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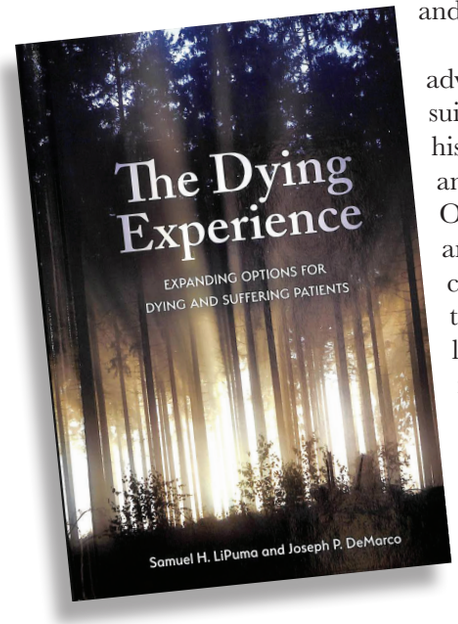
BOOK REVIEW:

The Dying Experience: Expanding Options For Dying and Suffering Patients

Stephanie K. Fabbro, MD, FAAD *is Chair of the Ethics Committee for the Ohio Dermatological Association and co-editor of the BENO Bio Quarterly.*

The Dying Experience: Expanding Options for Dying and Suffering Patients is a book about the examination of Western cultural implications and mores regarding the dying process and reviewing ways in which this process may be optimized. Authors Samuel Lipuma, Associate Professor of Philosophy at Cuyahoga Community College, and Joseph Demarco, Professor Emeritus at Cleveland State University, both have a longstanding academic interest in end-of-life bioethics and have published extensively on topics surrounding palliative care, brain death, advanced directives and physician-assisted suicide. The authors begin by examining historical attitudes on death, starting in antiquity with the origin of the Hippocratic Oath, and how populations viewed suffering and suicide in variable lights throughout a changing religious and cultural context into the twentieth century. They then review landmark cases in bioethics surrounding right-to-die issues including the pivotal Dax, Cruzan and Quinlan cases. The authors use this framework to review current legal status of palliative care and physician-assisted suicide in the United States as well as several other western countries such



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as the UK, Canada and Australia and scrutinize some of the current issues with palliative care such as difficulties with prognostication and the six-month prognosis rule to be eligible for hospice care in the United States.

After this thorough and masterful review, the authors delve into new proposed concepts for why progressive dementia disorders (such as Alzheimer's Disease or Parkinson's Disease) should also qualify for physician-assisted suicide. They suggest that states that have already passed physician-assisted suicide laws are too restrictive and that those who are facing the "death of their cognitive abilities" in some ways face a loss just as, if not more, profound as those facing physical terminal illnesses. After reviewing several contemporary cases, the authors recommend a specific model in which patients with progressive dementia disorders could go about obtaining physician-assisted suicide if they so desired; they follow this up with several counterarguments against their proposal. They delve into moral theory, making a provocative case for the concept that medical professionals already invoke euthanasia through the principal of double effect, to help to protect themselves from the mental and emotional burden of "directly kill[ing] a patient". They suggest that double effect seeks to separate one's intentions from one's actions, and when applied to the topic of hastening death, suggests that denial is a better option than acknowledgement of what is actually happening. Finally, they suggest that fostering a culture in the United States that would acknowledge the death and dying process, as opposed to denying it, would help drive further communication and progress on the topic.

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The authors make compelling arguments by using both famous and lesser-known cases that draw on their belief that "the desire for death over life is certainly tragic, but what is even more tragic is compelling dying patients to endure that which they would rather never endure". Their conclusions are that the current legal milieu on physician-assisted suicide in much of the United States is too restricted and violates patient autonomy, and that having a "good death" is a right to which all patients should have access. Refreshingly, they acknowledge several counter-arguments and objections, especially in the setting of physician-assisted suicide for progressive dementia disorders. This book would be an excellent choice for those looking for a comprehensive review on societal views on death, suffering, and suicide, as well as thought-provoking opinions on how to optimize the patient death process in the United States.

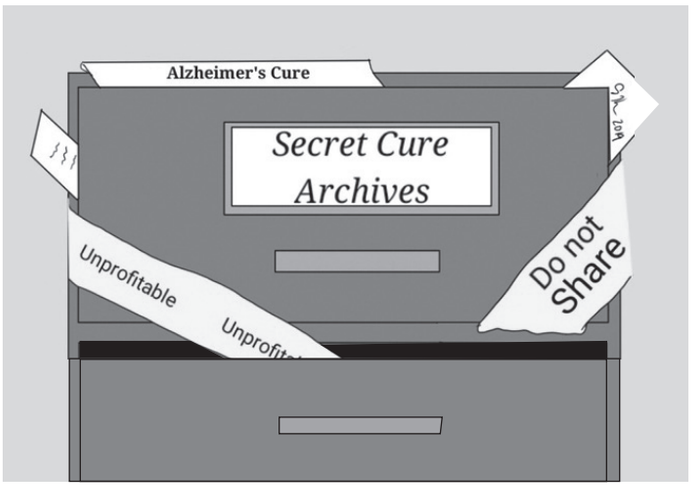
The Dying Experience can be purchased from Amazon.com for $34.95.

● Do Companies Have a Duty to Pursue Clinical Trials: Enbrel and the Suggestion of Alzheimer's

Craig Klugman, Phd *is a professor in the Health Sciences at DePaul University since 2013. He is a bioethicist and medical anthropologist with special interest in end-of-life issues, digital health, public health ethics, ethics pedagogy, and public engagement with bioethics.*

In 1983, NBC broadcast an alien invasion limited series called *V*. In one episode, as the U.S. devolves into a tyranny, the military invades scientific labs and finds—inside the filing cabinets (it was pre-computer days)—cures for cancer and other diseases that were simply never released because companies made more money treating disease than curing it. From that 36 year old television image has come a modern reality—Pfizer may have a drug that improves the chances of preventing Alzheimer's Disease, but they won't pay for the clinical testing.

Enbrel is a $5 billion per year prescribed biologic medication approved in 1998 for rheumatoid arthritis. It has since been FDA approved for plaque psoriasis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis. A recent Washington Post article reports that as of 2015, a Pfizer review of insurance claims found that the drug might also be effective in preventing Alzheimer's, the 6th leading cause of death in seniors. Pursuing clinical trials for FDA approval would have cost $80 million, a direction the company did not pursue as Enbrel nears the end of its 20 year patent life (though an unrelated lawsuit is seeking to extend that period until 2029). However, *The Post* reports that Pfizer also chose to keep the data secret and not publish it, a step that would have allowed another company or group to perform trials. Interestingly, in 2018, Pfizer announced that it would no longer be working on treatments for Alzheimer's.



Art by Craig Klugman

If there is a strong suggestion that a given drug has an effect on a disease, does the manufacturer have an obligation to pursue trials to test that hypothesis?

This case raises a number of scientific and ethical questions:

(1) SCIENCE: Is Enbrel a treatment that can delay the onset or slow the progression of Alzheimer's? No one knows though there is an intriguing possibility that it may. Stats 101 refresher: A correlation that people on Enbrel have lower rates of Alzheimer's diagnosis is not proof of causation. A clinical trial would need to be done to answer this question.

(2) ETHICS: If there is a strong suggestion that a given drug has an effect on a disease, does the manufacturer have an obligation to pursue trials to test that hypothesis? Can a drug company abandon an area of inquiry because of reduced profitability or does it owe an obligation to society to find a potentially useful (and lucrative if its patent wasn't ending) drug? Can companies be compelled to perform clinical trials that are promising if the company did not choose to pursue FDA approval for that prescribing purpose? The decision to pursue FDA approval is usually a business decision and in a [modified] capitalist society, companies and their boards have the freedom to choose

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what products to develop. Unless there is a declared emergency and public money made available for a company to produce or study a drug or a cure for a disease, there seems no way for society to compel a company to act in any particular way (though a vote from the shareholders or a drop in share value can certainly influence decisions). From a business perspective, Pfizer's decision makes sense. Why spend $80 million to prove that something works on a drug coming off patent? If the drug proves successful, then a generic manufacturer will reap the benefit of new sales, not the brand name.

However, a smart business decision is not necessarily a smart decision for the society or the public. In this case, there may be a duty (utilitarian; communitarian) for someone to pursue this line of research but it is not clear whose duty it would be.

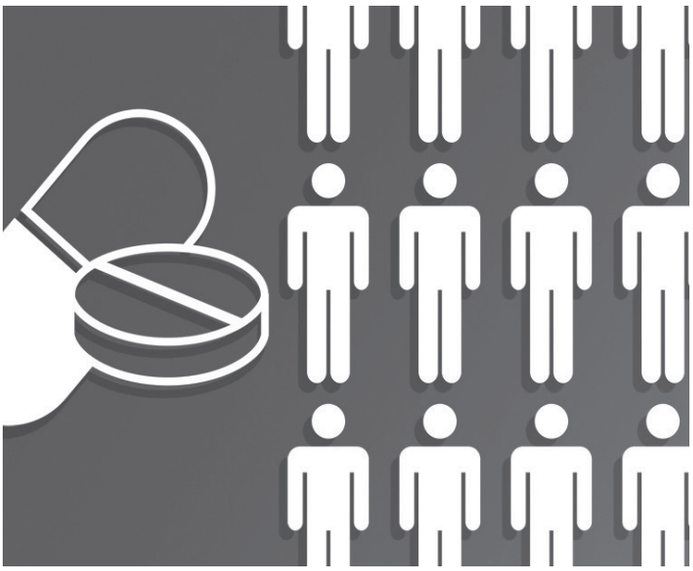
However, a smart business decision is not necessarily a smart decision for the society or the public. In this case, there may be a duty (utilitarian; communitarian) for someone to pursue this line of research but it is not clear whose duty it would be.

(3) ETHICS: If the company chooses not to pursue the trial, is there an obligation to pass that information on to another company, the federal government, or a university to take on the research? This question is akin to the doctor who refuses to perform an abortion or prescribe birth control pills. At least before the establishment of the DHHS Conscience and Religious Freedom Division, a physician (or any health care provider) who would not perform a procedure or write a scrip had an ethical obligation to refer the patient to someone who would. With the new Division, there is no longer a legal obligation to do so, but the ethical obligation remains. Similarly, companies have no legal obligation to give away their trade secrets or to pass this information on to another company. Ethically, however, they do. Companies are enriched by the public buying their product and that creates a reciprocal obligation to provide a benefit for the public (to share the riches). The public relations benefits of working with other companies or university researchers to set up this trial would also provide a huge PR boon to the company, even if there was a hit to the next quarter's bottom line.

(4) ETHICS and SCIENCE: Can double-blind placebo control trials ethically be done in this case when there is an agent that has shown a correlative connection to preventing (or slowing down) a disease, knowing that at least one arm of the study would not be getting the drug? One must consider that under the Declaration of Helsinki (to which the U.S. is not a signatory), a placebo controlled trial is not ethical if an arm of the study is receiving anything less than the current gold standard of treatment. At the moment, there is no medication that can prevent or slow down Alzheimer's, though there are medications to help alleviate some symptoms. Most recommendations for prevention revolve around exercise, eating nutritiously and (sometimes) avoiding aluminum in the diet. Thus, it is possible that Helsinki would permit a placebo trial. Imagine this trial thought: Most subjects are likely to be people with a family history of Alzheimer's and perhaps are even people who have the gene for the disease. Half of the participants would receive Enbrel and half would not. Given that there is a correlation between Enbrel and the onset of Alzheimer's, who would choose to be in the placebo group, especially when they can simply ask their doctor for an off label prescription? This is not a case with zero evidence; there is correlative evidence.

Companies are enriched by the public buying their product and that creates a reciprocal obligation to provide a benefit for the public (to share the riches)

(5) ETHICS: Can we ethically not do this study? Knowing there is an intriguing correlation, it seems that there may be an ethical directive to look deeper at this suggestion. The first step would be a larger epidemiologic study of existing insurance databases to see if the



correlation holds with a larger set of records. If it does, then there would seem to be an imperative to see if correlation is causation. Given that there may be 13.8 million people with Alzheimer's by 2050, is there not a need to see if any of these cases can be slowed, delayed, or prevented? If the answer is yes (and I think the answer is yes), then the question is, to whom does this imperative fall and who will pay for it? For that, I have no answers. Perhaps a patent extension on the drug could be dependent on completing clinical trials. Or perhaps a federal grant can be given to university researchers to complete this work.

(6) ETHICS: Did Pfizer commit an ethical faux pas when they hid these results rather than share this information? The answer is yes. While they may not have broken any laws, they certainly violated an ethics of transparency, responsibility, and working toward the better health of all. For this action, the company is ethically liable (might this require appearing before an ethics court?) and it would be intriguing if a case was brought to see if they were legally liable as well.

This is not the first situation where a company made an economic decision not to pursue a clinical trial. Physicians always have the right to prescribe a drug off label, but such efforts will not answer the question of whether this approach is actually effective. Then again, maybe that's the intent, to leak this suggestion in order to increase long-term sales to the 13.8 million future Alzheimer's patients. As strange as it may sound, that is the most likely of all these scenarios.

Article originally published on bioethics.net in June, 2019.

Ohio DNR Update

On September 1, 2019, revised Ohio Administrative Code regulations for Do Not Resuscitate (DNR) orders went into effect. Along with other smaller changes, the updated regulations introduce a new Ohio DNR form. The new form and related educational material approved by the Ohio Department of Health can be found at https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/do-not-resuscitate-comfort-care/DoNotResuscitateDNR

BENO members and patients they serve should be aware of an ongoing issue, predating the most recent regulatory review, that has drawn increased attention alongside the updated form. Due to an alleged conflict of laws, some Emergency Medical Services in Ohio do not plan to honor Do Not Resuscitate forms completed by advanced practice registered nurses or physician assistants. The state's DNR form and the statute that organize it explicitly permit APRNs and PAs to complete Ohio DNR forms. BENO continues to work with other stakeholders to resolve this issue. In the interim, members of the Ohio healthcare ethics community should apprise their institutions and patients of this risk, which will not be obvious from the form alone.

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