telemedicine practice. So that's the background on how the FDA regulates Mifepristone. I should also say that Mifepristone is among the drugs that have been the most substantially investigated. There have been over a hundred studies over decades of use performed on thousands–tens of thousands–of women, so we know a lot about this drug and how it can be used. And this is all background for understanding what's going on in this case.



The key thing to recognize is that Congress gave the FDA the exclusive authority to determine which drugs are allowed on the market, and thus to decide which drugs are safe and effective. The FDA also has a process, which has been specified in statute, for withdrawing approval. If new evidence becomes available that a drug is unsafe or ineffective, the FDA has a process for pulling that drug's approval, and that process also protects the due process interests of the drug company. The FDA has to show evidence why the approval should be withdrawn, and the company gets to provide its own evidence, but the idea is that the FDA is the expert on these decisions. The FDA has primary and exclusive authority over drug approval decisions. States cannot weigh in and say that they don't agree that a drug is ineffective; this is something that is exclusively in the purview of the FDA. The FDA has many scientists on staff that review the data submitted by the companies and evaluate all the potential safety concerns, so they can make an expert judgment.

In the Mifepristone case, a group of physicians and some others brought suit against the FDA, saying that they erred in approving Mifepristone, and that they erred not only in approving it but in reducing the safeguards that the FDA has peeled away over the years. So this group of physicians incorporated in a district in Texas with one federal district court and one federal district judge. They knew that this judge– his name is Kacsmaryk–would be the one to get the case, and he is on record as being anti-abortion. Normally, you are not allowed to bring a lawsuit unless you stand yourself to be harmed by what is happening. So these physicians are not claiming that they themselves have taken the drug and are being harmed. What they're claiming for standing to bring suit is that even though they do not prescribe this drug, they may be called upon to provide care for women who have been prescribed this drug, and they do not want to do this. This was a pretty unusual argument, but the court accepted it for standing. The court eventually then decided that the FDA was wrong. Judge Kacsmaryk essentially said, "I know better than the FDA, and the FDA did not do its due diligence on the drug, it was wrong in approving it, and I order that the approval go away." So really you have a single federal judge substituting his judgment in place of that of a federal agency which had decided this drug was properly approved. He adopted very clear anti-

abortion rhetoric and talked about how the drug starves a baby of nutrients. He also talked about abortion providers as abortionists and uses a lot of language that is very clearly from the anti-abortion movement. Kacsmaryk ignored the mounds of evidence that this drug is safe to take and relied on the studies of the physicians who are suing the FDA. These studies have been widely discredited, and some of them can't even be properly counted as studies–like a website, or a blog where people can post their experiences with abortion and articulate responses like regret or psychological harm. These are not studies; anyone can post there, so it's not something that can be validated or recognized as a legitimate source of data. In any case, Judge Kasmaryck cherry-picked the data, ignored the data presented by the FDA, and said that his data was better than the FDA's. His decision gets immediately appealed to the 5th Circuit, and the 5th Circuit says that it disagrees with Kasmaryck because the doctors waited too long to sue on the initial approval, but it will uphold his judgment about the reduction in safeguards that the FDA had peeled back. So the 5th Circuit said that Mifepristone can remain approved for the duration of this appeals process, but has to go back to the 2016 version with all of those added safety provisions attached to it instead of the status quo version. That was another very concerning opinion, because it is another group of judges saying they knew better than the FDA. This opinion then got appealed to the Supreme Court, and the Supreme Court said that it would grant a stay to revert back to the baseline: Mifepristone will remain approved with the additional safeguards during the rest of the appeals process. So now it has returned to the 5th Circuit, where the judges will decide on the merits of the Kasmaryck decision; previously, the court had made an emergency judgment because patients risked losing access to Mifepristone during the appeals process.

I have been involved in an FDA scholars brief that was submitted to the 5th Circuit, which said that the FDA did not err in approving the drug, but more importantly we cannot allow judges to insert their own opinions to overrule the FDA's expert judgment. The broader concern is that if anyone who disagrees with an FDA's approval is allowed to sue the agency, and if courts are allowed to step in to say that the drug should not have been approved, that will wreak havoc on the pharmaceutical industry. If I'm a company developing a drug, I know that I have to do my clinical studies and prove to the FDA that it's safe and effective. Once the FDA says that it's safe and effective, I can market my drug across the country. If companies think, "I've got a controversial drug, like a vaccine–which are now controversial–or hormone therapy that could be used for gender affirming care, or contraceptives, or abortion drugs, or drugs that were developed using fetal stem cells," whatever the point of controversy is, those companies are going to worry that they will be subject to litigation and that courts are going to second-guess the FDA. And that's going to cause them to think, "Maybe we don't want to invest in this space, maybe we can't rely on the FDA's authority here." So the worry is that allowing courts to substitute their judgment for the FDA will be very damaging for pharmaceutical innovation and policy. Happy to answer any further questions about that case, but right now it's at the 5th Circuit, and I think it's very likely that it will go to the Supreme Court. In the Dobbs decision, which was the Supreme Court decision overturning Roe v. Wade last year, they said they were going to leave abortion to the elected branches of government–courts are obviously not an elected branch of government–so you have this concern about what the Supreme Court will do. Are they going to recognize that this is about FDA authority, or will they treat it as a traditional abortion case?

In light of this case, and as you mentioned in light of the recent–or not so recent–COVID vaccine approvals, do you foresee any changes in the drug approval or repeal process, and what do you think the FDA will face challenge-wise in accommodating any changes?

I don't think there will be any changes. The FDA has very clear authority from Congress to make these judgments, and a very clear process to make these judgments, and they follow that process. I don't think the FDA's process will change, in general, but there are a few ways the FDA could respond to the Mifepristone decision. For example, imagine that the Supreme Court had not granted the stay, and said that the appeal could go through but Mifepristone would remain unapproved in the meantime. The FDA could use its enforcement discretion, which means that the FDA can decide to go after companies that are violating the Food and Drug Administration act. If Mifepristone was not approved, and companies continued to sell it, it would be up to the FDA to go after them for violating the law. The FDA could say that enforcing a Mifepristone ban is a low priority because the drug is safe, and it could be spending resources on going after other companies that are doing things that are actually unsafe; the FDA might not spend its resources going after Mifepristone's manufacturer, even though it would be technically illegal to continue to sell the drug. So that's enforcement discretion; even if someone is breaking the law, the FDA can decide who to go after.

The other thing the FDA could do is re-approve Mifepristone. They could say, "OK, the court said we erred in approval. Companies, re-submit an application and we'll go over it and just approve it again." It's possible the FDA could do this, but there would be a gap during the period where they re-review the application. The other issue is that even with enforcement discretion, there's worry that doctors and companies will be too afraid to break the law. Even if the FDA says it will not enforce a ruling, it would have a chilling effect on doctors being willing to prescribe the law and companies continuing to sell it. So I think it's something to watch. It's something that the pharmaceutical industry filed a brief on that said courts should not interfere with the FDA's

judgment; FDA scholars said that it was really dangerous for courts to be allowed to second-guess the FDA this way. So we'll see what happens, but I don't see anything changing in the FDA's approval standards as a result of this case.

It is widely known that the drug approval process is extensive and time-consuming. Given the growing prevalence of many diseases, including antibiotic resistant bacteria and most obviously the recent COVID pandemic, how do you think pharmaceutical companies and government bodies ought to fill the need for novel treatments while adhering to the strict standards set during drug development and clinical trials?

There is a tension where, yes, it takes a long time for companies to develop the data they need to show that their drugs are safe and effective, and there are efforts to reduce the amount of time it takes by making clinical trials more efficient and streamlined and still getting the data that we need. Once the data gets submitted, the FDA reviews the data pretty quickly, and they have a statutory requirement to make a decision within 6 or 10 months, depending on the type of drug. There are efforts to shorten that process as much as possible, but inevitably, it will take time to prove that drugs are safe and effective. While that research is happening, there may be patients that may not have time to wait to be certain that a drug works, so there's a few different things that the FDA can do.

The FDA has a few pathways to allow patients to access drugs before they are sure that they work. One is called accelerated approval–this was used most famously for a recent Alzheimer's drug approval called Aducanumab, or Aduhelm–where drugs get approved based on a surrogate endpoint or a laboratory marker and companies have to do an additional study after approval to prove that the surrogate marker actually does predict clinical benefit in how patients feel and survive. That is one policy approach that has been taken; there are some concerns about that approach, as it is hard to get those studies done quickly and well, so you end up with products on the market of uncertain value. There's another pathway called expanded access that allows patients to get access to investigational drugs outside of a clinical trial if they were ineligible to participate in the clinical trial. These are both ways to give patients access to something before we are sure that it works.

Sponsors are trying to find new formulations or combinations for products that will make a meaningful difference to patients, but their interest is to get their products to market as quickly as possible because they can only profit from them once they are on the market. So that is the tension: companies want to get their products to patients as quickly as possible and the FDA has to say "you have to prove that your products work" because if the FDA does not require that, companies could put their products on the market and we would have no idea whether they are good

products, whether we should want to take them, whether we should want our physicians to prescribe them, whether insurance companies should pay for them. So the FDA has this very important information-forcing function, and that is the tension. That can be very frustrating for patients who don't have time to wait, but we have to take a step back and recognize that if the FDA weren't there, we might have a lot of drugs on the market, but we would have no certainty that they were good drugs. So we have to differentiate between drugs and innovative drugs, valuable drugs, useful drugs: those are the ones that we want on the market.

In terms of the clinical trials necessary to secure FDA approval, it's been well documented that most of these trials have been performed on white men, even for drugs meant for use predominantly in other populations. Why do you think that regulatory agencies have allowed this discrepancy to persist, and what steps do you think can be taken to repair this mismatch?

The FDA has this question as to whether a drug is safe and effective for its intended use, and it has, for a long time, been willing to accept data that were not reflective of the population of interest. The FDA just put out a guidance last year about diversity action plans for more diverse inclusion in clinical trials. Now Congress recently gave the FDA the authority to require that companies submit these diversity action plans, and what they need to do as part of those plans is to submit to the agency what their target enrollment is, what the rationale is for that enrollment, and what their plans are for actually achieving that target enrollment. There is a wide variety of demographic groups that could be conceivably relevant to include in clinical trials; the idea though is that the company would have to explain where their targets are coming from. There are a few concerns. What would happen if a company fails to actually achieve their plans for diverse clinical trial enrollment? We will have to wait and see; these requirements are pretty new, and the FDA would have to take enforcement action and either say "we will not approve your drug until you achieve diverse inclusion in your studies" or "we will approve it and will require post-market study in a more diverse population."

There are a lot of questions about it. One is, we do not

want to focus on race and ethnicity in clinical trials on the assumption that there is a biological or genetic difference inherently between different races. There is not: race is a social construct, and we do not want to put more scientific value in it than there really is, but racism has an impact on health. So the concern is that different demographic groups have different disease burden, different comorbidities, different access to the healthcare system: all of those things could influence how they do when given an investigational drug. So, we need to be very clear on why racial and ethnic diversity matters in research. When we think about that from a scientific perspective, we have to design our studies in such a way that if we wanted to look at differences between demographic groups, we would have to have adequate statistical power to do that, meaning the studies might have to be very big. So that is why I think it is important the FDA is saying "What is your rationale? Why hypothesize that there might be differences in these groups? How are you actually going to measure it? How are you actually going to get access to those groups?" There are lots of ways to do that, including by making clinical trial participation more accessible to a wider swath of the population: have clinic visits not in the middle of the workday, pay for people to participate, provide support for commuting, or child care–all of the other barriers that make it hard for less privileged people to participate in research.

So there is a plausible scientific rationale for worrying about racial and ethnic diversity in research, but even beyond that, there are two other reasons we need to care about this. One is trust in research: if people see that a drug like aducanumab gets approved but the patient population is not demographically representative, people who are not in the trial population might say "How do I know this drug works for me? Can I trust that this drug is appropriate for me? Can I trust the research?" The other is that you can benefit from being in a clinical study: you can benefit because the product under study is a good product and it works, but you also benefit from added medical attention. We want those benefits of research participation to be fairly distributed across the population as well.

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