WITHHOLDING RELIEF: WHY CHRONIC PAIN PATIENTS DESERVE A QUALITY OF LIFE, AND HOW IT BECAME UNIMPORTANT IN THE COLLATERAL DAMAGE OF THE OPIOID CRISIS.

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DOCTORAL SCHOOL THESIS 2023
ROYAL HOLLOWAY, UNIVERSITY OF LONDON

PROGRAM LEVEL: POSTGRADUATE RESEARCHER
PROGRAM TYPE: MASTER OF ARTS
PROGRAM: PHILOSOPHY BY RESEARCH
SUBJECT: MEDICAL ETHICS
TOPIC: CHRONIC PAIN AND OPIOIDS

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Glossary

AASM: American Association of Sleep Medicine (https://aasm.org)

Acute Pain: Pain with a known source, such as an injury or surgery, lasting less than 3 months.

Analgesics: Medications that relieve pain

BMJ: The British Medical Journal

CMAJ: The Canadian Medical Association Journal

CDC: The Centre for Disease Control and Prevention (USA)

Chronic Pain: "Pain that lasts 3 months or longer, [which could] be caused by a disease or condition, injury, medical treatment, inflammation or an unknown reason" (CDC: CDC 2021) "[Persistent pain] that carries on for longer than 12 weeks despite medication or treatment" (NHS Inform, 2021)

DDE: The doctrine of double effect.

DEA: The United States Drug Enforcement Administration (USA)

Epidemic: "An increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area" (CDC, 2012)

ICD-11: The 11th revision of the World Health Organisation's International Classification for Diseases (WHO, 2015). The ICD-11 lists 15 "Disorders due to use of opioids" (6C43). These include:

1. 6C43.0 Episode of harmful use of opioids,
2. 6C43.1 Harmful pattern of use of opioids,
3. 6C43.2 Opioid Dependence,
4. 6C43.20 Opioid Dependence, Current Use,
5. 6C43.21 Opioid Dependence, Early Full Remission,
6. 6C43.22 Opioid Dependence, Sustained Partial Remission,
7. 6C43.23 Opioid Dependence, Sustained Full Remission,
8. 6C43.2Z Opioid Dependence, Unspecified,
9. 6C43.3 Opioid Intoxication,
10. 6C43.4 Opioid Withdrawal,
11. 6C43.5 Opioid-Induced Delirium,
12. 6C43.6 Opioid-Induced Psychotic Disorder,
13. 6C43.7 Certain Specified Opioid-Induced Mental or Behavioural Disorders,
14. 6C43.Y Other Specified Disorders Due to Use of Opioids,
15. 6C43.Z Disorders Due to Use of Opioids, Unspecified.

DSM IV: The 4th edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders

DSM V: The 5th edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders

NHS: The National Health Service (UK)

NICE: The National Institute for Health and Care Excellence (UK)

NIDA: The National Institute on Drug Abuse

NSAIDS: Non-Steroid Anti-Inflammatory Medications

Opiate: *The natural* analgesics derived from the opium from poppy seeds. Such as morphine and codeine

Opioid: *The synthetic/semisynthetic versions* of the analgesics derived from the opium in poppy seeds such as fentanyl and tramadol

Purdue Pharma (LP): The company which developed, owns the rights to, and sold the opioid *OxyContin* which instigated the current Opioid Crisis (Purdue Pharma, 2021)

PROP: Physicians and Health Professionals for Responsible Opioid Prescribing

PHE: Public Health England (UK)

WHO: The World Health Organisation

Primary Chronic Pain: Chronic pain that is pain in its own right, without being a symptom of an underlying condition (Treede et al., 2019)

Secondary Chronic Pain: Chronic pain that is secondary to an underlying disease/cause for that pain (Treede et al., 2019)

Abstract

A lot of people have heard of the ‘Opioid Crisis’ – the latest epidemic of opioid addiction and deaths in the United States. However, what gets far less exposure is those who have been harmed, and even died, as a result of how governing bodies tried to ‘fix’ the opioid crisis. The quality of life of too many chronic pain patients has been obliterated as collateral damage of the policies put in place to curb this catastrophic epidemic. Patients who are in excruciating chronic pain sometimes have to rely on opioid-based medications, in conjunction with other tools, to achieve a quality of life. The medications reduce their pain to a level at which they can function when performing basic daily tasks. Though now, these patients whose lives are dependent on their medication, some of whom have been on it for over a decade, have had it ripped away from them with no alternative being given as a way of relieving their suffering. In some cases, even leading to suicide.

This thesis is in no way at all *‘pro-opioid’* – opioids themselves are nasty things, with destructive effects. However, chronic pain patients deserve the right to a quality of life, and until progress in science creates an alternative which can give patients as much relief and functionality as opioids do, but without the horrendous risks and side effects – then unfortunately they’re all we’ve got. Patients who need opioids to relieve their pain don’t use them exclusively. For chronic pain patients, opioids are one ‘tool’ in an entire ‘toolkit’ of techniques, products, gadgets, supplements and medication varieties; and each patient will have their own ‘toolkit’ which works best for them.

This paper is a multifaceted approach to look at the ethics of how chronic pain patients need to be treated from now on – looking at *why* they deserve a quality of life, and *how* they became collateral damage as a result of the policies put in place.

Figures and Tables

Acknowledgements

My dearest Caleb, Maddie, Caoimhe, Stevie, and Noah.

The work and research in this paper is dedicated to my baby goddaughter, nieces, and nephews – the little lights and loves of my life. Who give me all of my happiness, hope, determination, and empowerment to work hard; and be the best role model for them that I can be. They’re the sunshine in my rainy days, my little best friends, who own every piece of my heart. I wouldn’t be here today, nor who I am, without them.

This is, without a doubt, for them.

I would also like to thank my advisors and supervisors, and Janey Fisher, who have all helped me on this academic journey; and additional thank you to Dr Kunal Sood, for letting me interview him when I started as a postgraduate.

Introduction

The first time that a doctor questioned my medications because of a crisis happening on the other side of the planet, I realised that something significant had begun happening to people with chronic conditions when trying to access the medical care they have a right to.

The events happening over there did not change my condition, my genetics, or the level of deterioration throughout my body; so I couldn't comprehend why this big thing that was happening in America was suddenly now relevant to the medical interventions that my body needed to survive.

To this day, the only answer is that it wasn't relevant to my body. Or, at least, it shouldn't have been. An opioid manufacturing company (see Purdue Pharma, 2021) manipulating doctors into overprescribing their products before I was born, bears no direct correlation to the fact that there's a genetic mutation deteriorating my body today, or which medicines that I need to survive it. That should be between a patient and their physician only.

Neither the needs of a medical condition wreaking havoc in a patient's body, nor a money-hungry pharmaceutical company's actions, are remotely close to being causally relevant with the other. Yet that hasn't altered the fact that chronic pain patients are now the collateral victims of the opioid epidemic, who are having their quality of life diminished as a result of something in which they had no part in (Atkinson, Schatman and Fudin, 2014). Which, to be candid, ultimately feels about as fair as the whole class being put into detention because of a few naughty kids *in a different class* misbehaving - just with fatal consequences.

Chronic pain patients didn't *ask* for an OxyContin boom (Van Zee, 2009); they didn't *want* for people to develop addictions; they didn't *encourage* doctors to overprescribe; they didn't *contribute* to the illicit heroin or fentanyl movements now with funding ties to terrorism (United Nations Office of Drugs and Crime, 2021); they didn't *cause* people to overdose from opioids in masses; they didn't *allow* Purdue Pharma to use falsified information to misrepresent the addictiveness of their drug (Van Zee, 2009). They don't *want* to be on opioids for any other reason than to not suffer. And yet they're the collateral victims who are facing repercussions of policy makers trying desperately to claw their way out of a crisis that should have dealt with long before it got to this stage.

In this dissertation, I am going to argue that chronic pain patients deserve a quality of life, and that the way opioids have been withheld as a result of the opioid crisis has harmed them. I am going to do it by undertaking a detailed philosophical analysis of this in-depth single case study of medical ethics: *the harm done to chronic pain patients by withholding opioids.*

'Withholding relief: why chronic pain patients deserve a quality of life, and how it became unimportant in the collateral damage of the opioid crisis' is going to be an exploration of multiple factors particularly important to me. 'Withholding relief' references not only the literal withholding of opioids, but the withholding of access to relief from excruciating pain. Chronic (secondary) pain patients deserve a quality of life – the best quality of life that's attainable for them – however just because they deserve a right to a quality of life, doesn't mean that's how they're being treated by the healthcare system or society yet. I would have assumed it's common sense that chronic pain patients should be treated with the same respect and dignity as healthy/abled people; however unfortunately that's something I still need to fight to prove. The purpose of proving this is to ascertain that with equal rights as human beings, and in conjunction with demonstrating how their quality of life is being diminished without the right medical support, then I will validate beyond reasonable doubt that chronic (secondary) pain patients have a right to access the medical care they are currently being denied.

Some other intentional lexical choices in the title are the nature of pain patients being 'unimportant'; and the damage to them being 'collateral' – in this context also being intwined with each other. There was no specific mandate to punish all chronic pain patients, no new initiative to prevent them having access to healthcare, no security on the doors there solely to turn us away. A war on opioids that did not involve us was waging, and in trying to battle that, chronic pain patients have become victimised by well-intentioned choices that shouldn't have infringe on their medical care. If chronic pain patients were deemed '*important*' enough, this would have been immediately rectified, it would have called for clinicians to be on alert that they're not causing unintentional harm in their opioid restricting. It would have called for a clearer separation of those who need long-term opioid-care, and those who could be treated successfully in other ways first. If we were '*important*', then some patients wouldn't have had no other choice but to turn to suicide to escape their suffering.

However, we simply don't matter enough when looking at: the bigger picture of the opioid crisis; the crimes committed by pharmaceutical companies; or to policy makers intent on stopping mass-dying but who forwent the quality of the lives left behind.

This thesis statement merits study because there are real lives which can be saved as a result – not just hypothetical ones in either hindsight or a hypothetical moral dilemma. Lives which have endured suffering through no one's fault, but could be prevented further unnecessary suffering if they had access to the healthcare they need and deserve. Healthcare improves every single day, but that doesn’t help patients when they’re being denied access to medications invented or developed for the exact purpose they’re being pursued for. There are few-to-no other academics researching this discrepancy in rights, one where lives are hanging in the balance, who have very little voice to speak up for themselves.

Even though the case study itself is specific, there is still a field of philosophical theory that can be developed in relation to it. The case study provides context, making the research personal to not only those who are experiencing it, but to anyone who knows someone suffering in long-term pain. It takes the importance of philosophical theory and application to an. elevated dimension.

Methodology: How This Is a Philosophy Dissertation

Philosophy matters when it’s applicable to the real world. This is why medical ethics is such an important field of philosophy, because of the way it uses philosophical technique to reflect on and better understand medical discourse.

This concrete and engaged reflection is what I undertake in the following paper. It isn’t a typical ‘philosophy paper’ in the sense of reconstructing or evaluating unattainably abstract concepts. Philosophy should be applicable in the real world; it should be there to reflect on the things that profoundly matter: the lives of real people. Using philosophy as a tool of analysis, this is a paper devoted to one real-world case study – and I am interested in investigating whether each of the components of this case study hold up to rational philosophical and ethical scrutiny. Philosophy is the skill I use in order to analyse a non-philosophical topic, using medical ethics to decipher the philosophical validity of the different facets of this case study.

It is my duty as a philosopher to bring philosophical skill and analysis to problems that lie outside the most frequently assessed of the philosophical canons. That is the power of philosophy – our ability to look at the world's challenges, to see when people are being hurt – and be able to look at it from a perspective that others may not see. Perhaps even find viable solutions to the problems. I use the case study of 'the harm done to chronic pain patients by withholding opioids' because it allows me to use my skills as a philosopher to help support people who are already suffering, and are being forced to unnecessarily suffer even further.

That means during my dissertation, I do not cite many philosophy *papers*, but I cite medical journals and research – and use (cited) philosophical *theories* to analyse them. To work out how effective medical-based moral frameworks, and whether their structure can be ethically justified.

Back in the medical ethics field of 1979, Edmund D. Pellegrino made the astute observation that "Fewer physicians subscribe to the religious foundations of medical ethics than before". Medical ethics and morality exists relative to the time in which the physicians live, and as Pellegrino had discovered, the moral frameworks that medical professionals are guided by began to move away from those rooted in religion, and into more secular moral approaches. Unlike other medical case studies – for example abortion rights – there isn't an overtly religious implication or affiliation for the issues surrounding chronic pain and opioids. It isn't a topic that has been secularised or associated with any particular religious values. Unlike discussions of, for example, euthanasia/suicidology and Christianity (St Augustine, 426AD), etc., the rights of disabled and chronically ill people are secularly fought for in this paper by philosophers such as Elizabeth Barnes in *The Minority Body* (2016). Barnes writes from her perspective with a chronic pain condition herself, and with no religious component, just as with a large percentage of the philosophers and philosophical theory in this thesis.

The first section is going to be focusing on the medical nuances and understanding needed in order to become fully informed on the context regarding the rest of the dissertation. Without a sturdy foundation, any arguments built on top of it can't uphond, and so therefore it is important that this is fulfilled correctly at the start. In order to develop and defend my application of philosophical theory, then I need to be able to clarify the details of the case study itself.

After looking at the nuances of the medical foundations, I will be able to look at the philosophical application of addiction versus dependency. Changing the approach from the currently blurred and indistinguishable way of distinguishing them, to being able to understand what the neurobiosocial differences between the two would mean that when applying to the thesis question, we can see how the opioid crisis lead to so much collateral damage to those who were dependent on their opioids, but not addicted to them. The importance of doing this also lies in the clinical representation, the way in which it impacts – and has the *potential* to impact – real chronic pain patients.

Continuing along this line of enquiry, I will carry on looking at the way in which pain and the way it affects patients' lives can inform the choices they make in regards to the medication that could give them relief, but potentially at a cost. This section, focusing on quantity and quality of life and quantity and quality of pain, speaks directly to the thesis question. To answer the question of *why* chronic pain patients have an ethical right to a quality of life, I will need to prove all the ways in which chronic pain destroys quality of life when left un/der-treated. The notion of looking at quantity and quality of pain, instead of only the more common exploration of the quantity and quality of life, will also help look at the individuality of each patient's priorities when it comes to pain care, furthering the point of a one-size-fits-all approach not being the most effective form of opioid reform.

All of this has been building up to perhaps most significant section of my dissertation in response to the thesis statement: the ethical framework. This is the section where I get to fully develop the scale of the anti-opioid frameworks by certain individuals in this situation, and the ethical approaches they take within their healthcare but also the way in which they impacted the CDC's change in policy (Dowell et al., 2016). The philosophical application of the previous sections is umbrellaed by the framework in which we need to apply to opioid prescribing in order to prevent unnecessary harm. After looking at the ethical frameworks that have been in play so far, I continue on to investigate and apply the doctrine of double effect (McIntyre, 2004). I explain what the theory is, how it's been able to be adapted to modern times to stay relevant and useful over time, the merits of the principle, the drawbacks, and finally the way in which it can be applied effectively to the case study of prescribing opioids in the context of chronic pain care.

The final section is a poignant forewarning of what could continue to happen, and could continue to get worse, if the way in which we approach the withholding of opioids in regards to chronic pain patients. After looking at how chronic pain patients became collateral damage of the opioid crisis, because they have not been considered worthy of having their quality of life upheld, it is important to round out my response to the thesis statement by showing not only how the collateral damage isn't just hypothetical – but also that it will continue to spread if changes are not made. After proving that chronic pain patients have a right to a quality of life, this chapter solidifies what happens if they are continued to be treated as if they don't; and if the ethical framework assessed as most applicable isn't facilitated, then people's lives will be at risk unnecessarily as a result.

The Case Study

As mentioned above, this paper is about applying philosophical theory, framework, and traditional discourse to the real-world – and very significant – case study of chronic pain patients being harmed by the withholding of opioids due to post-opioid-crisis policies. This builds on previous work in my undergraduate dissertation which discussed how the response to the opioid crisis has come to distinctly disrupt the lives of people who have chronic pain. I questioned the 'ethical implications of the harm done to chronic pain patients by withholding opioids, as a consequence of the opioid crisis' (Caplan, 2020)*;* and considered the ways in which policy had been put into place to try and curb the opioid crisis that had been happening. Said policy then had the consequence of being interpreted to take irrefutably required medications away from patients whose lives depended on their pain being relieved. Logically, if a doctor is taking away a patient's method of pain relief, then one of two things would be assumed to have happened. Either (i) their source of the pain has gone and therefore they don't need it to be relieved anymore; or (ii) they will be using another method, product, or medication to relieve the pain in its place (this could be for a number of reasons, such as not wanting to deal with the minor side effects anymore e.g. nausea; the current drug is causing damage to the body e.g. is compromising important tissues; or because the drug isn't having the desired effect on the patient and they are hoping another drug will etc). However, what the mass vilification of opioids missed was those who use opioids safely, for valid and justified reasons, and are not addicted. Patients who were subsequently still having their medications taken off of them.

Opioids aren't exclusively 'evil'. Yes, in some scenarios they truly have been, and will always have the potential to be. However, in correctly used, safe and valid cases – opioid pain relief can allow people with chronic (secondary) pain conditions[1] enough reprieve from their suffering to be able to, for example, enjoy time with their children; to go to university and study for a degree; to maintain personal hygiene and clean their home; to be able to go to work every day and contribute productively to society. A lot of patients who rely on opioid medications in order to function properly throughout the day would be bed-bound if not for the pain relief. Having their pain reduced to the level of functionality has the ripple effect of improving the lives of not just the patients, but their families, friends, co-workers, and their communities, too.

I took the HavardX Medical School course titled 'The Opioid Crisis in America (HHP100), where I was able to learn about the true depth of devastation and destruction because of opioid addiction, and also the extraordinary scale of the crisis, as well.[2] It is not something I take lightly, nor is the hundreds of thousands of families who are as a result going through an astronomical level of grief. They have my utmost sympathies and respect, and I truly pray that no more families have to face the heartbreak of it. I write this paper on behalf of chronic pain patients who are suffering unnecessarily, but write it with total and deep respect for those who have lost their lives or loved ones to opioid addiction.

To emphasise, this thesis is in no way at all 'pro-opioid' – opioids are not *good* things. They are, however, an effective tool for reducing suffering from pain. There are lots of different tools

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[1] I will explain the difference between chronic *primary* pain and chronic *secondary* pain in the first section. Opioids are appropriate for use in chronic *secondary* pain because there is a physiological source of the nerve signals for the opioids to connect to the opioid receptors on.

[2] HarvardX HHP100 "The Opioid Crisis in America", is an online course from Harvard Medical School, via edX course provider] My personal certificate is at: https://courses.edx.org/certificates/83ebaf7dc9a146358a648a6063ccb97e [Accessed 03.03.2022]

as options to reduce and try to control pain. From heat packs to herbal remedies, strong analgesics to NSAIDS, and the most natural and safest form of pain relief at all: orgasms[3]. Every form of pain relief has it's time and place, and every form of pain relief will work differently for each person, since no two people and their conditions are the same. Each individual does not use just one of these methods for controlling their pain. Most people who live in pain 24/7 have a whole 'toolkit' of techniques, products, gadgets, supplements, medicines, and more to help them cope with their condition.

All of these pain relief options are on the metaphorical 'table' to choose from, and it is my job here-forth to explain that until there is a safer yet just-as-effective-alternative available: opioids shouldn't be removed as an option from that table, because chronic pain patients have a right to a quality of life. If current scientific and medical progression means that the *only* way to achieve a quality of life is through the use of opioids, then I am going to argue that it is unethical to let innocent chronic pain patients suffer when they do not have to, when they had no contribution to the cause of these changes.

I will be looking at the ethical and moral frameworks currently in place in regards to opioid prescribing for chronic pain in the *post 2016 guideline era*. This being the guideline dramatically restricting opioid prescriptions. I research how chronic pain patients are currently viewed and treated by doctors – whether they be either infantilised or respected – and find a sturdier ethical framework that considers both (i) the harm done by opioids, and (ii) the harm done by *withholding* opioids.

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[3] I wish I had the time to fully develop this point and explore just how much a totally natural and entirely safe pain relief tool that human bodies have the ability to create by themselves in chemical response could revolutionise pain relief – however for this paper, at least, I do not have the time to explore. I just may have to write a separate paper on it

I also uncover the harm done by particular individual(s) and policy makers. The CDC themselves have now acknowledged and admitted[4] that their policy did, as a fact, cause unintended harm because of it being able to be weaponised to withhold opioids from patients who did truly need them. The way in which doctors can manipulate, misinterpret, or misunderstand the policy is one of the most significant impacts to chronic pain patients of the policy – other than just the one-size-fits-all approach of the policy itself. As far as I am concerned, since that admission is from the Director of the CDC himself, this CDC guideline causing harm (be it unintended or otherwise) is an indisputable fact. Therefore I will be moving forward under the confirmed working assumption that the policy causing harm is not in question, and what I am here to philosophically analyse the *'how'*, *'why'*, and *'what'* of the harm – not the existence of the harm itself.

There are a number of important objectives I wish to achieve with my research.

The first significant objective is for people to learn, understand, and appreciate through reading this the difference between being *addicted* to opioids, and being *dependent* on them. Recognising that distinction just in itself would have a massive impact on not just the stigma that people who rely on opioids face, but also on the medical community as well – as the misconception that 'everyone who is on opioids long-term must be addicted to them' is preventing opioids from being prescribed appropriately. Without misconceptions around the terminology, anybody needing to make decisions about opioids has all motivations and true

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[4] Letter to Dr Daniel Alford, 10 April 2019. See https://static1.squarespace.com/static/54d50ceee4b05797b34869cf/t/5caf661d7f312b0001bac1b8/1554998814907/Alford+Final+.pdf [Accessed 18.09.2022]

information about either addiction or dependency laid out on the table. It allows for genuine informed consent.

A further objective of this thesis is the emphasis I wish to place on the importance of not only asking about quantity of pain, but (especially in the case of chronic pain treatment and triaging) communicating the quality of pain as well. I look at how acknowledging the ethical importance of *quality* of pain, in addition to its *quantity*, can (i) help create a clear visual of a person's priorities for both the patients and their medical professionals; (ii) can help patients communicate their suffering and daily struggles more effectively with the people in their lives; and (iii) when triaging a chronic pain patient, can more accurately guide medical professionals on the best way to react to a patient with a long-term condition.

Ultimately, I want readers to emerge with the realisation that, as awful and addictive and utterly complicated as opioids are; until there is a better resource available, then people who are having to rely on opioids for any kind of quality of life should have the moral and legal right to use them as one of the 'tools' in their 'toolkit' of pain control mechanisms. Patients on opioids have nothing to be ashamed or embarrassed about. Hence, this paper is about more than reporting what has been happening. By focusing on ethical frameworks and philosophical application to the case study, I hope it can be used as a tool to safely and positively improve medical care for chronic pain patients, as medicine and medical ethics progress further.

Section 1: The Medical Foundations

As stated in my introduction, the most important thing that I am going to clarify in this whole paper is that I am not ‘pro-opioid’, nor am advocating for an increase in opioid use. What I am is ‘pro-quality-of-life’. If there were a non-harmful and non-addictive alternative, which could provide the same level of relief for chronic pain patients, then I would advocate for the abolition of opioids all together. Unfortunately, science and medicine aren’t at that stage yet, and in the meantime, a chronic pain patient’s fundamental right to their quality of life is not changed in accordance to the level of scientific development.

Section 1 will lay the foundations of the key discussion points within the case study. It is important to make sure that the case study itself is not ambiguous, by using clear scientific boundaries including the different types of chronic pain, the progression of the epidemic, and what opioids and opiates actually are. When discussing the impacts of a neurobiosocial scenario, the specifics of the ethical application are going to be dependent on there being no leeway or discrepancies in the information being discussed. If there is a recess in understanding of the medical foundations, then the ethics would become inconsistent.

My first section is particularly important in my response to the thesis statement, because in order to discuss a medical case study within the parameters of philosophical application, I need to make sure that the relevant medical terminology and the neurobiological nuances are not lost within the greater development of the point. There are some small lexical differences, such as the differences between chronic *primary* pain and chronic *secondary* pain, which although may seem irrelevant in the greater picture when discussing chronic pain and those who suffer from it – neither of them being more or less valid in the experience or perspective of the patients having to experience it – has a neurobiological difference which if ignored could undermine my entire position of opioids still being a viable last-resort options for pain relief, due to the way in which opioids work at a neurological level being effective in chronic (secondary) pain, but not in the primary counterpart. These small nuances impact the bigger changes during the damage (both collateral and otherwise) of the opioid crisis, nuances which need to be explored if I am going to be able to explain how chronic pain patients became harmed collaterally as a result. This section will lay the foundation for the rest of the dissertation, a groundwork which without being laid securely could leave all that stands upon it unsteady.

Different Types of Chronic Pain

Severe chronic pain is soul-destroying; and living with chronic pain is metaphorically a way of losing your life long before you're ever buried in the ground. No one deserves to live every moment in pain; and even though 'chronic pain' is a term used no matter what the source of the pain is, chronic pain can be distinguished into further definitive sections. Although this doesn't change the experience of the patient, or affect the validity of the pain depending on which category it falls into, it has the potential to impact treatment options for the patient's future making it an invaluable and incredibly important tool – as well as being particularly relevant in the pursuit of safe opioid-based-treatment. *The International Classification for Diseases-11 (ICD-11), of the* WHO (2015) categorises chronic pain into 7 separate categories: *Primary* chronic pain, and 6 types of *Secondary* chronic pain – as shown in Figure 1 below.

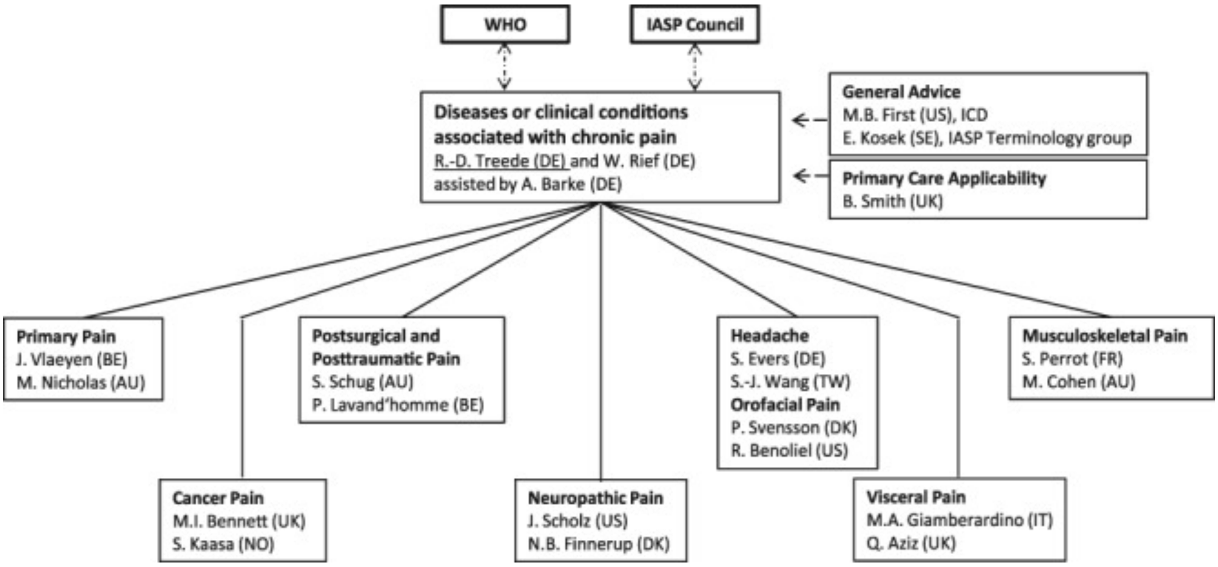

Figure 1 Seven Categories for Chronic Pain (Treede et al., 2015)

The diagram represents the ICD-11's 7 categories for chronic pain, which are listed as:

> "(1) chronic primary pain, (2) chronic cancer pain, (3) chronic posttraumatic and postsurgical pain, (4) chronic neuropathic pain, (5) chronic headache and orofacial pain, (6) chronic visceral pain, and (7) chronic musculoskeletal pain (Treede et al., 2015).
>
> Chronic primary pain is a new diagnosis in the ICD-11 classification for chronic pain that is intended to embrace a number of poorly understood conditions while avoiding obscure and potentially laden terms such as "somatoform," "nonspecific," or "functional." Chronic primary pain syndromes can be conceived as health conditions in their own right, whereas in the other 6 groups of chronic pain conditions (chronic secondary pain syndromes), pain may be considered a symptom of some other underlying diseases" (Treede et al., 2019).

The particularly important specification within the ICD-11 is that pain conditions such as fibromyalgia and CRPS have been recognised as a source of chronic pain without there needing to be an underlying physiological condition. Chronic primary pain is what is being referred to when doctors say that opioids aren't particularly useful in the treatment of chronic pain, which is because opioids work by activating the opioid receptors on nerve cells, interrupting the relay of pain signals from a physiological source to the central nervous system.[5] When there isn't a physiological or acute pain source such as in cases of chronic primary pain, then there isn't the same signal relay to be interrupted by the activated opioid receptor on the nerve cells. With evidence against opioids being effective for treating chronic (primary) pain, it would be irresponsible to prescribe them for it long-term, unlike in scenarios of chronic (secondary) pain with physiological triggers.

When I am discussing the use of opioids in order to improve a chronic pain patient's quality of life, I am referring to a patient with chronic (secondary) pain – pain which is secondary to an underlying condition/disease/injury, and therefore has a physiological source of the signal being sent to the brain, which can be intercepted by activating opioid-receptors on the nerve cells. This is not to imply in any way that chronic (primary) pain is any less deserving of treatment, or any less severe than chronic (secondary) pain – but simply where we are with the neurological understanding of chronic pain conditions presently in medical care.

The Opioid Crisis in America

In order to fully understand what is at stake in the withdrawal of opioids from chronic pain sufferers, the first concept that needs to be understood is 'the opioid crisis' itself. Why waves are relevant. I am going to be looking at diagrams in which the CDC shows how the most recent opioid crisis has come in waves (National Vital Statistics System Mortality File, 2019).

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[5] I will go into much more detail about opioids work in the next section. Paul Chrisp of NICE (2021) explains that "Based on the evidence, for most people it's unlikely that any drug treatments for chronic primary pain, other than antidepressants, provide an adequate balance between any benefits they might provide, and the risks associated with them." See also National Institute of Health (2018).

Looking at these waves is important in understanding the way in which the crisis developed over time, in order to see how the changes in the crisis environmentally have been changing the way that chronic pain patients have been treated by healthcare providers, but also how many waves of exponential increase it took for a policy to be implemented – waiting long enough to need a drastic shut down to curb a crisis moving as rapidly as this one has been.

There have been a number of opioid crises in America. The mid-1800s saw America's first opioid crisis, when Civil War soldiers became addicted to morphine that was being prescribed to them; and simultaneously middle-aged housewives were also becoming addicted to it as well, since they could afford to go doctors whose whole practice was devoted to the prescription of morphine, and those who could afford to, could visit up to three times a day for a dose. By the late 1800s, the epidemic was severe, and there were high levels of morphine overdose. There became an awareness amongst health officials in the US that it was risky to prescribe morphine. During that first opioid epidemic, the Bayer Corporation introduced a new opioid called 'heroin', which was ironically marketed as an alternative to morphine, that was supposedly safer.

It is in this context of recurrent opioid crises that we need to ensure we are aware of the history of opioid use in the West — and Figure 2 provides a helpful overview. Understanding the crisis is, from a contextual purpose, to look at how over-prescribing became such a problem to begin with, starting with the over-prescription in the OxyContin boom. The opioid crisis that we hear about so often is the most recent/current opioid epidemic, that has been split into three separate 'waves' by the CDC (2021a).

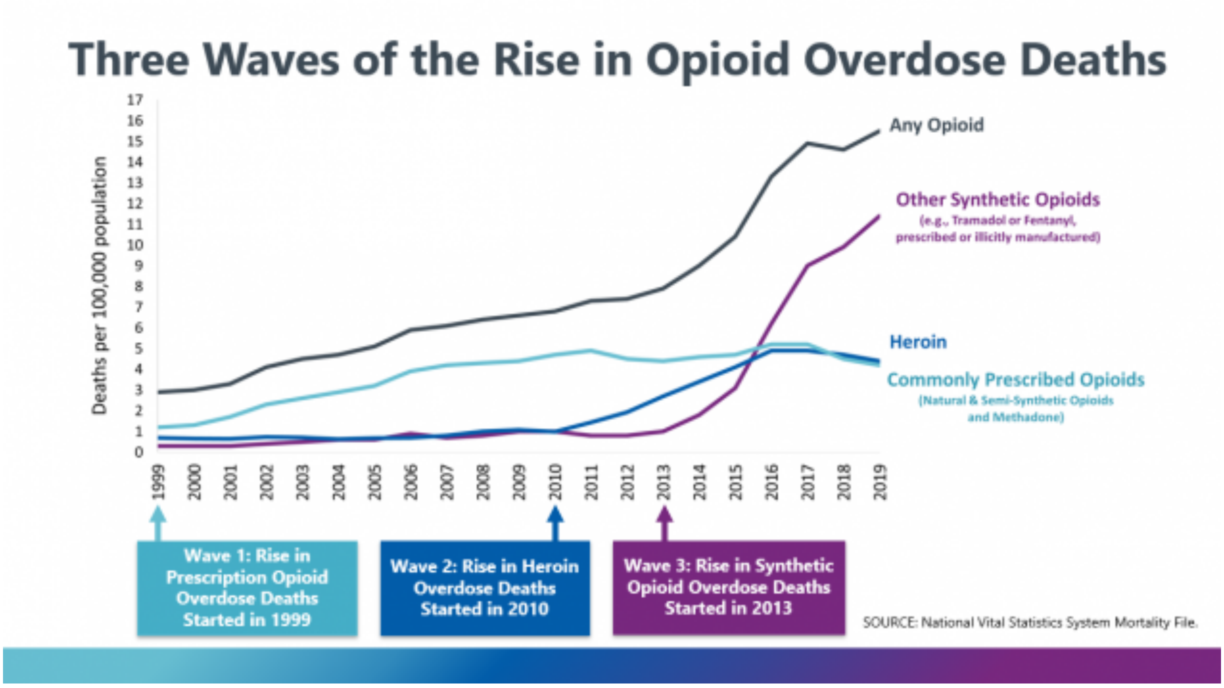

Figure 2 Three Waves of the Rise in Opioid Overdose Deaths (National Vital Statistics System Mortality File, 2019)

The first wave of the opioid crisis came with the creation and violent push of OxyContin. When Purdue Pharma LP[6] first released their slow-release drug OxyContin, they originally claimed that because of the long-term release coating around the drug, there were lesser-addictive properties to it than if the oxycodone was being taken in another way. However, it was still just as abusable as any other oxycodone delivery system, because all anyone had to do was crush the pill and therefore the outer coating, as explained that "the remarkable commercial success of OxyContin, however, was stained by increasing rates of abuse and addiction. Drug abusers learned how to simply crush the controlled-release tablet and swallow, inhale, or inject the high-potency opioid for an intense morphinelike high" (Van Zee, 2009).

This was also not unprecedented, nor unknown, as:

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[6] "The company was virtually unheard of when a trio of research psychiatrists and brothers—Mortimer, Raymond, and Arthur Sackler—bought it from its original Manhattan-based owners in 1952" (Macy, 2018, p.6).

> “There had been some precedence for the diversion and abuse of controlled-release opioid preparations. Purdue's own MS Contin had been abused in the late 1980s in a fashion similar to how OxyContin was later to be; by 1990, MS Contin had become the most abused prescription opioid in one major metropolitan area. Purdue's own testing in 1995 had demonstrated that 68% of the oxycodone could be extracted from an OxyContin tablet when crushed” (Van Zee, 2009)

Purdue Pharma LP had already had their previous drug – a morphine slow release – abused in the same manner. By 1995, Purdue knew that they were pushing a product that was being marketed as having “less than one percent” of patients get addicted to (Van Zee, 2009), which was able to be crushed in a way that people already knew how to, allowing them to access 68% strength oxycodone. Unsurprisingly, this was a major trigger for the first wave of the opioid crisis.

Wave two of the most recent opioid crisis is considered to begin when there was a spike in heroin overdose deaths, starting around 2010 (see Figure 1). Between 2010 and 2019 “heroin-involved overdose deaths were nearly 5 [times] higher in 2019 than in 2010” (CDC, 2019; DEA, 2019). According to the CDC (2019), heroin is typically injected, but is also sometimes smoked and snorted; and there were nearly 130,000 deaths from overdoses related to heroin from 1999 to 2019.

The third wave of the opioid crisis came with a distinct increase in overdoses of synthetic opioids (National Vital Statistics System Mortality File, 2019), particularly with the introduction of *Fentanyl*.

> “Previous reports have indicated that increases in synthetic opioid-involved deaths have been associated with the number of drug submissions obtained by law enforcement that

> test positive for fentanyl but not with fentanyl prescribing rates. These reports indicate that increases in synthetic opioid-involved deaths are being driven by increases in fentanyl-involved overdose deaths, and the source of the fentanyl is more likely to be illicitly manufactured than pharmaceutical." (CDC, 2018)

The drugs that enter the United States illegally, such as heroin, can be laced with a much stronger synthetic opioid, *fentanyl*, which is so potent that it makes the heroin (or whichever drug it has been added to) much more deadly than it otherwise would have been. Key to my argument is the fact that the above quotation from the CDC speaks of "deaths… have been associated with the number of drug submissions obtained by law enforcement that test positive for fentanyl but not with fentanyl prescribing rates."

The prescription of fentanyl as a pharmaceutical to those with severe pain who need it has not impacted the death rates in the way that it does when it's added to already illegal substances.

Though the impact of synthetic opioid overdoses is thoroughly awful, and the spike in deaths was disastrous, the CDC clearly implies here that it was *not* as a consequence of *prescription* fentanyl. Yet, the prescriptions of all opioids have been continually reduced, as well as vilified, as a result of the crisis. As of April 2017, the CDC further claim:

> "Although fentanyl is a medicine prescribed for post-surgical pain and palliative care, most of the fentanyl responsible for this surge of deaths is made illicitly in China and imported to the U.S. via the mail or via Mexican drug cartels. Its high potency and ease of manufacture make it enormously profitable to produce and sell. According to the DEA, one kilogram of fentanyl can be purchased in China for $3,000 to $5,000 and

> then generate over \$1.5 million in revenue through illicit sales in the U.S." (O'Donnell, Gladden and Seth, 2017)

The desire to make exuberant amounts of money from sales of illicit fentanyl is not only leading to a devastating amount of deaths, but is now having the knock-on effect of patients being prevented from obtaining their prescription medication. The point, however, is that fentanyl sales through illegal channels are responsible for the significant overdoses in the third wave of the current opioid pandemic. According to the CDC's Morbidity and Mortality Weekly Report (MMWR), "the strongest risk factor for heroin use and dependence is misuse of or dependence on prescription opioids; approximately 75% of persons who initiate heroin first misused prescription opioids, although only a small percentage of persons misusing prescription opioids begin using heroin" (O'Donnell, Gladden and Seth, 2017). It's recognised that only a small percentage of people misusing prescription opioids – 4-6% according to the National Institute for Drugs Administration (NIDA, 2021) – will turn to heroin, *and they themselves already only make up a small percentage* (8-12%) of those prescribed opioids for chronic pain, who end up developing an opioid use disorder (NIDA, 2021) – the patients turning to heroin being a subset of the patients who develop an opioid use disorder, being in turn a subset of those who are on opioids long-term. This means between the parameters of 0.32% and 0.72%[7] of those prescribed opioids for chronic pain turn to heroin. In the positive context it means 99.28% to 99.68%[8] of patients prescribed opioids for chronic pain don't turn to heroin. This is particularly relevant because an argument that is presented against the prescription of opioids for medical use is that patients will then turn to illegal street-opioids such as heroin as a result, therefore

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[7] (0.04 x 0.08) x 100 = 0.32; (0.06 x 0.12) x 100 = 0.36

[8] 100 – 0.72 = 99.28; 100 – 0.32 = 99.68

the prescription of opioids supposedly contributing to the illicit opioid trade. (Kolodny et al, 2015).

The CDC Guideline That Changed Pain Care Globally

On the 18th of March 2016, the CDC issued a new sweeping policy regarding the use of opioids when treating *any form* of chronic pain (Dowell, Haegerich and Chou, 2016). The policy was declared as follows:

> “This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. It is important that patients receive appropriate pain treatment with careful consideration of the benefits and risks of treatment options. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.”

The guideline undertook a drastic turn away from the quality of life of the patients being treated with opioids for their non-cancerous or non-end-of-life pain and attempted to employ an entirely risk-reduction based criteria, keeping opioids from getting out to patients who could become addicted, and eventually die from an overdose of them.

The CDC developed a quantified checklist, which was designed to be used no matter what the condition and no matter which of the 7 types of chronic pain was under examination (Figure 1). This was a one-size-fits-all approach, and despite there being some good considerations, every single patient has their own individual needs, as well as source and category of pain. Checklists like that of the policy, which when converted into clinical real-world practice employ a one-size-fits-all approach for the sake of risk-reduction, unfortunately don't allow for individuality of patients and their conditions, no matter how broad or similarly how detailed they are. No two patients will ever be the same. Two patients could present with the same primary condition, that same primary condition being a chronic (secondary) pain condition. They could present with the same symptoms, in the same areas of the body, and claim in a quantitative way that they had the same number out of 10 on a 1-10 pain scale. However, how their bodies work, how their neural pathways which transmit pain signals and which opioids block, how they subjectively interpret the 1-10 scale, the expanse on those same areas of the body etc. will never be the same, no matter how much it presents as such. This is why it's important for pain-care and pain-relief prescriptions to be done on such a case-by-case basis: because two identically presenting patients could be given the same dosage of the same pain relief – and one of those patients could respond well to it while the other feels no effect.

This principle leads me to my next point, just how much of a decrease there was, because while for some patients a decrease in opioids may be the right thing for them (for acute pain conditions, or even for *some* primary chronic pain), it was not what was right for others. And using it on everyone meant that the way in which the policy was being used caused too much of a decrease too fast, with no way to control which of those reductions was right for the individual patient it impacted – and which ones weren't.

In reference to Medicaid prescriptions specifically, "Opioid prescriptions declined overall from 2016 to 2019, driven by a 44% decline in the number of prescriptions for opioids used to treat pain. At the same time, prescriptions for medications used to treat OUD or rapidly reverse opioid overdose doubled, driven by an increase in buprenorphine prescriptions" ((Medicaid) Williams, Saunders, 2023).

In realising how much opioid prescriptions have declined within Medicaid– a state-and-federally-funded provider of healthcare coverage for American adults who have low-incomes, for children, for the elderly, and for disabled people, I wanted to next look at the general population, since the American healthcare system is a privatised one with people having many variations of healthcare coverage.

According to the CDC, "The overall national opioid dispensing rate declined from 2012 to 2020, and in 2020, the dispensing rate had fallen to the lowest in the 15 years, for which we have data at 43.3 prescriptions per 100 persons (total of more than 142 million opioid prescriptions)." (CDC, 2020) It goes onto explain that in 2006, opioid prescriptions were at 72.8 per 100 persons. They peaked at 81.3 in 2012, then reduced down to 66.5 per 100 persons when the opioid prescription restrictions came into policy. By 2020, this dove down to 43.3 per 100 persons.

The decrease in opioid prescriptions from 2006 (72.8 opioids dispensed per 100 persons) to 2016 (66.5 opioids dispensed per 100 persons), which is the year of the opioid prescription restriction, is only a 10-year decrease of 8.65%.

The decrease in opioid prescriptions from 2016 (66.5 opioids dispensed per 11 persons) to 2020 (43.3 opioids dispensed per 100 persons), which is less than half (40%) of the time it took for an 8.65% decrease, is a 4-year decrease in 34.89%.

This analysis is not to say that there didn't need to be a decrease – the very fact that there was at some point 81.3 opioid prescriptions per every 100 people is unparalleled by anything else other than a form of opioid; and what should have happened was that it never got to that point in the first place. Once the country was facing that point in an epidemic, it needed restricting and dealing with. But it needed doing so in a way that would have minimised collateral victims, and minimised the opportunities for doctors to weaponise it towards those victims.

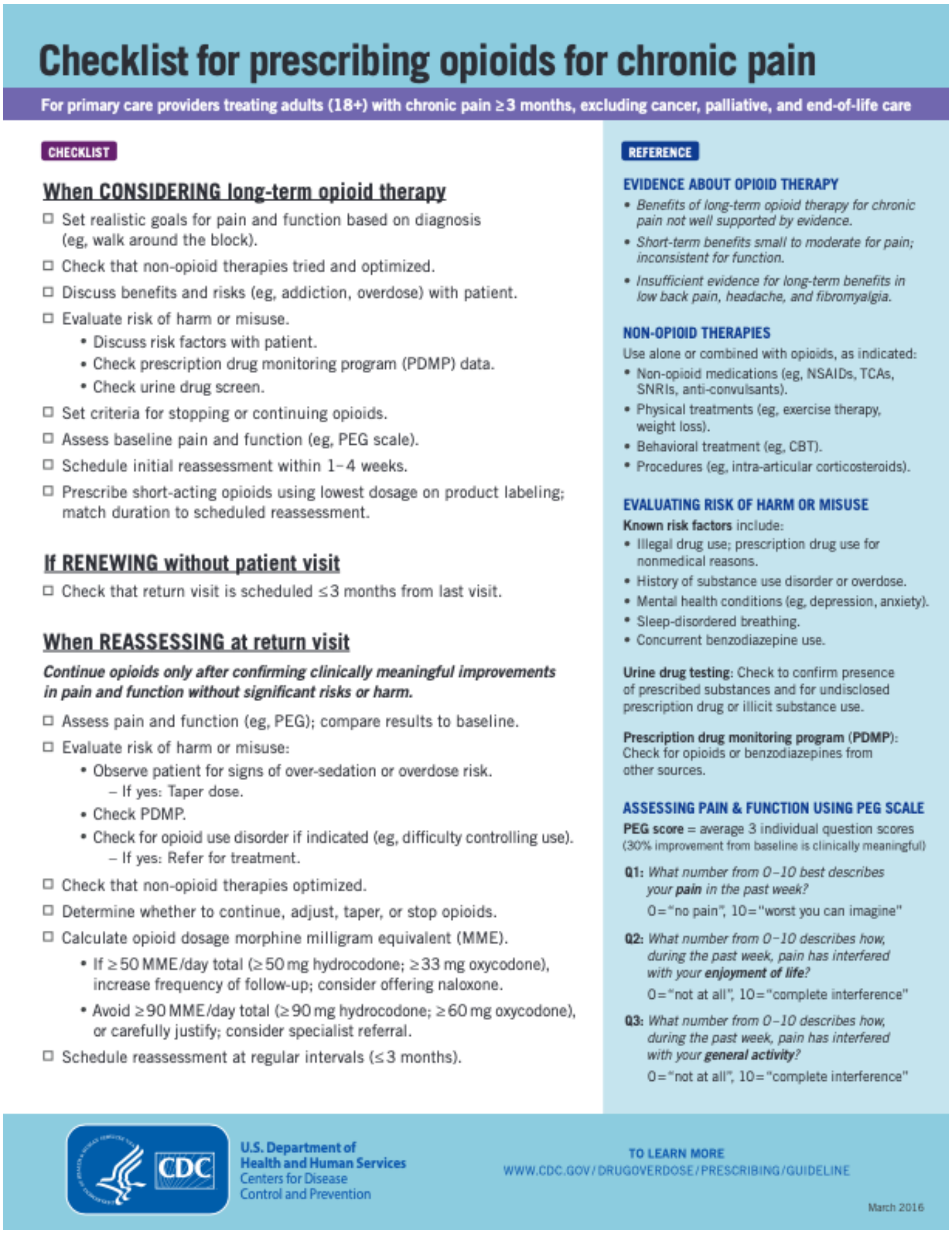
A pre-policy drop of 8.65% in 10 years, (average drop of 0.865% per year) to a post-policy drop in just 4 years of 34.89% (average drop of 8.72% per year), means that:

After the policy was put in place, prescriptions dropped nearly 10 times as fast.

This can't have been done in a controlled-enough way. **It should have never been so high, but dropping it ten times faster after the policy was unreasonable, because it let vulnerable people slip through the cracks.**

It was done in a way that was able to be used as a one-size-fits-all blanket, and with a driving attitude of taking opioids away generally, not just from those who don't really need them. Because any opioid prescribed to any patient was more opioids being dispensed out into the country, even if that individual patient deservedly needed them.

Below is a figure of some of the actual CDC policy itself.



Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

☐ Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
☐ Check that non-opioid therapies tried and optimized.
☐ Discuss benefits and risks (eg, addiction, overdose) with patient.
☐ Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
☐ Set criteria for stopping or continuing opioids.
☐ Assess baseline pain and function (eg, PEG scale).
☐ Schedule initial reassessment within 1–4 weeks.
☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If RENEWING without patient visit

☐ Check that return visit is scheduled ≤3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

☐ Assess pain and function (eg, PEG); compare results to baseline.
☐ Evaluate risk of harm or misuse:
  - Observe patient for signs of over-sedation or overdose risk.
    – If yes: Taper dose.
  - Check PDMP.
  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    – If yes: Refer for treatment.
☐ Check that non-opioid therapies optimized.
☐ Determine whether to continue, adjust, taper, or stop opioids.
☐ Calculate opioid dosage morphine milligram equivalent (MME).
  - If ≥50 MME/day total (≥50 mg hydrocodone; ≥33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid ≥90 MME/day total (≥90 mg hydrocodone; ≥60 mg oxycodone), or carefully justify; consider specialist referral.
☐ Schedule reassessment at regular intervals (≤3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores (30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your **pain** in the past week?*
0="no pain", 10="worst you can imagine"

Q2: *What number from 0–10 describes how, during the past week, pain has interfered with your **enjoyment of life**?*
0="not at all", 10="complete interference"

Q3: *What number from 0–10 describes how, during the past week, pain has interfered with your **general activity**?*
0="not at all", 10="complete interference"

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

TO LEARN MORE
WWW.CDC.GOV/DRUGOVERDOSE/PRESCRIBING/GUIDELINE

March 2016

Figure 3 CDC checklist for prescribing opioids for chronic pain (Dowell et al., 2016)

Unfortunately for all chronic pain patients, the CDC released a one-size-fits-all chronic-pain-guideline the year *after* the ISD-11 defined very clearly that there are 7 categories of chronic pain. It also features the '*PEG Scale'*, a problematic scale in itself, which I will explore in much more detail in section 3. Although the policy on the surface seems appropriate – for example wanting non-opioid pain relief therapies to be optimised etc; the way it has been able to be misused and manipulated by clinicians, and weaponised against all chronic pain patients (including those with chronic secondary pain) means there was too rigid a structure, and far too much room for error.

The CDC guideline was advocated (Zalkind, 2016) by the PROP, and particularly their current president Dr Andrew Kolodny (Business Wire, 2022).[9] For example, Kolodny talks of the CDC guidelines (Zalkind, 2016):

> "It's a game-changer," says Andrew Kolodny, the director of Physicians for Responsible Opioid Prescribing and the chief medical officer of Phoenix House, a non-profit drug rehabilitation organization. "It's the first time that the federal government is clearly communicating to the medical community that opioids are not appropriate for long term use, that the risks outweigh the benefits."

Kolodny was right about something in particular: *the guidelines were a game-changer.* A game in which chronic pain patients have to play every day of their lives just to be believed by doctors. A game that just became a lot harder to play, and a lot easier to lose.

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[9] For a profile of Dr Kolodny, see https://heller.brandeis.edu/facguide/person.html?emplid=fed1af017db070b94ce59c13714f1e7970a787ad [Accessed 25.04.2022]

It is Erin Migdol (2017b) who has best described the hidden damage caused by the CDC guidelines for those with chronic pain who are now suffering.

> “When society’s only representation of opioids is that they lead to addiction, millions of people with chronic, incurable conditions that cause debilitating pain … ultimately suffer. Suddenly, society looks at them as if they’re addicted to their medication, too. They’re questioned in doctors’ offices and refused in emergency rooms when they ask for pain relief. Even though they already sign contracts and submit to random drug tests to ensure they’re taking their medication as prescribed, politicians have enacted laws that limit the amount of opioids doctors can prescribe, leading to patients’ dosages being cut and their pain levels to rise.”[10]

It was in this vein that Migdol (2017b) collected patient testimonies, including an article containing 15 patients’ statements on ‘What they wish politicians knew about opioids’. These testimonies include claims such as: “I shouldn’t suffer because others have abused a medication I need, a medication I’ve obtained legally, a medication I use as prescribed, and a medication that is a highly controlled substance” (‘Leigh K’), and “Without opioids, I would have zero quality of life. Because of them, I can care for my son and my husband the way I need to and not have to spend days on end in bed” (‘Jennifer G’). My research is there to support patients like these, who are suffering. Who responsibly need their opioids to obtain the quality of life they deserve.

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[10] Unfortunately, I don’t have the space to fully develop how the socioeconomic differences in access to pain-care affected this; nor do I have the space to develop the gender and race discrepancies in pain and specifically pain-relief-prescription care either. Both are significant and sadly prevalent in medical care globally.

In the past, Kolodny has rejected these kinds of opinion from pain-advocates; for example, he is reported as saying, "'the backlash from pain advocates – many of whom are funded by pharmaceutical companies – is akin to naysayers of global warming. … It's a manufactured controversy,' Kolodny says" (Barstein, 2020). Despite what Dr Kolodny has here claimed in the past, this is not a *manufactured controversy*, but a very real one. A controversy opposing the harm that the director of the CDC has, as we have seen (Page 19), openly admitted to causing.

This is similar to another claim from Kolodny that "the movement countering his stance on opioids as a movement "trying to controversialize science" (Barstein, 2020). This movement – or more specifically, my contribution to it – isn't about *controversializing science,* it's about giving people a quality of life they deserve. It's about looking at real people in an individual, informed way. It's about valuing patients as real human beings, who shouldn't suffer if there is a way to prevent the suffering.

The Don't Punish Pain Rally

Kolodny also made similar accusations (Barstein, 2020) towards the Don't Punish Pain Rally (DPPR) founder, Claudia Merandi,[11] who heavily criticises Kolodny for his attitude to chronic pain patients, and for his part in campaigning for the opioid restrictions which swung the pendulum so far in the opposite direction (DPPR, 2021). The DPPR is incredibly important to my analysis, because it is a clear example of the sheer scale of those who have been harmed as a result of the way that the new opioid guidelines were used. People whose quality of life has

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[11] See https://dontpunishpainrally.com/about-dppr/ [Accessed 25.04.2022]

been significantly impacted as a result. It is (self-testimony) evidence that it's not just one or two people who have been affected, but nearly a thousand who have given their testimony t this one organisation. It's relevant to my thesis because it shows that I'm not the only one desperately trying to make sure the voices of these people are being heard. This is a very real issue, and others are recognising it as well.

An example of the DPPR's publications inviting people to join their rallies is the poster shown in Figure 4. The poster is particularly clear about the effect of the 2016 change CDC guideline. These effects include medical professionals now having abandoned pain patients to fend for themselves – a logical conclusion, when considering that guidelines were put in place to reduce the amount of pain relief that patients who are in pain would have access to.

Those living with chronic pain now abandoned.

Are you or someone you know suffering from excruciating and debilitating chronic intractable pain?

Have you been reduced or denied effective pain medication or treatment?

Has unrelieved pain restricted your daily activity level, reduced your quality of life, or confined you to your home?

Has government or insurance interference eroded your doctor/patient relationship?

Join us!

STAND UP FOR YOUR RIGHTS!

DON'T PUNISH PAIN RALLY™

OCTOBER 14, 2021
11am to 1pm

Lawyers Mall
Directly in front
of the Statehouse
Annapolis, MD 21401

Maryland Don't Punish Pain Rally
RSVP: DontPunishPainRally.com/MD
email: MD@DontPunishPainRally.com

Join the fight at:
Don't Punish Pain Rally Nat.
www.DontPunishPainRally.com

Figure 4 Don't Punish Pain Rally poster

There are 20,000 members of the DPPR, and in the section of their website allowing people to share their stories about having their pain relief/opioids withheld/denied there are 931 stories shared as of the end of 2022 (DPPR, 2022).[12]

In their letter template for their members to send to legislators (DPPR, 2018), they – just as I do – separate the tragedy of the opioid crisis, from the need for compassionate, proactive pain care for patients suffering with serious medical conditions. The letter states that:

> "These are two very separate issues – the use of prescribed opioids to treat painful, intractable conditions, and the abuse of illicit drugs – The illicit drug use is causing unintended consequences for chronic pain patients. Both chronic pain and addiction are very serious medical problems that deserve compassionate care, but recent efforts to identify and target "pill mill" doctors and pharmacies are causing innocent pain patients to lose the medical care they require."

It is once again important to redirect back to my reassurance that believing chronic pain patients deserve a quality of life is to in no way diminish the suffering nor the tragedy of the opioid crisis.

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[12] The number of stories is as of 28.04.2022. See also https://dontpunishpainrally.com/about-dppr/ [Accessed on 28.04.2022]

Section 1 Conclusion and Philosophical Application

The answer to this mess – and by mess, I mean how an entire epidemic of deaths has in turn led to a wave of harm and even more deaths from trying to solve it– cannot be black and white. When the CDC legislates to improve the opioid crisis, pain patients suffer. But if restrictions are lifted too much and opioids are promoted as they once were, the crisis will grow again, and people will develop addictions and suffer. All we can do now is find the best way to move forward that respects patients' quality of lives, as well as the lives lost in the crisis. The attempt to curb the opioid epidemic meant the pendulum swung too far in the opposite direction – and now we have to try and centre it, without letting it swing all the way back.

One of the most important conclusions to be drawn from this section, setting a clear precedent for the thesis ahead, is the distinction between different types of chronic pain. The way in which the different types of chronic pains have been defined is actually very helpful in the context of opioid care. If chronic pain was considered as one collective, then prescribing opioids would become even more unsafe due to the inconsistency of results, because some with chronic pain would find it extremely effective, and for others it wouldn't be an effective long-term tool. However, since the chronic pains have been separated, more specific opioid treatment can be delivered.

It has also been important to look at the history of the opioid crisis, including seeing how it was divided up into separate 'waves' by the CDC, because it will put all of my philosophical analysis of the guidelines that were released to curb the opioid crisis into perspective. The crisis caused unimaginable heartbreak and grief throughout hundreds of thousands of families, and the true numerical scale of the devastation and expanse of the epidemic is almost unimaginable by human perspective. It also shows the timescale of the crisis, and how it took over 16 years for this generalised policy to even be put into place, leading to additional harm to chronic pain patients.

In the following sections, my thesis will follow this cue by remaining contextually theoretical in its exploration and evaluation of chronic (secondary) pain and opioids. The harm that has been done to chronic pain patients, however, can never be ‘theoretical’, and so most importantly I will be looking at ethical literature to try and discern how we can move forward to improve pain care in the real lives of those with chronic pain, without losing control of opioid prescribing again.

As chronic pain patients, we know we are going to be in pain for the rest of our lives – we know that, and we accept it – but we hope desperately that our doctors are willing to support us throughout our lifetimes of pain. We don’t deserve to be in pain – yet we are, and if there is a way to be in *less* pain, then it should be our right to choose if that is an option for us or not. This has been best said by Joanna Dwyer (2018), who suggested that:

> “Maybe it’s the doctors (and our government) who need to practice ‘pain acceptance'. I accept that my pain will never go away, never be anywhere near a zero, and that there is no magic pill or exercise that will fix it. I accept that while my doctor is doing everything he can to help me maintain the best quality of life possible, I will do the same. But if my doctor cannot accept the fact that I have a disease that causes me perpetual pain, nor accept the fact that opioid medications are often the most effective and practical pain management option, then maybe that doctor shouldn’t be treating patients with pain.”

Accepting a life of pain takes a lot of blind faith in one's own strength. The determining of functionality is important in disability philosophy (be it Boorse's 1977 naturalism, or Carel's 2007 phenomenology – both look at functionality as a key principle). Barnes (2016) makes a particularly germane argument, in her explanation of the possible definition of function as "whether you can perform [a] task pain-free", suggesting how this affects the importance of quality of life in regards to the amount a person can function. This is something also found in the work of Havi Carel (2007), who says: "The actual function – how active the individual is; what sort of physical activity she does or would be suitable for her etc. – is left out of medical records, despite a well-documented discrepancy between objective parameters and actual functionality."

The prospect of functionality remains front and centre for a chronically ill person hoping to achieve a quality of life. If the use of opioids for a chronic (secondary) pain patient is what helps them return to a level at which they can function in their day-to-day life because it allows them to perform daily tasks such as household chores or personal hygiene, then withholding these opioids is harming those patients.

Section 2: Addiction *versus* Dependency

At stake in this section of my thesis is an attempt to define a difference between being *addicted* to opioids and being *dependent* on opioids. I will be operating under the working hypothesis that: The primary theory on addiction that I will be proceeding with is *The Disease View* (Leshner, 1997) (though a softer version of it (Hyman 2005) which accounts for objections of changes to the neurological pathways). This is the perspective that addiction is a *psychological illness* in and of itself; whereas I am arguing that dependency is a *physiological side effect* of a medication taken to treat the symptoms of an illness. There are comparative models of understanding addiction, which I will explore fully below, however I believe that when it comes to both behavioural and neurobiological evidence, that the disease view upholds better than any other perspective. Working under this 'disease' hypothesis while analysing medical literature, neurobiological evidence, and behavioural examples, means that I can approach the need for the definition between the two terms while keeping the spotlight on the most important part of my thesis: on the chronic pain patients who without this distinction remain in suffering, but who can begin to have their life back once this distinction is properly made and distributed. It is especially important to investigate this section because the separation of addiction and dependency means that chronic pain patients who are on long-term opioid care without being addicted are correctly labelled, instead of a label that does not apply but still unfortunately attaches to chronic pain patients, causing them to face barriers and prejudice.

This section is a large portion of the evidence of *how* chronic pain patients have become collateral damage of the opioid crisis. With so many individuals becoming/who became addicted to opioids, there is a necessity to be more clear in our understanding of who is addicted to opioids, and who is dependent on them, so that unfair prescription restrictions are not implemented when they don’t need to be, which cause harm.

Presupposing a difference between dependency and addiction will allow me to provide further evidence for it throughout the chapter, such that it will become clear that such a distinction is necessary. In particular, I will evaluate the way that these two simple words can change the way that opioids are used in chronic (secondary) pain treatment, when medical professionals as well as governing bodies and legislators are able to distinguish them. I plan to achieve this by formulating a definition that is accessible to all, by bringing both the theoretical work and the real-world-application equally into the foreground.

My working hypothesis is, then, that addiction differs from dependency with respect to the mental capacity to choose to stop taking opioids, regardless of the withdrawal/unsupported pain one knows will be experienced. The *dependent* patient could choose for whatever motivation to taper off of their opioids until they stop taking them, even if it means coping with untreated pain and potential withdrawal symptoms. I am proceeding with the opinion that to best define addiction, the *addicted* individual can no longer make that choice, their addiction makes that choice for them. An illness in itself is by nature not something which one chooses to have, and in the context of developing the illness after using pharmaceuticals to treat a different illness, it is certainly not a choice to gain a second illness. The reason I mentioned above choosing a softer perception of the disease view to illustrate is because the traditional disease view (Leshner) is fallible to the way in which it implies opioids alter the neural pathways. The traditional disease view:

> “states that there is some “normal” process of motivation in the brain and that this process is somehow changed or perverted by brain damage or adaptation caused by

> chronic drug use. On this theory of addiction, the addict is no longer rational; she uses drugs as a result of a fundamentally non-voluntary process. Alan Leshner is the most famous proponent of this hard version of the Disease view. Leshner has defended the view that an addicted person's actions are the direct result of brain adaptations caused by chronic drug use—that their actions are more like reflexes than normal rational behaviours" (Foddy, B, Savulescu, J, 2014).

However the part of the brain that opioid narcotics affect are the reward systems (specifically the mesolimbic reward system in regard to opioids, which I will explore in much more depth below) – the opioid receptors being able to interrupt the pain pathways and the chemical response is one which, for an addict, created a pleasurable 'high'[13]. Foddy and Savulescu point out that this theory is however vulnerable when pointed out that it's not just pleasure-seeking behaviour that's affected by addiction, but motivational behaviour as well, due to the planning that has to go into seeking out the required necessities to achieve the next dosage – using the example of a heroin addict needing to seek out needles, a spoon, flame etc. However, I would counter this with the point that even if the neural pathway being affected is the pleasure-seeking one, the motivational behaviour needed to attain the next dosage or needed paraphernalia is still part of the pursuit of the 'pleasure-seeking', it's just a necessary step to achieve it. Hyman's 'softer' version of the disease view aligns with this counter point, claiming that "it is not the chronic brain changes that alter the process of motivation, but the fact that drugs directly stimulate the pleasure pathways, which he says "hijacks" the normal motivational process." (Foddy, B, Savulescu, J, 2014).

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[13] When not directly reducing physiological pain, what we know to be the mesolimbic reward system is in this perspective being referred to (by Foddy and Savulescu, and Leshner) as a pleasure-seeking reward system within the brain, because though opioids are activating the mesolimbic reward system, this is not the only form of addiction being discussed when creating a more generalised definition for the term addiction.

Ironically, the theory which most refers to the loss of choice is one which opposes the disease view: the *Willpower View* (Foddy, B, Savulescu, J, 2014). This is the theory on addiction which is typically the oldest (and perhaps, by that logic, outdated) because it is the implication that even if an addict wanted to stop consuming their addiction, their personal will is not strong enough to be able to achieve it. Although I fundamentally argue that addiction is not a 'choice', I also reject vehemently that the reason a person remains addicted to a substance is not strong enough to stop. Besides being categorically insulting, addiction is far more complicated than simply a lack of self-control. As an example of why this theory doesn't make sense as a definition of addiction, even when an addict has the supposed 'self-control' to stop consuming their addicted substance, they must remain abstaining from it for the rest of their life or they will lose control again. Be it opioids or gambling, if an addict –after 5, 10, 15, even 30 years – consumes their addiction one again then they will fall straight back into the loss of control. No matter how much they believe they may be able to consume it once and be able to stop again, that pleasure seeking pathway is still reactivated. They may be able to get clean again, and that includes if they even fall off-the-wagon just once, however it is not because of lack of willpower that the substance is still able to ignite the pleasure-seeking part of the brain. It is why the saying *'once an addict, always an addict'* is so apt. It is an illness which can lie dormant, but is chronic in itself, nevertheless.

There could also be a more broad criticism of this school of thought, suggesting that a secondary illness developing off of medication for a primary illness is a rare example, and only since it only applies to opioids is too obscure to claim. However, this is not an isolated example of when medication side effects can lead to secondary illnesses. Another key time in which this happens is when gastroenterology-related symptoms have the tragic consequence of leading to the development of anorexia nervosa, bulimia and other forms of eating disorder. (Tanigawa, T et al, 2001) I find this a particularly poignant example because there are many parallels between the two case studies. It is yet another representation of how medication which is taken for primary physiological illness can lead to secondary psychological illnesses (of which eating disorders are, and for the perspective of my argument, addiction is). Since we can hereby establish that medication is causing the development of a secondary psychological illness is a proven consequence of some pharmaceuticals, there is a precedent set for the way in which addiction – whether caused by opioids or not – can be considered a psychological illness that is developed as a consequence of medication side-effects.

This is why I believe the most suitable definition for addiction – specifically applicable in the context of opioid addiction as well as any other addiction – is the 'soft' disease view. Neurological changes are made within the brain when *dependency* becomes *addiction*, and although it is made to the pleasure-seeking pathways, it also affects the motivational behaviour in an addict as well as the behaviour directly resulting in the 'high'. It is a neurobiological and a behavioural difference than dependency, and an illness within itself.

How the Lack of Definition is Impacting Patients

I am going to explain how the lack of definition is impacting patients because without that definition, there is no definitive separation between victims of the opioid crisis, and victims of their chronic conditions – two different and distinctive category of persons. The impact on patients is in direct answer to analysing the collateral damage of the opioid crisis. In order to experience I'm certainly not the first person to begin to question why there isn't an official separation of the two relevant terms. Joanna Dwyer (2016) reports that:

> "The government does not acknowledge that there is a difference between addiction and dependence. I openly and honestly depend on my pain medication. Without it I can't work or perform normal functions around the house or go for walks with my children. Am I addicted? Absolutely not. I take my medication exactly as my doctor prescribes it and take no illegal drugs. But the government is positioned to take away my quality of life and I am scared."

Patients should never have to be afraid of losing their quality of life because there is no solid foundation for understanding the difference between a patient who depends on their pain relief to get through tasks that they could not be doing if they were experiencing the level of pain that their condition causes; and people suffering with the psychological illness of addiction, who cannot choose not to take the drug that they have become addicted to. It runs their life, their social, economic and health becomes centred around the drug, and getting ahold of the next hit of it. Life as a chronic pain patient isn't just rest, sleep and hospital appointments – pain patients can be parents, employees, employers, students, and every other variety of people who have responsibilities that they need to meet. Quality of life is about much more than pain, it's also about one's ability to function to the level that a patient can function in the ways they are required to by the facets of their life (a point explored in more detail in 'Quality of Life versus Quantity of Life' below). Dwyer (2016) continues in this:

> "We are all scared and have no voice. We have no say in the matter. It's the government's way or the highway. It's like the government is shrugging off all the downsides of limiting opioid use and saying, "Yeah, but at least there are 25 percent less opioid prescriptions out there!" This is happening and the government is bulldozing the chronic pain community. They have created a culture of fear and now many doctors are too afraid to treat their patients and patients are too afraid to speak up for themselves. If we speak too loudly, we may be labelled a pill seeker and an addict. The

> government is not my doctor, and my medication should be a decision between me and my own doctor."

This once again speaks to the root of the problems with the CDC policy – the real-world interpretation and application of the one-size-fits-all checklist. Pain patients know that when they approach their doctor or end up in emergency care situations where they are at their most vulnerable, this can now be seen as 'drug-seeking' (explored below).

Current Definitions and (lack of) Distinctions

Without having official definitions of both addiction and dependency separately, there is no way for the two entities to be separated in a clinical environment. Having it in black and white means that chronic pain patients would have an extra layer of protection in the form of the ICD (WHO) or DSM (American Psychiatric Association), and the way they inform legislation. An extra protective barrier moving ahead in the future may be unable to undo the harm already done to patients as collateral of the opioid crisis – but it could reduce it in the future. Present definitions only prolong the harm done as collateral damage of the opioid crisis. At present, the ICD-11 (WHO, 2022) under 6C43 defines "Disorders Due to Use of Opioids" as:

> "Disorders due to use of opioids are characterised by the pattern and consequences of opioid use. … Therapeutic opioids are prescribed for a range of indications worldwide and are essential for pain management in cancer pain and palliative care, although they are also used for non-therapeutic reasons. In some countries morbidity and mortality related to therapeutic opioids is greater than that related to heroin. All opioids may

> result in Opioid Intoxication, Opioid Dependence and Opioid Withdrawal. A range of Opioid-Induced Disorders occur, some of which occur following Opioid Withdrawal."

At present the definition of 'disorders due to use of opioids' includes the consideration that all opioids will lead to both 'opioid dependence' and 'opioid withdrawal.' Although they are discussing the use of opioids for a therapeutic purpose, they only mention opioid withdrawal and dependence, not addiction (WHO, 2022). The importance of a distinction here under the category of 'disorders due to use of opioids' lies in the stigma and assumptions made about people who are using opioids. A disorder due to the use of opioids implies that the phenomenon of withdrawal and physiological dependency to opioid medications are disorders themselves – however, withdrawal is merely a side effect of stopping a drug that has built up within the body; and dependency is the long-term side effect from the absence of/in the prevention of opioid withdrawal itself.

At present, the definition of *opioid dependence* (WHO, 2022, 6C43.2) reads:

> "Opioid dependence is a disorder of regulation of opioid use arising from repeated or continuous use of opioids. The characteristic feature is a strong internal drive to use opioids, which is manifested *by impaired ability to control use*, increasing priority given to use over other activities and persistence of use despite harm or negative consequences. These experiences are often accompanied by a subjective sensation of urge or craving to use opioids. Physiological features of dependence may also be present, including tolerance to the effects of opioids, withdrawal symptoms following cessation or reduction in use of opioids, or repeated use of opioids or pharmacologically similar substances to prevent or alleviate withdrawal symptoms. The features of dependence are usually evident over a period of at least 12 months, but the diagnosis

> may be made if opioid use is continuous (daily or almost daily) for at least 3 months." (My italics and underline)

As already argued above, categorising opioid *dependency* as a disorder in its own right implies that it is a singular condition that develops both independently and in combination with opioid use. Opioid dependency can only occur when someone is on opioids for a long time. *Addiction,* a disorder in itself, can be developed with or without opioids – as it is a condition in its own right. One could be 'addicted' to junk food, or nicotine, etc. Since opioid dependency cannot exist without the primary instigation of being on opioids, and is the state of being in which is the *prevention of withdrawal*, it shouldn't be considered a disorder by itself, since a dependency is not possible without the substance that the brain has become dependent on, and can be tapered down off of to safely undo the dependency because those changes in the neural pathways which affect pleasure-seeking and contributing motivational behaviour are not there. A dependency can be undone safely (though may be uncomfortable due to withdrawal), whereas an addiction is an illness that remains there chronically once it has been formed.

I do not want to underrepresent the harm that opioid addictions do to a person, their life and their family and friends. There can be bad patterns of use with opioid medications, which can affect both people being treated for chronic pain and those who aren't, in exactly the same manner. The current definition of 'a harmful pattern of use of opioids' (WHO, 2022, 6C43.1) is:

> "A pattern of use of opioids that has caused damage to a person's physical or mental health or has resulted in behaviour leading to harm to the health of others. The pattern of opioid use is evident over a period of at least 12 months if substance use is episodic

> or at least one month if use is continuous (i.e., daily or almost daily). Harm to health of the individual occurs due to one or more of the following: (1) behaviour related to intoxication; (2) direct or secondary toxic effects on body organs and systems; or (3) a harmful route of administration. Harm to health of others includes any form of physical harm, including trauma, or mental disorder that is directly attributable to behaviour related to opioid intoxication on the part of the person to whom the diagnosis of Harmful pattern of use of opioids applies."

In its description of opioid dependence (WHO, 2022, 6C43.2), the current ICD-11 definition makes a comment ("impaired ability to control use") which implies that dependency involves the impairment of mental capacity because of biological dependency – making it a psychological issue and not just a physiological one. This to an extent could be perceived as the inability to choose to stop taking opioids without incurring a period of withdrawal. However, without separating 'opioid addiction' and 'opioid dependency', there is no other way to address the issue of an impaired ability to still have the capacity to choose whether to take opioids or not. To imply that dependency is what happens when an individual loses their capacity to decide in regard to their opioid usage, is simply incorrect. Someone only dependent on opioids, not addicted, still has the capacity to choose whether or not to continue their treatment.

By keeping these definitions separate – with dependence meaning a physiological side effect of a medication, and addiction meaning a psychological illness – doctors can begin to discern those who are merely existing on their opioids with the medication supporting their daily life; and those who have begun abusing the medication.

The categories relevant to opioid *addiction* (WHO, 2022) are all subordinated to dependency as subcategories of it. This is problematic, since patients whose bodies are dependent on the medication so as to relieve some of the pain and function day to day – are going to be continually associated with addiction and all the stigmas and attached to it. This is put nicely by Maia Szalevitz, Khary and Wakeman (2021) in their paper, 'Drug Dependence is not Addiction – and it Matters': "It is not surprising that physicians frequently conflate patients with 'addiction' and 'dependence' when the ICD terms used to code for addiction are themselves misleading."

In order to progress positively in both chronic pain care and opioid prescribing, we need to have clear, concise, and robust definitions that distinguish between the two. Definitions that patients, doctors, general public, and even those with addictions can rely on. The American Psychiatric Association's (2000) DSM-IV was more specific about this, prior to being merged with the DSM-5 (American Psychiatric Association, 2013). The DSM IV hasn't been in effect since 2013 when the DSM-V replaced it, however that replacement changed the way in which opioid-based disorders were perceived. Before 2013, the DSM-IV (American Psychiatric Association, 2000) included two individual definitions of "Substance Abuse" and "Substance Dependence" – each with their own diagnostic criteria.

The criteria for diagnosing 'Substance Abuse' under the DSM-IV was: "A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following, occurring within a 12-month period" (National Library of Medicine – National Centre for Biotechnology Information, 2000).

The ‘maladaptive pattern’ is particularly important. Patients who are only biologically dependent on opioids will be using them in a safe and recommended pattern of use as directed by their doctor. When the pattern of use develops into a detrimental one and diverts away from the dose or frequency that the doctor has given instruction for, then it is a sign someone who was once just dependent on opioids may be developing an addiction to them (American Psychiatric Association, 2000).

> “…Recurrent substance use resulting in a failure to fulfil major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household). Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating machinery when impaired by substance use). Recurrent substance-related legal problems (e.g., arrests for substance-related disorderly conduct). Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights).”.

The ‘recurrent substance use’ isn’t just in those who are using an opioid medication ‘regularly’, it is also referencing people who may have begun using an opioid substance recreationally once or twice, who are now progressing to using it more often. It also describes the consequences of opioid addiction, such as social or interpersonal problems like getting into fights. Opioid *dependency,* being a side effect of a medication (which shouldn’t fall under a disorder classification without further explanation) does not in itself cause social or interpersonal repercussions in the way that opioid *addiction* does.

The criteria for diagnosing 'Substance Abuse' under the DSM-IV (American Psychiatric Association, 2000) was:

> "A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring any time in a 12-month period: Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of the substance to achieve intoxication or desired effect, or (b) markedly diminished effect with continued use of the same amount of the substance."

When someone is on opioids for an increasingly long time, we know they develop a level of tolerance at which the same amount of opioids does not have the full effect on the opioid receptors than it did when originally starting the medication. Of the conditions above, 'a' is more descriptive of opioid tolerance within recreational use, and 'b' is explanatory of opioid tolerance in a therapeutic scenario.

"Withdrawal, as manifested by either of the following: (a) the characteristic withdrawal syndrome for the substance, or (b) the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms" (American Psychiatric Association, 2000). Similarly, the two parts of this explanation take a different perspective. This time, 'a' implies withdrawal in the traditional sense of therapeutic use, however 'b' introduces another type of withdrawal referring to the scenario of recreational use. The definition also continues to recognise the use of a substance even when it is known a problem has developed. This is what I would definitely categorise under addiction, and not under dependency, because the intention behind the taking – particularly in scenario b – is referred to as taking the opioids for the sake of staving off the withdrawal, which behaviourally implies taking them to retain the effects as long as possible.

In dependency, I would expect the intention to be solely focussed on relieving the pain, or to prevent the pain in the lulls between use of pain killers, not on the prevention of withdrawing. If the true intention really is on pain-relief, then even the prospect of withdrawing is worth it if the patient still chooses to not take them anymore, for whatever reason they have. The capacity of deciding to take them is on the patient, and they are taking them for the intention of their pain being relieved (American Psychiatric Association, 2000):

> "The substance use is continued despite knowledge of having a persistent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, continued drinking despite recognition that an ulcer was made worse by alcohol consumption)."

There are more criteria for the diagnosis of a substance dependency in DSM-5 (American Psychiatric Association, 2013) as opposed to the diagnosis of substance abuse under the DSM-IV. The dependency definition starts to mirror the physiological aspect of the dependency that I am trying to instil – however, certain features are hard to differentiate from progressive symptoms of disorders which cause the chronic (secondary) pain in the first place. This including, for example, the "need for markedly increased amounts of the substance to achieve intoxication or desired effect", which could actually be the natural progression of a degenerative illness causing more pain and damage throughout the body which could result in the need for an increased dosage as well.

Although fundamentally I do agree with the separation the DSM-IV created between dependency and abuse, the term 'addiction' was not included. The term 'substance abuse' in particular – in contrast to ‘substance dependency’ – is technically a reference to over-using opioids as opposed to the illness actually causing the need to abuse the opioids. ‘Substance abuse’ is the action of abusing a substance. Nevertheless, the definition of ‘dependency’ to be found here is helpful for my purposes: for example, it speaks of the removing of the medication causing a *“withdrawal”,* a deficit causing an imbalance, as I will explore below.

The DSM IV, which included the separation of dependency and abuse has not been in use since 2013 when it was replaced by the DSM-5 (American Psychiatric Association, 2013). This, however, was the closest we have gotten during the opioid crisis to differentiating between addiction and dependency. According to the “Impact of the DSM-IV to DSM-5 Changes on the National Survey on Drug Use and Health” (Substance Abuse and Mental Health Services Administration, 2016) there was a “major change from DSM-IV to DSM-5 [in] the combination of substance abuse disorder and substance dependence disorder into a single SUD”. My most significant objection to the current ICD-11 analysis and the DSM-5 description of opioid based disorders is the very definitions used. By not including the term ‘addiction’, the term ‘dependency’ has to pick up the slack, and is overwhelmed with scenarios it must include.

This, unfortunately, has meant that those with a physiological side effect and a psychological illness are all merged into one category. They should be separated both for the sake of medical professionals and patients to allow them a more nuanced approach to opioids, but also to prevent the stigmatisation of people who are surviving on opioids as ‘addicts’. Although addiction is a serious illness, there is a major stigma surrounding addiction – particularly in the wake of the opioid crisis. This again brings into view the fact that chronic-pain patients who simply wanted support from their doctors have ended up being punished for it by since the crisis.

Wanting their deserved, needed, and prescribed medication did not contribute to the opioid crisis, and yet pain patients have become collateral victims. The way to resolve this is to create a distinction between dependency and addiction, and to try to ensure that it is as widely used as possible. It goes beyond just the label of the stigma, it can disrupt treatment for chronic pain patients, too, because they are seen as 'drug seekers'. In short, collapsing opioid addiction and dependency into one definition, "hurts people with chronic pain on long-term opioid therapy: if addiction is confused with dependence, they, too, are mischaracterized as having addiction" (Szalavitz, Rigg and Wakeman, 2021). Chronic pain patients already have the weight of the world on their shoulders, the last thing they need is to be stigmatised as something they're not, too. A stigma which is a barrier between them and receiving the support they need.

Roger Collier (2018) develops this particular fear of chronic pain patients in 'Complainers, Malingerers and Drug-Seekers – The stigma of living with chronic pain'. When a patient is reliant on opioids as part of their daily routine, even though they're not addicted to them, the way the media has portrayed opioids exclusively as villains and never as the heroes that actually help some people has lead to stigmatisation. It's a damaging assumption that all chronic pain patients using opioids as pain treatment are addicts. Collier (2018) quotes Maria Hudspith, Executive Director of Pain BC, as saying that:

> "The stigma associated with having an invisible condition has been made worse by the ongoing opioid epidemic. The rise in misuse of opioids and the associated overdose deaths has made many patients with chronic pain feel under attack, and has made many

> doctors wary of prescribing opioids. “Now the pendulum has swung so far in the other direction that we have physicians putting signs up in their waiting rooms saying they no longer prescribe narcotics-” said Hudspith, “The problem I see in that pendulum swing is that nuance is being lost.””

Collier highlights the unfair way that the opioid epidemic, and the misuse of opioids, has entirely discredited and invalidated genuine, safe therapeutic use. It has shrouded chronic pain patients under the stigma of a separate illness that they don’t have. In trying to correct a harm done by Purdue Pharma, policies were created which have over-corrected it – by vilifying them exclusively. Instead of just punishing those responsible for the crisis, chronic pain patients were punished as well.

Neurobiological Changes

When opioids are taken by a patient, the reason that patient could become either dependent or addicted to them is as a result of the neurobiological changes those opioids are making within the patient’s brain. It is important for me to consider these because it is the empirical side of separating addiction and dependency, because it forms a foundation for the evidence to separate, supporting the above point of hopefully minimising the collateral damage to chronic pain patients in the future with this definition in place. Even though the core of my argument focuses on how dependency and addiction should be separated literarily, it’s also important for the sake of validity to also explore the neurobiological differences. Having neurobiological support behind the separation between the two terms can only strengthen the need to define them as such, which ultimately benefits chronic pain patients, making it the ethically responsible thing to do. To do this, I will be looking in particular at the ‘mesolimbic reward system’ (Kosten and George, 2002), as depicted in Figure 5 below.

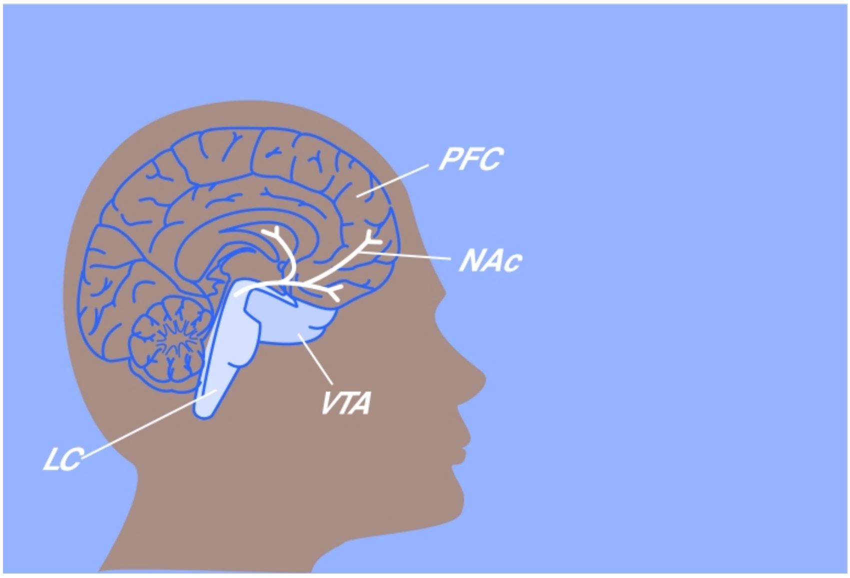

Figure 5 The mesolimbic reward system (Kosten and George, 2002)

An opioid works to relieve pain by travelling through the bloodstream to get to the brain. The chemicals in the opioid attach to particular proteins, which are called ‘*mu* opioid receptors’ which are on the surface of “opioid sensitive neurons (brain cells)” – the brain cells which have the mu opioid receptors on them (Kosten and George, 2002). When the chemicals from the opioids activate the receptors on the cells, there is a biochemical response in the brain. The ‘ventral tegmental area’ (VTA, as seen in the diagram above) is activated, which releases the chemical ‘dopamine’ (represented as DA) in the ‘nucleus accumbens’ (represented by NAc). Dopamine is the same chemical that makes us feel pleasure when we engage in activities that “promote basic life function” (Kosten and George, 2002). This therapeutic release of dopamine as a result of the opioids – when there is severe physiological pain in the body, being recognised through nerve signals being sent to the brain – results in the decrease of pain. However, if or when this same system is triggered without any pain to decrease, the ‘pleasure’ feeling of the dopamine can be felt as a ‘high’ on its own. This is how people with no pain get their euphoric feeling from taking opioids.

As pointed out by Kosten and George (2002), "from a clinical standpoint, opioid withdrawal is one of the most powerful factors driving opioid dependence and addictive behaviour". This was written pre-opioid crisis, so although I would argue now that withdrawal is a *symptom* of dependency and not a contributing *cause* of it, the implication that the avoidance of withdrawal could be contributing to not wanting to stop taking opioids could be significant, considering the potential severity of the withdrawal symptoms and the likelihood of wanting to avoid it as much as possible.

Clinical Representation

As a case study, the denial of opioid prescribing as collateral damage of the opioid crisis is a frequent problem, that has been happening globally to far too many people. I am going to be looking at the clinical representation of addiction and dependency, because unlike some one-in-a-million hypothetical ethical question, there is important and widespread real-world application of these ethical changes needed, and those happen both in and as a result of, clinical settings. Clinically, opioid dependence can be defined as the state when the brain's operating equilibrium is balanced when there is opioid use, i.e., the body's 'normal' level of function is achieved when there are opioids in the body; hence, it becomes imbalanced when opioids aren't ingested. The *'locus cerelius'* (LC) is the part of the brain which procures *'noradrenaline'* (NA) – the chemical which stimulates the body's faculties that operate in homeostasis, such as breathing, blood pressure, wakefulness and more. When there is use of opioids repeatedly over time, the LC learns to operate the normal level of the faculties even when there are opioids in the system… (Kosten and George, 2002)

> "…by increasing their level of activity. Now, when opioids are present, their suppressive impact is offset by this heightened activity with the result that roughly

> normal amounts of NA are released, and the patient feels more or less normal. When opioids are not present to suppress the LC brain cells' enhanced activity, however, the neurons release excessive amounts of NA, triggering jitters, anxiety muscle cramps and diarrhoea."

Unfortunately, this also means that when the body finds its equilibrium on a particular dosage of opioids, the body develops 'opioid tolerance' (Kosten and George, 2002), a situation where the body learns to tolerate the level of opioids being taken and they no longer have the effect that they used to, because once the LC learns the amount of NA it needs to release to keep the body at a functional stasis, than the previous amount of opioids needed to either feel a 'high'(recreationally) or to reduce a particular amount of pain (therapeutically) – will no longer be enough. This means patients find over time their opioid dosages might need increasing just to achieve the same level of relief.

I was fortunate enough to interview Dr Kunal Sood at the start of this project. He is an anaesthetist and pain specialist in Maryland, in America. We began discussing the topic of opioid tolerance (American Psychiatric Association, 2000), and how over time the build-up of opioids in the system can mean the desensitisation of opioid receptors, and therefore over the course of the treatment opioids sometimes have to be increased in dosage to achieve the same pain-relieving effect. Dr Sood informed me how ketamine infusions can be used to 'reset' a patient's opioid tolerance level. For example, if someone started at needing about 12 mcg of fentanyl and grew over time to 100mcg, then the ketamine infusions should regain the function of the opioid receptors to respond to just the 12 mcg again. The NCBI reports a pilot study exploring this as a treatment option (Neunhoeffer et al., 2017).

This particular study was done in the context of a paediatric intensive care unit, because the patients on ventilators there were on prolonged opioid treatment and therefore developed a tolerance while they were on the ventilators. The conclusion of the study was that: “Drug rotation with ketamine in mechanically ventilated children with opioid tolerance is feasible and seems to reduce the rate of fentanyl infusion” (Neunhoeffer et al., 2017). The children in the paediatric intensive care unit were able to have their fentanyl infusions reduced as a result of the ketamine treatment. There are a number of similar studies as well, such as one led by Dr Sebastiano Mercadante, Patrizia Villari and Patrizia Ferrari (2003) in the context of cancer pain treatment. Thus, the concept of treating long-term opioid tolerance with intermittent ketamine infusions has been showing promise since at least 2003.

The idea of using ketamine treatments to reduce the amount of opioids that a patient is taking is striking in the context of this dissertation. It means that opioids could be able to provide the same level of quality of life in lower doses even in long term opioid use. It would reduce the risks associated with taking opioids, reduce the adverse side effects, and mean that prolonged use could become much safer. If this could become more widely explored, adapted, and tested – then it could be revolutionary in making opioid care safer for long-term treatment within chronic (secondary) pain care.

Section 2 Conclusion and Philosophical Application

In order to best translate this section across into a clinical use, it is important for me to create the tools to help clinicians understand and improve opioid care. A simple table (albeit likely my autistic brain’s easiest form of comprehension) is the most dynamic way I can create to show how the separation of the definitions could lead to prevent harm – and even more apt for this thesis question, the simplification of separating them shows the level of confusion and blurriness that has occurred without the separation in comparison, contributing to the *'how'* chronic pain patients became collateral damage of the opioid crisis. In order to simplify how the new definitions of 'dependency' and 'addiction' need to be defined biologically, behaviourally, and in summary – I created the following table.

Definitions:	**Dependency:**	**Addiction:**
Biologically:	**Susceptibility to Withdrawal.** When if one were to stop taking their opioids, the surge of NA because of its new balanced amount *will cause the physical effect of withdrawal.*	**An Illness in Itself.** The hardwiring in the brain has changed. The baseline level has been 'reset' and *the brain cannot function without seeking out the next dosage of the drug or being under the influence of it.*
Behaviourally:	**The Capacity to Choose.** The individual *still has the capacity to choose to stop taking opioids* even though they know they will face the awful withdrawal symptoms.	**Can no longer choose.** The individual has lost the capacity to choose if they take an opioid again, cravings begin to take over and *their behaviour becomes based on finding the next fix.*
Summary (new precise definitions):	**The capacity to choose to take opioids or not, despite knowing withdrawal will happen as a result of changes to the neurobiology.**	**An illness that takes away one's capacity to choose whether or not to keep taking opioids, as the individual cannot function without their next 'fix'.**

Table 1 Defining dependency and addiction.

An individual's capacity to choose whether or not to continue with taking medication is a key differentiator between whether someone is *addicted* to opioids or physically *dependent* on them – which philosophically speaking, returns to the fundamental question of what an illness is. If we are categorising addiction as its own illness, whereas dependency as a side effect secondary to a medication – then this has a number of implications for the philosophy of illness. For instance, Boorse (1977) is criticised by Barnes (2016) and Carel (2007) precisely on this issue of side effects.

Side effects could be said to be causing discomfort and detriment, and potentially (in the context of opioids) in very extreme cases, hyperalgesia; however, as a consequence of relieving the pain caused by a chronic secondary pain condition, the dependency does not inherently or typically cause pain and discomfort. On the contrary, addiction causes inherent pain and discomfort in many forms, from the rollercoaster of mental illness to the physical agony that come-downs may cause, along with all the physical implications that over-use of any drug when it's not needed and the social implications that cause more harm. This is why there is philosophical grounds for separating dependency and addiction and why distinct definitions are urgently needed.

Section 3: Quality of Life *and* Quality of Pain

The previous section began to set up a model in which we can begin to move forward in pain care and better support patients. This section provides structured, sound reasoning in not just why we need to move forward from where we are, but how to do so while upholding the ethical integrity that the doctrine of double effect gives. One of the ways in which we need to move forward is the recognition of quality of life versus quantity of life, and quality of pain versus quantity of pain. I need this section in my thesis to answer the question of why chronic pain patients deserve a quality of life – far more developed than simply because they're human beings just like anyone else. To understand *why* chronic pain patients deserve a quality of life, it is my responsibility to first lay the foundations of why and how chronic pain has been the cause of a deterioration in quality of life. Furthermore, a patient's quality of pain is also a contributing factor to the nature of their quality of life, but will also inform their priorities of how they would choose to manage their pain when it comes to opioid pain relief. The exploration of quality of pain is also going to be extremely important in the transference of this ethical work to a clinically applicable piece. I have created figures in order to demonstrate this, and with those figures, as well as a clinical application, there is also an informative feature in regards to how patients choose their pain management plan. This is because of what we assign to have value our lives.

Throughout time, we don't just assign value to the length of our life, but to the *quality* of the time we spend alive.

Quantity is in regard to the *'how much*' of something – either physical measurement or measurement of time. In application to 'quantity of life', quantity is the measurement of length of one's lifetime before they pass away. However, in a collective form, the 'quantity of lives' (plural) refers to the amount of people whose lives have been either saved or lost.

Quality, on the other hand, is the *'value'* of which we assign something – the enjoyment, the sorrow, the hardships, the happiness etc. which one experiences whilst living through the journey of their lifetime. Something unilaterally agreed on in the pursuit of improving one's quality of life is the minimising of pain and distress.

I am suggesting that these two criteria of measuring one's life should also extend to evaluating one's *pain*, too.

'Quantity of pain' has two components when asking *'how much pain?'*. The first is the expanse of the body that is experiencing pain. Perhaps a patient's whole body is in pain, or maybe it's restricted to their arm or a leg. Another way of quantifying pain is how much time has passed since the pain developed. The other component of quantity of pain is time. For example, someone with a short-term injury may be in pain for only a week; in comparison to someone with a chronic pain condition who could spend years – even decades – in pain. Both *time* and *expanse* are the ways of quantifying pain.

'Quality of pain', though, isn't something often discussed in either clinical or emergency settings. The closest there is to a consistent enquiry is the 1-10 scale: a generalised question about the intensity of the pain being experienced. The qualities of a patients pain are the aspects of that patient's individual experience, which can in turn give us information about the source of the pain, and how to best treat it.

Philosophically, there can also be benefits to pain, too. If there was no pain – no suffering or hardship – then their counters of pleasure, happiness, and positivity couldn't exist either. It's the concept of needing one extreme in order for the other extreme to be able to exist. (Nietzsche, 1882)

But this 1-10 school of thought doesn't translate fairly for patients with chronic pain like it does for the conceptual existence of pain. In the context of a pain that is intensely endured over a long period of time, theoretical principles of 'pain being a good thing because it means appreciating pleasure, too' implies that the pain patients are experiencing is proportional to the pleasure they will receive, too.

Chronic pain is anything but proportionally relative to the time in absence of it. In fact, it's distinctly disproportionate, meaning the correct treatment strategies are even more important. By definition, 'chronic' pain is long-term. To be very specific, according to the NHS Inform (2021), it's pain that lasts longer than three months. But it is more than simply pain that lasts longer than a few months – chronic pain can also seem unpredictable, cruel, and relentless. It will take down anything that gets in its way; it seems vicious, with a vindictive, almost sentient way of targeting its apparent victim. It dramatically extinguishes the quality of life of a patient, in a way that can seem impossible to imagine without first person experience.

In order to look at the importance of quality of life and quality of pain, I am going to be exploring the philosophical significance of 'autonomy', and its subsequent impact on quality of life and pain. Specifically, whether or not a patient has a modicum of control over their own treatment. Autonomy can be defined as "the capacity to be one's own person, to live one's life according to reasons and motives that are taken as one's own and not the product of manipulative or distorting external forces, to be in this way independent" (Christman, 2003). In a medical setting, a patient having autonomy will look different from one patient to the next, and one doctor to the next. A doctor has the ability to offer the treatments they see fit for a patient, but a patient having the ultimate decision in regards to any procedure and treatment is them being able to exercise their autonomy. And in order to exercise autonomy, they need to be of sound mind. A 'sound mind' is in reference to a patient's mental capacity (NHS, 2022) – their ability to make decisions sensibly and within reason for themselves.

This phrase, the 'quality of life', comes up a lot in medical care. The 'World Health Organisation Quality of Life User Manual' (WHOQOL, 2012) outlines the different properties which contribute to a quality of life. The manual takes concepts of value – the things that happen within a life that add or subtract value to it – and made it into a list which can be quantified point-by-point. In the context of this case study, I will be looking at the way in which chronic pain impacts each of these qualitative evaluations, and demonstrate as a framework how pain detriments the patients, and how the use of opioid medications have the potential to improve a patient's quality of life (but also how it could potentially negatively impact it, as well).

The WHOQOL (2012) description of 'dependence on medical substances' (which includes opioid pain killers just as much as it would wheelchairs or oxygen tanks) is that:

> "Medications may in some cases affect a person's quality of life in a negative way (e.g., side effects of chemotherapy) whilst in other cases it may enhance the person's quality

> of life (e.g., cancer patients using pain killers). This facet includes medical interventions that are not pharmacological, but on which the person is still dependent, for example a pacemaker, artificial limb or colostomy bag. The questions do not include detailed enquiry into the type of medication."

In a perhaps ironic way, I entirely agree that being dependent on medication is a *negative* thing. I reiterate that being (physically) dependent on medication is not an active choice that pain patients would make if it didn't have any positive outcomes – it's not something desired, or wanted, or glorified. It's a passive consequence of the desire to have less pain, it doesn't mean that opioids aren't awful things.

But being in pain every day for the rest of your life is also an awful thing. If there are no additional risk factors (e.g., family history of addiction) and a patient is of sound mind and is fully informed in their consent of taking them, then autonomously they have the right as a human being to be able to make decisions about their own medical care.

Autonomy

Patients have a moral, ethical, and legal right to self-determination of their own bodies in the healthcare they receive – namely, a right to autonomy.

Autonomy, and the ethical debates surrounding it, are an absolute necessity in any debate surrounding medical practice. Patients in this case study, when coping with medical gaslighting and doctors who don't want to treat their pain, coping with clinicians want them out the door and care incredibly little about any pain they are in since they are not the ones enduring it, are stripped of their dignity. When dignity is gone from a medical decision, a right to autonomy is all that remains. In order to evaluate effectively how chronic pain patients became collateral damage of a crisis not concerning them; and furthermore, to evaluate how much of a quality-of-life chronic pain patients are currently having to get by on, I need to establish their rights to decisions regarding their own healthcare, and their responsibility to their own wellbeing.

A human being's right to the control of decisions made regarding their own body should be a basic level of common sense. Autonomy is, in itself, a principle of both right and responsibility – an agent's right to have one's own personal freedom, to enact their own free will and their right to self-determination; but a responsibility to never use one's own freedom to infringe on someone else's, and in medical decisions to self-determine decisions in pursuit of wellbeing. In a medical scenario such as this, bodily integrity as a form of autonomy is also important, under physical privacy. (Allen, A, 2014)

Autonomy, in the context of medication, is the right and ability of an agent to decide if they want to take medication in pursuit of reducing the amount of pain they're in, not the choice in dose or specific pharmaceutical. A patient needs to enact their self-determination in the pursuit the specific wellbeing-relative goal they wish to attain (relaxants to relax muscles, antispasmodics to reduce muscle spasms etc). They do not choose a medication and a dose out of thin air, and decide that is their free-willed choice[14] – doctors still have the responsibility to inform them of the appropriate and safe options they have, before enacting their ultimate power as physician of a final decision of prescription. If patients are using autonomy to make an

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[14] This is never going to be as safe and consistent of a balance as it could be while pharmaceutical direct-to-consumer advertising is still allowed in America by the FDA, because it encourages patients to pursue particular medications from their physicians, as opposed to be presented the appropriate options for their situations from their physicians.(https://www.fda.gov/drugs/special-features/manufacturers-mouth-your-ears-direct-consumer-advertising)

informed decision they consent to, they need to be fully informed of the risks and harm that using opioid medications can lead to, in an unbiased presentation; and are aware of any potential factors which would put them at a higher risk of addiction. If knowing the full picture a patient still decides it is worth it within the pursuit of wellbeing and a quality of life to take the medication, that is their right as a human being to determine for themselves.

The Royal College of Surgeons of England explain w a sr33300that in the wake of *Montgomery v Lanarkshire* (2015):

> "The Supreme Court held that patients have the right to exercise autonomy over their own bodies and over the treatment they undergo. When making treatment choices it is the surgeon's duty to advise and the patient's right to decide. This right of autonomy over treatment is a common law right. It does not come from the European Convention on Human Rights but has been created by British judges in cases beginning with Sidaway [1985]" (Poole, 2016).

As a blanket-term, 'treatment' under common law is anything from in-patient care to pharmaceuticals. Common law, therefore, says that patients should have the autonomy to decide if they take opioids to treat their chronic (secondary) pain.

The phrasing of 'the [doctor's] duty to advise and the patient's right to decide' is particularly poignant: a doctor holds knowledge and training as well as a background of observing other patients; but the patient is who holds the knowledge of exactly what the life they're experiencing is like while they are suffering. They are the only ones who have a right to make the decision as potentially-life-altering as this. The quality of life should be the contributing factor to a doctor's duty to his patient's wellbeing[15] - and the only person who can truly agree or disagree that the maximum quality of life has been achieved is the patient themselves. If a physician is fulfilling a patient's right to autonomy in pursuit of the patient's own quality of life, that physician has no right to detriment that patient's wellbeing on personal opinion, so also says the current Hippocratic oath (1964). For example, if a physician in America believes that their patients deserve their right to autonomy, they cannot also pursue a harm to that patient's wellbeing such as removing the pain-care their patient was on. Their own personal beliefs may be that opioids are harmful, however if they professionally respect their patient, and have given them all their available knowledge to unbiasly inform their consent, then that patient has the right to pursue their improved wellbeing and quality of life in the way they determine for themselves is best – even if it could cause them harm, too.

Physicians preventing a pursuit of wellbeing that does not provide harm to those around the individual patient, even if they don't agree, would be unjust if there is no threat to the patient or those around them. Illustrating this best is Mill's harm principle (J.S. Mill, 1824), which in this context can be used to argue that if the patient is not harming those around them with the prescribing of opioids for their pain care, then there is no justification to restrict their liberty to make a decision (in the context of medical care, referring to their self-determination of treatment). For a physician to inform a patient's consent, they provide the knowledge for the patient to make the decision autonomously. That knowledge needs to be full and unbiased: providing the whole picture and potentials – the harm opioids can do, and the level of relief they can provide. Without the full picture, the physician is impeding the consent and determination a patient has the right to make for their own body.

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[15] Perhaps in my PhD I will explore how we should redefine wellbeing as the pursuit of the best possible quality of life.

The Supreme Court's ruling on medical autonomy was that:

> "An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo … The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative" (Poole, 2016).

The Supreme Court emphasises the rights of the patient, but also the responsibility of the doctor. I have begun to look at the law currently impacting patients' right to autonomy in pursuit of an improved quality of life in order to determine the current challenges, prevention and detriment that an ethical framework is going to be working in conjunction with. Opioids are harmful, powerful things which should be prescribed with great care and consideration: consideration of both the risks, but also of the quality of life they could enhance. They should be used as a last resort – a Hail-Mary – a product used when someone is suffering and all other – safer – means have been implemented to no avail on their own. The above ruling also discusses the responsibility for doctors to fully inform the patient of the risks of opioids, however there is a fine line between wanting to ensure patients know the risks, and trying to divert a patient away from using them with biased 'horror stories', which would breech into the unethical.

The second half of the Court's statement poses an interesting point:

> "The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it" (Poole, 2016).

This being of no impact on whether the consent is informed or not – but merely the ability to recognise that although they are already suffering, and their quality of life is diminished, taking opioid medications means risking and sacrificing the little quality of life they do still have left. Being able to make that choice under the desperation that chronic pain causes has the potential to cloud decision making. The decision needs to have somewhat of an objectivity to it, even though patients in this case study are incredibly desperate for relief.

Autonomy is a vital philosophical resource in moving forward under the case-study of chronic pain and opioids, because it draws into question the rights and responsibilities of each individual patient.

Paternalism

When this autonomy is denied or prevented, the result is a consequence of *paternalism.* "Paternalism is the interference of a state or an individual with another person, against their will, and defended or motivated by a claim that the person interfered with will be better off or protected from harm (Workin, 2020)."

I am discussing paternalism to exemplify the damage that is possible to be done when doctors make life-altering decisions without giving patients the respect or decency to allow them determination over own bodies or healthcare. This is directly relevant to my thesis, because it shows how paternalistic decisions made by physicians and policy makers in response to the opioid crisis has had the consequence of leaving pain patients as collateral damage.

In the context of this case study, paternalism (of which I will explore further in the assessment of the paternalistic model of a physician-patient relationship) varies from a doctor trying to gently sway their patients away from opioid medications by telling them only failure-stories and over-emphasising the risks, to not allowing the patient to use their own intelligence or right to determination – such as 'The Opioid Prophet' (Blaming, 2018) deciding they had a right to make decisions regarding theirs (and consequently thousands) of human beings' bodies.

Jennifer Jackson (2000), in writing about paternalism in medical ethics, explains: "Those in the medical profession have a basic duty to be worthy of the trust their patients place in them." If a doctor is going to be exercising their own will and opinion above a patient's, then it means they are assuming a trust from their patients of which they have not earned. In order to build the relationship of trust, a patient has to be sure that a doctor has their patient's quality of life at forethought, not a tragic statistic instead. There is a balance between the trust a patient has in their doctor to make medical decisions for them; and the need for a doctor to give the freedom of consent to a patient to determine their own medical decisions in order to gain that trust to begin with.

In application to opioids, this means that for safe and balanced opioid prescribing there needs to be a reciprocal trust: trust that the patient has in the doctor that they will provide them deserved medication if they need it; and doctors trusting their patients that they will use the medications as directed and not abuse them, and have been open and honest about any personal or family history of substance abuse[16]. There is also a higher power at play though, one that

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[16] If there does happen to be a history of substance abuse, or a family history of it, then alternative methods of pain relief such as infusions, injections, intrathecal pumps, topical treatments etc need to be exhausted.

doctors and patients both need to have trust in: the policy makers who set the guidelines on limiting opioid access.

It was a necessity to implement some sort of policy in order to curb the worsening opioid epidemic. It was a necessity far before then, too. However, the 2016 policy in its current form stripped the rights and dignity of patients who did genuinely need those medications in one fell swoop as well. There is a very unlikely chance that a 'worthiness of trust' in the policy makers and the doctors who abused it can be built upon now. The trickle-down of paternalism throughout the system has created a culture of distrust between patients, their doctors, and the policy makers. It is hard to trusts higher up the food-chain when they preach paternalistic values, preach their belief that patients don't have the intelligence to self-determine their own medication (Blaming, 2018) and disregard harm through gaslighting of anyone who tries to speak up.

Paternalism in medical care doesn't just demean the patient's capability of decision-making for themselves, but it disrespects them by taking that decision away from them. In the context of drug policies as a given example:

> "When they are justified solely on the grounds that the person affected would be better off, or would be less harmed, as a result of the rule, policy, etc., and the person in question would prefer not to be treated this way, we have an instance of paternalism" (Working, 2020)

The intention of preventing harm to someone is admirable, but in this particular context disrespectful, and a violation of right to self-determination (autonomy).

Common law ruling for patients having autonomy in medical decisions regarding their own bodies, whilst policy law having taken it away (CDC, 2016), leaves blurred line between *autonomy* and *paternalism* shrouding patients. Information is infiltrating patients' perceptions from both perspectives, adding more and more confusion to a tenuous situation. Patients are doing their absolute best to make their decisions rationally, whilst though their bodies are screaming at them for help.

By evaluating both the quality versus quantity of *life*, and the quality versus quantity of *pain*, the goal is to reduce this confusion and break it down in a structured, systematic way that makes it easy for patients to evaluate their priorities, their experiences, their objectives, and their hopes.

Emma Bullock, one of the most pivotal figures in paternalism,[17] in the context of medical decision-making states:

> "I argue against two consequentialist justifications for a blanket prioritisation of informed consent over the duty of care by considering cases in which patients have imperfect access to their overall best interests. Furthermore, I argue that there are cases where the mere presentation of choice under the doctrine of informed consent is detrimental to patient best interests" (Bullock, 2016).

The concept of the 'patient's best interest' is paramount in autonomy, both in the consequentialist result and in the intention. Any doctor can claim look out for a patient's 'best interest', however the only person who can be guaranteed to have the patient's true best

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[17] Bullock, Emma: University of Southampton 2011-2013; Australian National University 2012; University of Birmingham 2012; Kings College London; 2013-2014 (https://philosophy.ceu.edu/people/emma-bullock-0, accessed 04.09.2022)

interests at heart is the patient themselves[18]. Isn't just the *intention* behind the best interest that affects the impact of the patient's medical treatment plan – but having a patient's best interest implies they know with a degree of certainty what is best for the patient overall.

'Best interest' doesn't imply perfect decision making. There's no way to tell with *absolute* certainty how the future will turn out – but it calls for the best-case-scenario with the information one has to work with. Due to the differing perspectives between someone who is experiencing the pain themselves and is desperate for relief, and a spectator of the pain who knows the severity of the damage opioids can do – it is understandable that perspectives will differ. Differing perspectives does not excuse tyrannical decision making, though. Particularly as Bullock describes, in a veil of having choice but when consent is ill-informed, though presented to the patient as the contrary.

In moving forward, doctor and patient need to build a relationship of trust, where the individual patient's own perspective and right over their own body is respected, and their presentation of choice a real one for the patients to make.

The way in which patients can receive the personalised care they need in order to make a safe and evaluated decision, is for the patient care to be individualised to the patient where policy must be suitable for the masses. It asserts that the responsibility needs to trickle down more onto the doctors than the policy makers being followed blindly (though this may make access to medical care less standardised). It still gives doctors who want to exercise a certain modicum of control the ability to carefully monitor the patients who they are concerned about, but it

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[18] Not to say that a patient cannot be wrong, or cannot have self-harming intentions (though we are discussing the context of pursuing an improved quality of life, therefore is not applicable in this discussion). I merely mean that an individual is the only one who can truly have their own best interests at heart with no ulterior motives.

allows for patients who are ideal candidates for being helped by using pain relief methods to have their treatment approved as a unique and supported case. An ‘individualised patient-care’ could look like doctors making sure all other options that are on the table are sought after first, and working out which of those are successful enough to still be implemented in the long-term treatment plan of the patient – adding more ‘tools’ into the ‘toolkit’ as such. Opioids won’t support a quality of life by themselves, they are one of many ‘tools’ that need to be utilised in conjunction with others, but that does not mean that policy makers or doctors have the right to make decisions without the respect for patient autonomy.

Unfortunately, not all people who are in positions where they *could* help pain patients have endeavoured to look for the genuinely appropriate place in medical care for opioid pain killers.

Edward Helmore (2018) writes:

> “Now US experts, including leading members of the American Pain Society (APS), are declaring in the strongest terms yet that opioids are not the answer for chronic pain. For chronic conditions, “Opioids shouldn’t be on the table to begin with,” … “There is no evidence that opioids are helpful. The evidence is they should be offered rarely, if ever.””

If there was another option on said metaphorical ‘table’ which actually relieved chronic (Secondary) pain just as significantly as opioids do in order to achieve functionality, without the harm and side effects that opioids have, then opioids could and should be removed from the table. Which would mean from a philosophical standpoint that the disjointed trust between doctors, patients, and policy-makers wouldn’t need to employ as much of a culture of paternalism.

But there is no such alternative. No way of achieving the reprieve of reduced pain in order to achieve a better quality of life, without the sacrifice that comes with a potential for addiction. Not yet at least, not with where science and medical care has reached thus far.

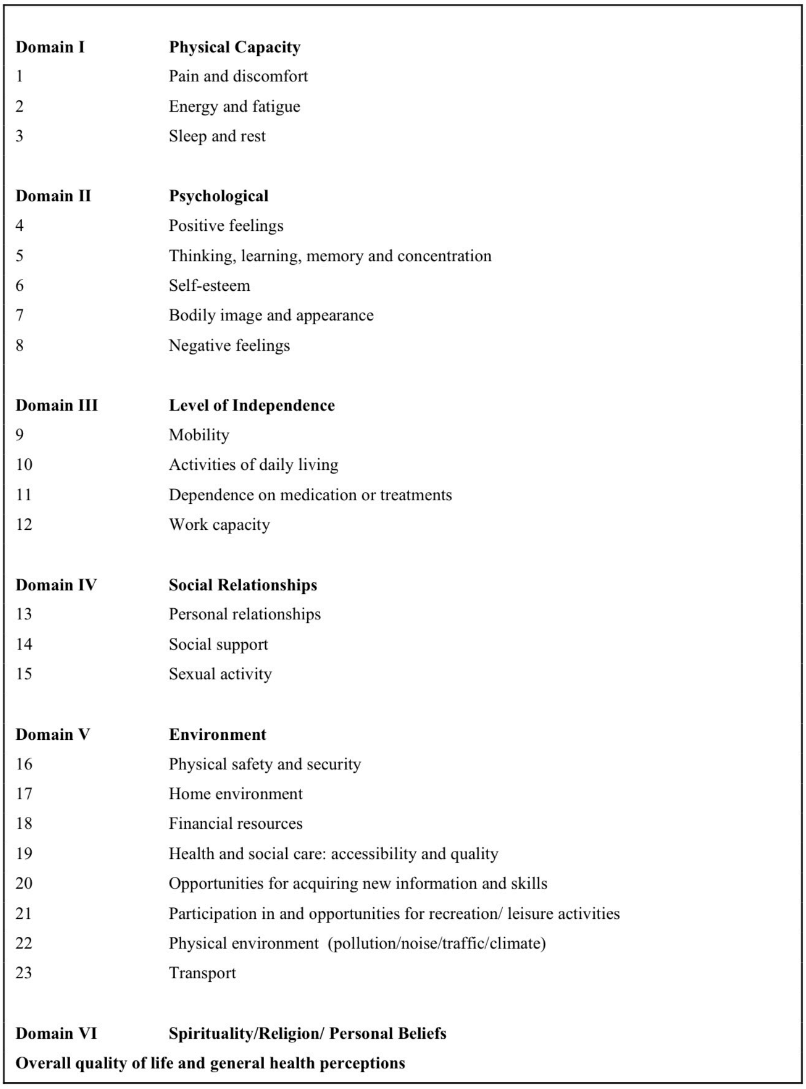
Dan Brock (1993, p.24) writes about the importance of information in regards to patient autonomy – or lack thereof.

> "The ongoing process of informing and discussion would have less value if the patient's decision could be ignored, and the right to refuse a particular (or any) treatment would be less valuable if there were no means of ensuring the *availability of information* on which such a refusal reasonably might be based." (My italics)

When a doctor restricts a patient's access, or refuses access, to pain-relieving drugs based on the information of opioid overdose deaths and not on the information about how it helps patients, then the information available to the patients is not complete, and not fully informed. The CDC, however, only issue a 'guideline'. It's not an absolute informative that all doctors must follow to the letter. Although this means that doctors should have some leeway to support patients who could find opioids helpful, it has been abused and manipulated. When doctors entirely restrict all access to opioids, even in situations they could be appropriate: **they are acting with either paternalistic malice, or negligence.** They are taking the choice to be fully informed about both the risks and rewards of an improved quality of life out of the patient's hands, decimating their right to autonomy.

Quality of Life

In a patient's medical decision making for themselves, autonomy helps us understand the right to a life of improved *quality*.



Domain I	**Physical Capacity**
1	Pain and discomfort
2	Energy and fatigue
3	Sleep and rest
Domain II	**Psychological**
4	Positive feelings
5	Thinking, learning, memory and concentration
6	Self-esteem
7	Bodily image and appearance
8	Negative feelings
Domain III	**Level of Independence**
9	Mobility
10	Activities of daily living
11	Dependence on medication or treatments
12	Work capacity
Domain IV	**Social Relationships**
13	Personal relationships
14	Social support
15	Sexual activity
Domain V	**Environment**
16	Physical safety and security
17	Home environment
18	Financial resources
19	Health and social care: accessibility and quality
20	Opportunities for acquiring new information and skills
21	Participation in and opportunities for recreation/ leisure activities
22	Physical environment (pollution/noise/traffic/climate)
23	Transport
Domain VI	**Spirituality/Religion/ Personal Beliefs**
Overall quality of life and general health perceptions	

Table 2 WHOQOL-100 domains and facets (WHOQOL, 2012)

A patient's quality of life is a broad spectrum of conditions and qualifications that assess a person's life, and how much value to the individual that life has. The categories attributed to quality of life in the WHOQOL are shown in Table 2.

Quality of life is one of the most important topics that I need to discuss in order to answer my thesis question, because in order to explain and support *why* chronic pain patients deserve a quality of life, I need to fully develop what a quality of life actually means; but also need to prove the ways in which chronic pain itself minimises a well qualitied life, therefore needing opioid pain relief to regain that quality again.

The physical categories could be assumed to be most commonly associated with the way that chronic pain might affect a patient's quality of life. In actuality, every single one of the subcategories of the WHOQOL manual (WHOQOL, 2012) is impacted in some way or another when a patient is suffering in chronic pain.

Out of the initial subcategories, the first is 'pain and discomfort' (WHOQOL, 2012) itself. The manual explains the way that pain *directly* and *overtly* impacts a person's life:

> "This facet explores unpleasant physical sensations experienced by a person and, the extent to which these sensations are distressing and interfere with life. Questions within the facet include the control the person has over the pain and the ease with which relief from pain can be achieved. The assumption is made that the easier the relief from pain, the less the fear of pain and its resulting effect on quality of life. Similarly changes in levels of pain may be more distressing than pain itself. Even when a person is not actually in pain, either through taking drugs or because the pain is by its very nature on and off (e.g., migraine), his/her quality of life may be affected by the constant threat of pain. It is acknowledged that people respond to pain differently, and differing tolerance and acceptance of pain is likely to affect its impact on quality of life. Unpleasant physical sensations such as stiffness, aches, long-term or short-term pain, or itches are

> included. Pain is judged to be present if a person reports it to be so, even if there is no medical reason to account for it."

The mention of 'distress' is particularly appropriate. Being in pain all of the time, especially severe pain, is incredibly distressing for the person experiencing it.[19] It creates a turmoil within all aspects of their life.

The direct quote "the easier life from pain" as opposed to saying 'the less pain' speaks volumes for insistence that opioids are not a preferable choice, but a necessity in improving quality of life. However the preferred choice would be a non-harmful alternative, or to not have the chronic pain and therefore the need for medication at all. Unfortunately, because lack thereof such a magical cure in existence, opioids are at present the most successful form of relieving pain and therefore improve the ease of accessing quality of life.

When looking through all of the subsequent facets of quality of life: there is the underlying baseline that the 'prevention of opioid use' which leaves a patient in a very distressing level of pain, and therefore a reduction in quality of life; and the ease of relieving pain from opioid treatment (amongst a team of other options) reduces the pain and distress, leading to the improvement in quality of life.

The subsequent facets following the 'pain and discomfort' (WHOQOL, 2012, domain 1.1) category are all facets of life quality which chronic pain disrupts. I am going to look at each

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[19] It seems a very abstract philosophical example, but the concept of torture as a form of interrogation would not exist without the bare minimum of being in pain causing distress.

facet individually, each of which working in cohesion towards the reduction in a patient's quality of life, as a result of the pain.

- Domain 1, Facet 2: *Energy and Fatigue*: Chronic pain is exhausting. It doesn't just mentally drain the body by forcing the patient to endure day after day of distress with no end in sight – causing hopelessness; it also physically fatigues the body, because even simple tasks become much harder work to complete when compensating for physical pain in the body.
- Domain 1, Facet 3: *Sleep and Rest*: 'Painsomnia' (Sleep Foundation, 2022) is a colloquialism used by chronic pain patients who experience trouble sleeping or whose sleep is interrupted by their pain. It is a common term amongst patients, but the American Academy of Sleep Medicine categorises it under 'insomnia due to a medical condition' (Sleep Foundation, 2022). When your body is crying out from pain, sleep is a much more difficult task, no matter how exhausted the pain makes you.

  Domain 2, Facet 4: *Positive Feelings:* This facet of 'positive feelings' includes words such as 'hopefulness', an emotion that gets significantly diminished by living in a state of perpetual pain with no hope of the condition ever improving.
- Domain 2, Facet 5: *Thinking, Learning, Memory, and Concentration*: The ability to focus on a task at hand when your mind is being permanently distracted by the pain coursing through their body becomes extremely difficult. Memory, concentration, and learning are all compromised by lack of sleep, and directly by pain as well.
- Domain 2, Facet 6: *Self-Esteem*: When a person's body is their own worst enemy, it impacts their self-worth; it is like being at war with their own physical presence. It's an environment that can lead to self-destruction. The term 'position in life' is also used in the facet description. Pain interrupts job prospects, interrupts opportunity for education

– and therefore can cause a patient's 'position in life' to become one that is stagnant. Stagnancy can cause one to believe their self-worth is less than if they were being productive or progressing through life's journey.

- Domain 2, Facet 7: *Body Image and Appearance*: While self-esteem is effected by the patient's relationship with their body and what it's capable of; this particular facet also focuses on aesthetic parameters. Pain can prevent simple tasks like showering, resulting in lack of hygiene. It can make dressing yourself a difficult task; makeup and skincare go down the priority list of things that are worth spending one's limited energy on.[20]
- Domain 7, Facet 8: *Negative Feelings*: The categories that this facet posits are despondency, guilt, sadness, tearfulness, despair, nervousness, and anxiety. All of which can be exacerbated – if not, caused – by living in a constant state of unpredictable pain. Tearfulness in particular stands out. It's an emotional response to what is already an awful situation to have to be in.
- Domain 3, Facet 9: *Mobility*: The way in which chronic pain effects mobility is profound, for example, when the pain is particularly centred around the joints (Beaumont Health, 2022). Joints are the human body's moving mechanism, and when the source of the pain is within those mechanisms the body will stop being able to be used efficiently, reducing range of motion.
- Domain 3, Facet 10: *Activities of Daily Living*: WHOQOL (2012) refers to the 'ability to perform usual daily activities'. When a person is in pain, even the simplest tasks becomes extremely arduous. Making a cup of tea or a sandwich; vacuuming; washing the dishes etc. Being in pain, no matter where the pain is located, makes tasks difficult and prevents patients from being able to do them.

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[20] See Miserandino (2003). Spoon Theory is a highly recognised theory about the limited volume of energy that people with chronic illnesses have in comparison to the rechargeable and unlimited potential energy that healthy people have.

- Domain 3, Facet 11: *Dependence on Medication or Treatments*: The dependence on medication – particularly on opioids in this case – is not something pain patients actively want to do. It is an unfortunate sacrifice that we have to willingly make in order to achieve a reduction in pain. If the option was available to not have to take any medication because there was no pain to reduce, then the quality of life would be thankfully restored. However, unfortunately when dealing with chronic secondary pain, often the primary condition in the patient isn't curable to completion. Therefore, the dependency on medication is necessary, and unfortunately reduces the quality of the patient's life as a result.
- Domain 3, Facet 12: *Working Capacity*: The *British Medical Journal* reports (Dobson et al., 2022) that

  > "Workers with severe pain symptoms were more likely to not be currently working at 18 months (33%) vs those without pain symptoms (16%), and had poorer self-reported physical and mental health. Workers with severe pain symptoms had higher probabilities of benefit durations of 12–18 months (OR=9.35), higher lost-earnings costs (~47.7% higher) and higher healthcare expenditure costs at 18 months (~125.9% higher) compared with those with no pain symptoms."

  People who are experiencing chronic pain are statistically more likely to lose earnings as a result of their chronic pain, in comparison to people who are not battling chronic pain.
- Domain 4, Facet 13: *Personal Relationships*: Maintaining any type of personal relationship is a difficult thing to do when chronic pain is involved. The unpredictability of pain can cause patients to have to cancel their plans at the last minute, creating the unfortunate reputation of being 'flaky'. This can result in the breaking down of

friendships and other social relationships, which naturally progresses into isolation. There is also an overwhelming amount of guilt when in a relationship where one's partner has to take a carer role for the patient.

- Domain 4, Facet 14: *Social Support*: The 'need for practical assistance from family and friends' is prevalent in the cases of chronic pain. Support from other peoples is a necessity, which is a way of losing one's independence. A patient relies on their personal relationships to fill in the gaps, even when they are receiving care support. It can put a strain on the relationships, and cause a build-up of guilt in the patient, bubbling up more and more over time, and even perhaps becoming resentment.
- Domain 4, Facet 15: *Sexual Activity*: This facet concerns the urge and desire for sex; and the physical ability for it. There are many studies on the pain-relieving effects of orgasms, due to the endorphins relieving pain naturally (Andersen, 2019). Sex when dealing with chronic pain, though, can be difficult. It means not only do patients lose the above health benefits of sex; but socially they lose that opportunity for intimacy in their relationship, too.
- Domain 5, Facet 16: *Physical Safety and Security*: To quote the WHOQOL (2012), "This facet examines the person's sense of safety and security from physical harm". When looking at chronic secondary pain, there's a physical source of the suffering. It's an environment that breeds vulnerability, and is difficult to feel physically safe when one's own physical being is what's attacking them. There's also the safety implication of feeling unable to protect yourself in defence from a potential attacker. It makes you vulnerable, and live in a perpetual state of feeling unsecured too.
- Domain 5, Facet 17: *Home Environment*: Factors that become impacted by pain vary from the struggles in cleaning one's own home and the physical labour that involves; to facilities in most standard homes becoming impractical with things like stairs to

climb, and narrow doorways unsuitable for wheelchairs. The immediate neighbourhood around the residence is also considered under this ‘home’ category, however with chronic pain it is often difficult to even leave bed some days, let alone enjoy the amenities of the local neighbourhood.

- Domain 5, Facet 18: *Financial Resources*: The obstacles in finding and sustaining employment as well as the extra costs of things such as small medical equipment, meals when it’s too painful to cook, and taxis when one can’t drive them self all contribute to financial reduction and instability. Then bigger costs such as house adaptations, medical equipment such as a wheelchair or power support with can be in the thousands and tens of thousands of pounds price range. There are costs on people suffering with chronic pain that healthy people would never even have to think of.
- Domain 5, Facet 19: *Health and Social Care: Availability and Quality*: This facet includes the “quality and completeness of care” attributing to the patient’s quality of life. Chronic pain is chronic in it’s very definition: it goes on forever, meaning there is no cure for those who are suffering. Unfortunately, as with all incurable illnesses, there can never be a feeling of ‘completeness’ to the healthcare beyond that.
- Domain 5, Facet 20: *Opportunities for Acquiring New Information and Skills*: A ‘desire to learn new skills’ is particularly hard to achieve when there are an entire track full of obstacles from the chronic pain that lies ahead. It can reduce the ability to take part in sports and physical activities; makes concentration harder; and reduced financial prospects limit opportunities to travel and learn about new cultures at the source.
- Domain 5, Facet 21: *Participation in and Opportunities for Recreation and Leisure*: “This Facet explores a person’s ability, opportunities and inclination to participate in leisure, pastimes and relaxation”. Activities that one would normally do in leisure could

become more difficult, and relaxing when one is in a constant existence of pain and suffering is a near-impossible task.

- Domain 5, Facet 22: *Physical Environment*: If someone with chronic pain is to review their environment, then the outlook they are viewing said environment with – no matter how much of a positive person they are – is a gaze of the world that seems to have it out against you. Pollution can trigger flare ups in some chronic conditions, exacerbating chronic pain (Hickey et al., 1970). Noise can exacerbate pain such as headaches, migraines; and living in cold or rainy climates can exacerbate joint pain (Boxall, 2021).
- Domain 5, Facet 23: *Transport*: Trying to use public transport is far more complicated with chronic pain conditions. For example, only has two-thirds of London Underground stations are step-free (Mansfield, 2021), and of those the routes between the accessible stations need to be accessible as well, which means only certain cross-changing stations.
- Domain 6, Facet 24: *Spirituality/Religion/Personal Beliefs*: Going through a never-ending struggle of enduring pain can make or break one's faith. The book *Touched by Their Faith* by Rabbi Yechiel Spero (2014), for example, is a book of stories of people whose faith kept them strong through hard times, including stories of people who have relied on their faith to hold them strong through awful medical challenges. Pain can reaffirm one's faith in higher power or spiritual workings that provide a reason for the suffering. On the other hand, it can also entirely disillusion one's faith and hope in the world, isolating them from any belief that things happen for a reason. On the middle ground, it could also lead to a mass of conflicting feelings and becoming distinctly agnostic as a result. There's also the pragmatic implications that religious buildings are often historical buildings, which are notoriously inaccessible.

Ultimately, every single facet that the World Health Organisation contributes to an optimal quality of life is disrupted or interrupted by chronic pain.

Quality of Pain

The second factor of autonomy that I need to explore is the seldom, if ever, explored ‘quality of pain’. Too often the *quality* of pain is the missing parameter, the *quantity* of being the information about pain that is gathered in clinical settings (the secondary question of the location of the pain following, still under the ‘expanse’ component of quantity).

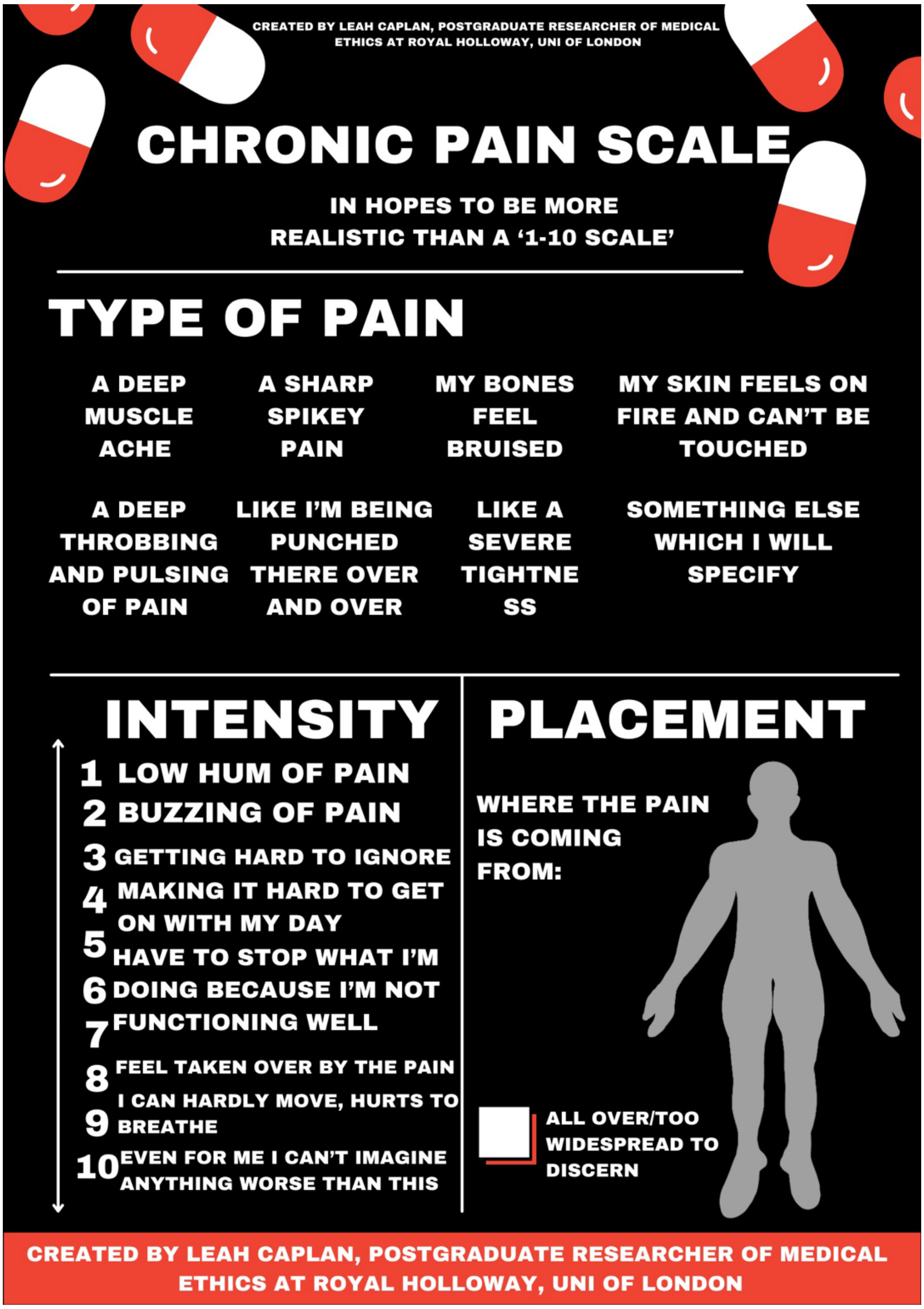
Quality of pain is generally seldom-discussed within pain management. This could be for a number of reasons, varying from the financial aspects of the pharmaceutical industry to the need to get patients quickly in and out of the door, to the simple lack of care for the humanity of chronic pain patients (all of which I unfortunately don’t have the space to develop further here). However it is exceedingly important to discuss the quality of a patient’s pain in reference to answering this thesis question, because when an individual is living with chronic pain, the life-long aspect can often supersede the nature and the information about the pain. ‘Chronic’ itself is in reference to the qualitative value of how long the pain is going to last. However, just because pain is chronic does not mean that it will be the same every day. It can vary in intensity, in strength; and when we discuss using opioid care for chronic pain long-term people may assume that we are talking about being on opioids all day, every day. Whereas, in fact, there are days with chronic pain where it is less intense, and dull. There are days when it could be quite a sharp pain, meaning high intensity, but it’s not overly strong. It is on the worst pain days which I am referring to the need for opioid care, because as I explained in section 1, there is a whole host of ‘tools’ for chronic pain relief on the ‘table’, opioids are just one of them – and are for when all the other tools are no longer working. In the context of this thesis question, a person’s quality of life and quantity of life, as well as their quantity of pain, can all be re-prioritised when assessing the quality of the patient’s pain. It also has the practical, clinical use of assisting doctors in understanding the experience of their patient much more, hopefully being able to prevent further collateral damage – and even with the potential to reduce opioid prescribing if more effective alternates are available (which I will explain in much more detail below).

A patient’s pain isn’t just individual to each patient – no two people, even those with the same condition, experience the same pain – but it’s also subjective, too. The significance of this exploration of subjectivity, both clinically and philosophically, is understanding that pain is subjective can lead for more personalised treatment plans.

> “The discussion of clinical significance in pain has largely centred on the assessment of treatment effectiveness, although it has also been used to categorise pain intensity. Used in these ways, determining, the clinical significance of pain is useful for describing pain prevalence or for judging treatment success. Looking at what kind of pain they are experiencing is the basis of understanding the quality of their pain (Birnie, McGrath and Chambers, 2012).”

Assessment of pain entirely impacts the treatment, though unfortunately the old version of the ‘1-10 pain scale’ doesn’t correspond well to the way that chronic pain fluctuates. The 1-10 scale can only be surface level; can only describe the ‘volume’ or ‘intensity’ of pain, not anything about it; and it’s entirely subjective to the person experiencing the pain. One person’s 5 could be another person’s 10, for the same pain signals being sent.

In order to try and actively improve this situation, I created a new pain-scale (Caplan, 2021) to try to reach some chronic pain patients, in order to help them communicate more effectively with their doctors in order to represent their pain better in medical scenarios (see Figure 8). Since I released it around a year ago, the outreach and feedback has been beyond anything I could have anticipated (over 18,000 patients).



CREATED BY LEAH CAPLAN, POSTGRADUATE RESEARCHER OF MEDICAL ETHICS AT ROYAL HOLLOWAY, UNI OF LONDON

CHRONIC PAIN SCALE

IN HOPES TO BE MORE REALISTIC THAN A '1-10 SCALE'

TYPE OF PAIN

- A DEEP MUSCLE ACHE
- A SHARP SPIKEY PAIN
- MY BONES FEEL BRUISED
- MY SKIN FEELS ON FIRE AND CAN'T BE TOUCHED
- A DEEP THROBBING AND PULSING OF PAIN
- LIKE I'M BEING PUNCHED THERE OVER AND OVER
- LIKE A SEVERE TIGHTNESS
- SOMETHING ELSE WHICH I WILL SPECIFY

INTENSITY

1 LOW HUM OF PAIN
2 BUZZING OF PAIN
3 GETTING HARD TO IGNORE
4 MAKING IT HARD TO GET ON WITH MY DAY
5 HAVE TO STOP WHAT I'M
6 DOING BECAUSE I'M NOT
7 FUNCTIONING WELL
8 FEEL TAKEN OVER BY THE PAIN
9 I CAN HARDLY MOVE, HURTS TO BREATHE
10 EVEN FOR ME I CAN'T IMAGINE ANYTHING WORSE THAN THIS

PLACEMENT

WHERE THE PAIN IS COMING FROM:

☐ ALL OVER/TOO WIDESPREAD TO DISCERN

CREATED BY LEAH CAPLAN, POSTGRADUATE RESEARCHER OF MEDICAL ETHICS AT ROYAL HOLLOWAY, UNI OF LONDON

Figure 6 Caplan's Chronic Pain Scale (Caplan, 2021)

The purpose of the first section of the diagram is to be able to assist patients articulate to the doctor the *sensation* of the pain they're experiencing, in the hope of more accurately treating the pain. This could hopefully also lead to less of a need for opioid prescriptions whilst still improving quality of life, because if a doctor knows more about the pain a patient is in other than just how much of it they're in[21], then the pain can be more accurately treated. For example, if a patient can describe a deep muscle pain then a doctor could choose to treat it with antispasmodics or an NSAID (non-steroid anti-inflammatory drug) and hopefully reduce what is causing the pain, instead of just prescribing generic pain killers.

The second section is a scale of 1-10, however descriptor words mean less of a discrepancy due to subjectivity between patient-to-patient. It standardises numbers of 1-10 with more information than a frowny-face through to a smiley-face.

The third section is a typical diagram used to show location of pain – which is a quantitative analysis – however what makes it unique is that there's also a box to acknowledge when the pain is too widespread to discern. It can sometimes be that chronic pain is so overwhelming for the senses across the whole body, meaning it can't be singled out to certain areas.

The importance in valuing the quality of a patient's pain can change the effectiveness of treatment, and can mean that opioids could be only used in situations they're absolutely necessary, and other forms of treatment could more successfully target specific forms of pain.

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[21] Although these are the kinds of follow up questions doctors may ask clinically about an injury or acute pain, it can be harder to articulate in regards to chronic pain.

Comparative Scales

I wanted to find a representative way to examine the correlation between the quality and quantity of life, and the quality and quantity of pain. The comparison between the quality of life and the quality of pain is easier to do when put into a visualisation of the four properties. By creating these pain scaled, I have been able to create a visual explanation of how every patient's priorities and the way they feel about their pain will be entirely individual. In understanding their priorities, we can further understand how their quality of life is impacted by the withholding of opioid based pain relief.

With the 'quality of life versus quantity of life', there are two distinct schools of thought (and some middle ground in between them). Some may prefer a longer life which may unfortunately be spent in pain as a result, but to them the additional pain is worth being able to live for longer. Other people may believe that being in less (or ideally, no) pain is worth a shorter life. That they would prefer to live for a reduced amount of time if it could mean not being in as much pain. Then, there is the middle ground – those who would settle for a bit of a medium. A medium amount of pain and a medium variation of the length of time.

The same schools of thought also apply for the 'quality of pain versus quantity of pain'. On one hand, there are people who may prefer the idea of being in pain for a longer amount of time or more widespread across the body, but the pain be duller or fainter. There is also the counter-thought that it would be better to be in a more intense, 'worse' pain but for it to only be a short amount of time or for it to only be concentrated to a certain area of the body.

These can both be compared using a visual comparison chart of sorts, representing the percentage variations of an individual's preference in regards to *quality and quantity of life*, and *quality and quantity of pain.*

I have represented the chart using an X and Y axis, as shown in Figure 9 below

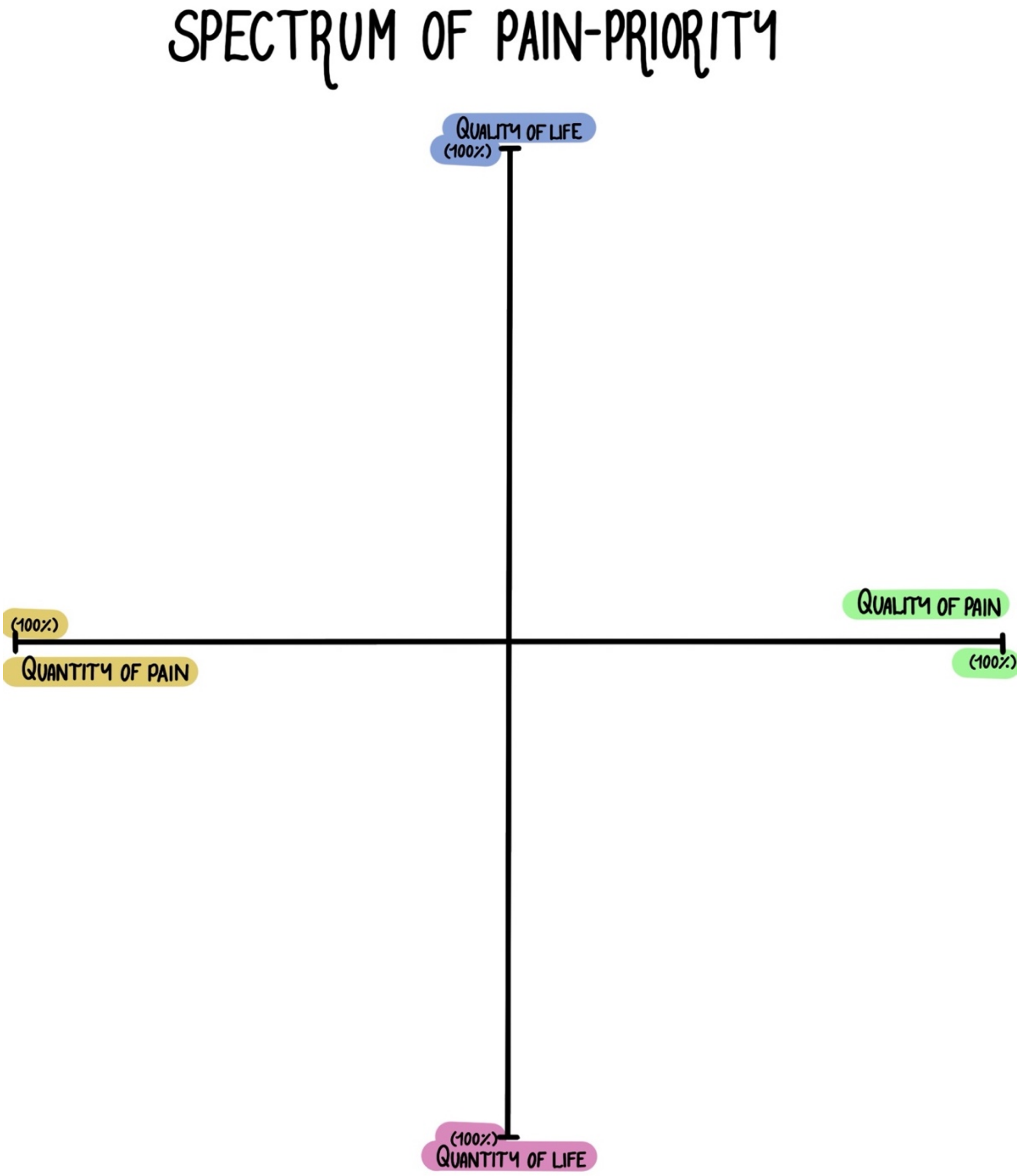

Figure 7 Quality and quantity of life, quality and quantity of pain[22]

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[22] This sequence of diagrams are my own and not derivative of any secondary work.

The graph is next shown with an explanation of what each axis point means (see Figure 10).

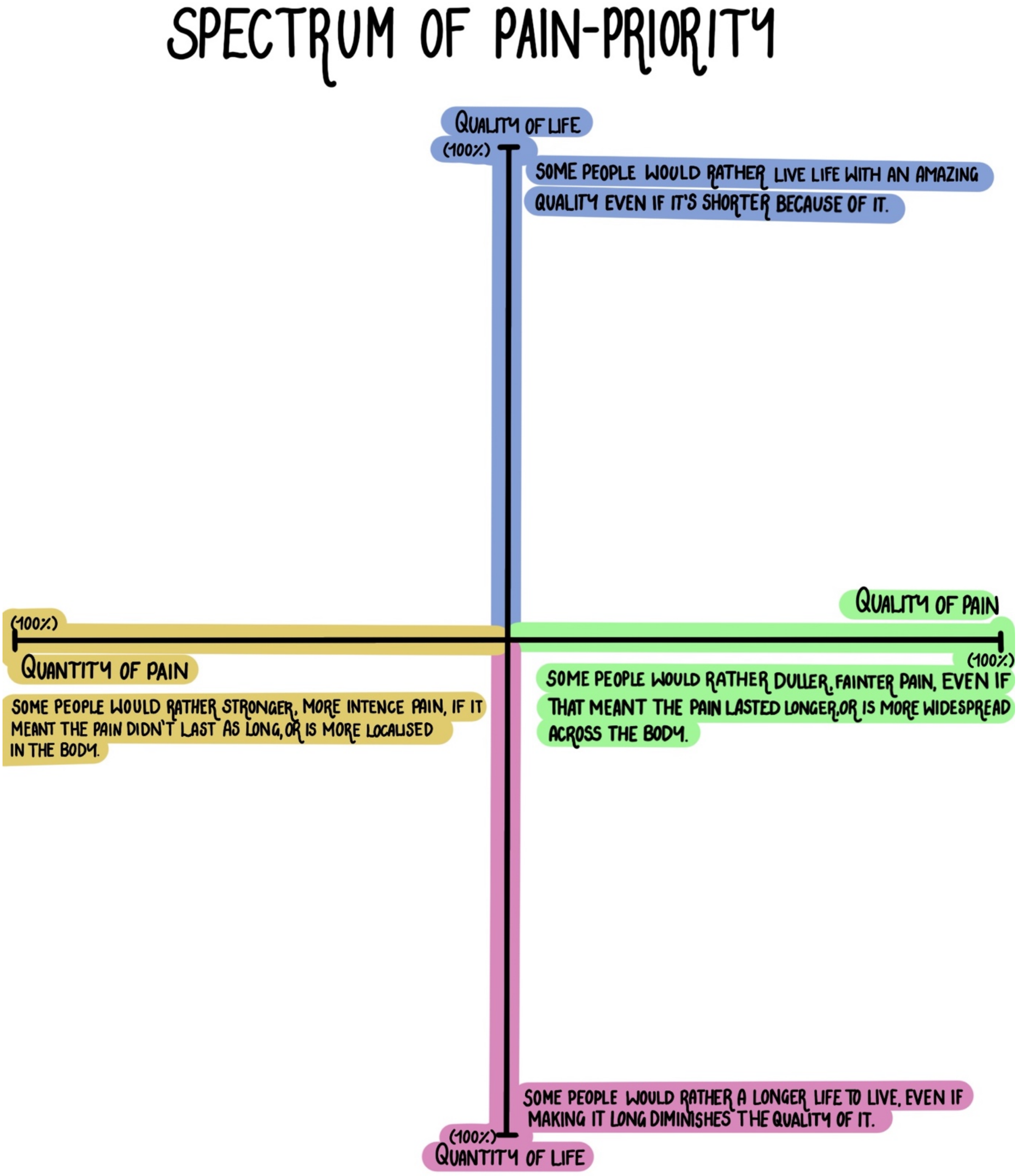

Figure 8 Explanation of the four quality/quantity sections.

The purpose of this is to visually represent that every patient will have their own priorities, and in knowing their own priorities and being able to visualise them more clearly, then ideally a treatment plan can be formed with it in the back of mind.[23] Its purpose is indicative of a patient's wishes, and each patient has the right to exercise the autonomy and let their priorities be known. It would be a moral violation for a doctor to decide these priorities in absentia of their patients.

Figure 11 is an example of a comparison: a visualisation of my own personal priorities in the way a patient could represent theirs.

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[23] Of course, one shouldn't actively try to shorten their life just to reduce pain if that's what their preference is, however it informs both doctor and patient (much more subtly) that a patient's priority is in their quality of life, making medication side effects much more worth it to the patient. Or perhaps it's. In the longevity of it – meaning they're unlikely to want to risk the side effects of medications so strong as opioids.

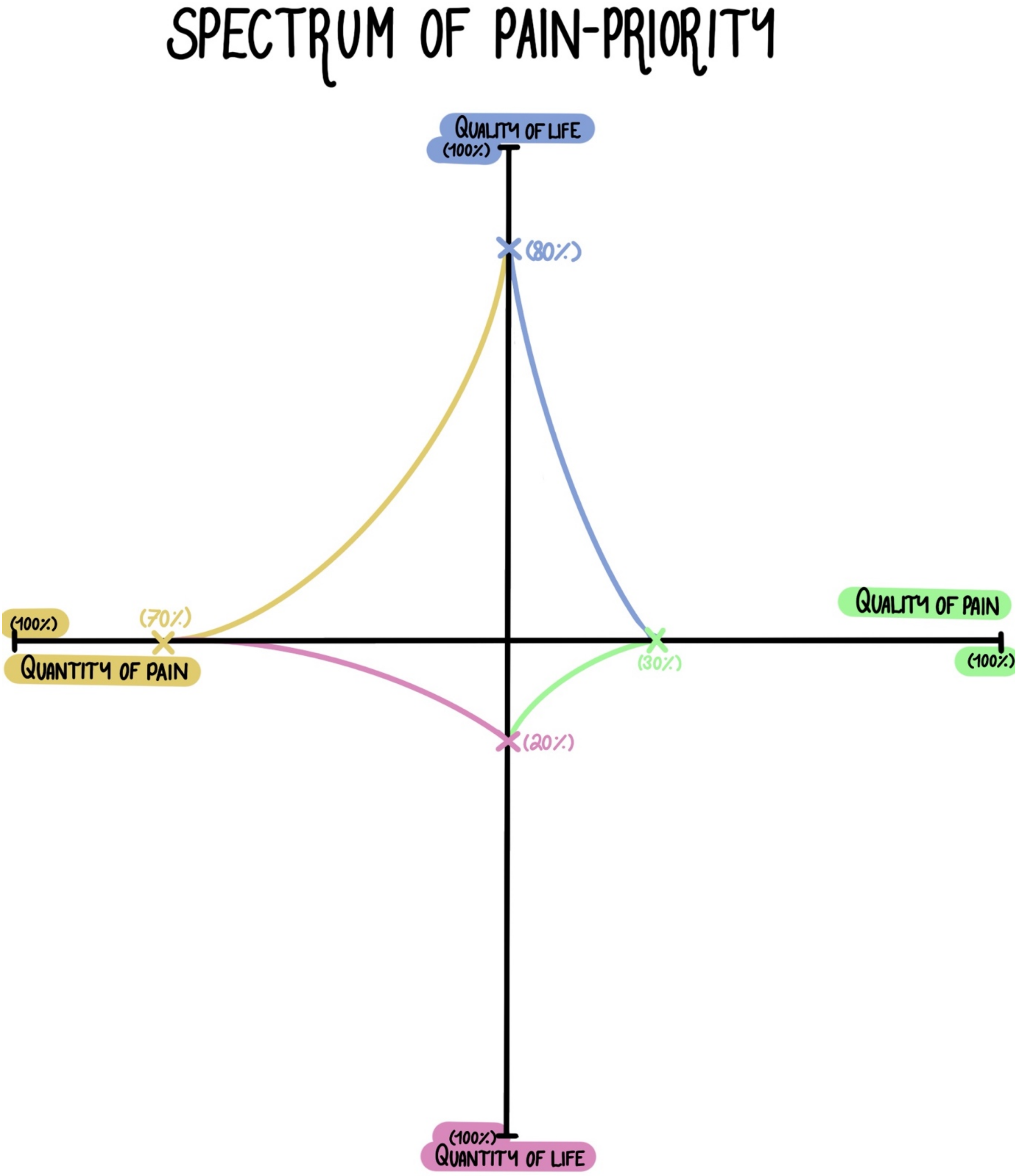


Figure 9 A personal example of the quantity/quality paradigm.

CDC Policy

The CDC's own (2016) guideline is earmarked as the point in time that opioid prescriptions began to be withdrawn, meaning the quality of life of chronic pain patients began being diminished after that point. The Don't Punish Pain Rally (DPPR, 2020) displays on its website 964 stories so far about those who have been hurt by this CDC ruling, and had their quality of life reduced because of it. Stories of people in car accidents, who when they wanted to seek help following unsuccessful treatments were accused of being a 'drug seeker' (Cathy Hall); stories of people who have lost their job, because without the support of their pain medications anymore they were unable to contribute to society in that way, and therefore lost their financial independency (Zonra); stories of military veterans with infections untreated for the pain; and nearly a thousand more other stories like them. I need to look even further into the CDC policy than in the medical foundations, because the interpretation of the policy may be at the heart of the collateral damage done as a response to the opioid crisis, but a policy that would impact so many hundreds of thousands of lives should have not left room for such a large margin of error by allowing doctors to weaponise it in order to victimise their patients. A one-size-fits-all approach, even if that one-size is supposedly set up to be able to be individualised if a doctor so chooses, is still one-sized.

The 2016 policy (and the way it has been allowed to be interpreted by physicians) had significant implications, particularly for patients who have been on opioids for a long time and already having successful treatment with them, but who are now unable to access them.

> "Overly aggressive adoption of the CDC guideline may lead to harm if physicians try to abruptly transition patients already receiving opioids at high doses to much lower doses. Harms could include withdrawal reactions, uncontrolled pain, anxiety for patients and loss of trust in their physicians. Such consequences could leave patients desperate (Busse, Juurlink and Guyatt, 2016F)."

These were all things that were apparently recognised for happening back in 2016 – the same year the policy came out – and yet still today they are recognised effects which seem to have been swept under the carpet in comparison to the support that the policy gained, leaving the few who speak out to try and yell over the voices of the many.

Opposition to the CDC's policy – and in particular to Dr Kolodny – due to its impact on real chronic pain patient's quality of life also came from Willem Scholten, who in the article "Response to Kolodny: Negative outcomes of unbalanced opioid policy supported by clinicians, politicians, and the media*"* (Scholten and Henningfield, 2016) explains his worry, that: "Unfortunately, blunt instrument efforts to reduce opioid prescribing are clearly causing hardship in pain patients who may face increasing hassle and stigmatisation in efforts to obtain effective pain medications and may be denied effective medications altogether."

The key word in this for exploring quality of life is 'hardship'. It is a hardship in itself, to be denied access onto medical care that is needed to uphold a quality of life. It is a hardship to lose autonomy and free will because of a policy made by governing bodies. This, too, was in 2016. These were issues that could have been seen coming – were seen coming – and should have been prepared for by the CDC within its own initial guideline to prevent the harm to those patients being correctly prescribed them. Instead, they chose what Scholten referred to very aptly as a "blunt force approach".

The CDC, to its credit, has proposed now (in 2022) to make some revisions to the policy. In February the CDC released a docket (2022) with a provisional update to the guidelines that were released in 2016. The updates to the CDC policy were introduced by the following statement from the CDC:

> "The Centres for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the proposed clinical practice guideline, CDC Clinical Practice Guideline for Prescribing Opioids—United States, 2022 (the clinical practice guideline). The clinical practice guideline updates and expands the CDC Guideline for Prescribing Opioids for Chronic Pain— United States, 2016, and provides evidence-based recommendations for clinicians who provide pain care, including those prescribing opioids, for outpatients age 18 years and older with acute pain (duration less than 1 month), subacute pain (duration of 1–3 months), or chronic pain (duration of 3 months or more), not including sickle cell disease- related pain management, cancer pain treatment, palliative care, and end-of-life care" (CDC, 2022).

The docket was released for a couple of months in early 2022 in order to gain feedback on the possible provisions the CDC was considering making, surrounding the guidelines for primary care physicians, amongst others, when prescribing opioids for chronic pain. It will be incredibly interesting to see the guideline changes when they are officially released, and I pray that it will allow for a more individualised approach to prescribing instead of a one-for-all methodology. Although it cannot undo the way that hundreds of patients have had their quality of life taken away from them, it could certainly help progress opioid prescribing safely,

Section 3 Conclusion and Philosophical Application

In order to understand the impact of quality of life and quality of pain on the way chronic pain patients have been harmed by the withholding of opioids, there were multiple factors that needed exploring.

The importance of autonomy over paternalism as a philosophical methodology in medical care is rooted deeply (and will be explained further in physical-patient relationship models in section 4), because of both moral and legal precedent. Autonomy isn't about giving a patient free-reign over their medical care; but a patient, particularly with chronic pain, is an expert of their own body: they're the ones having to live with it day-in, day-out. They should be given free will when making decisions pertaining to their body. Through the legal right of common law, and through moral and ethical principle: autonomy should be the most prevalent factor when treating a patient. Paternalistic attitudes are particularly unfair on patients, a doctor may have the educational background, however they are not the ones who have to endure the pain consistently. Patients will have an infinitely varying level of knowledge when it comes to biological study, however they're experts of their own condition and the way in which it impacts themselves. To take away a patient's autonomy isn't just harmful, but it's insulting. It infantilises the patient as if they don't know what is best for their own bodies.

Furthermore, the treatment of pain also needs to be individualised to each patient's care. This includes using alternative forms of evaluating pain – such as my chronic pain scale – in order to better understand the pain that the patient is experiencing, and then more accurately and effectively treat it. Individualism and autonomy go hand in hand, each individual having to make choices that affect themselves in their own living situations. They are not making decisions that impact thousands of people, unlike in the creation of the CDC policy.

There also needs to be a balance of priorities understood when implementing a pain care regime. It shouldn't wholly inform a treatment plan, but will help the doctors understand the ways in which patients determine whether or not side effects of a medication are worth the risk for themselves. Hopefully these new ways of making progress – in combination with the CDC's new guidelines that are in the pipeline – will allow the next stages of chronic pain care to be safe and progressive, even when opioids have to be involved.

The value-neutral model (Barnes, 2016) is a particularly fitting philosophical framework to help understand the compromises that are involved when implementing medications, when there are known risks of something which has the potential to be life-changing in the most positive of ways – but has the risk to be life-changing in all the wrong ways, too. The principle looks specifically at scenarios when dealing with focal points that can be bad in one context, and good in another. When defining these good and bad simpliciters – the things that positively or negatively impact an individual's well-being – then "we need to go beyond the effect on well-being" (Barnes, 2016, pp.83–84). Something can be a bad thing – such as opioids – however can have a bigger-picture effect of being either a neutral simpliciter or even a good one, such as when opioids improve the quality of life of those with chronic pain. Opioid treatments for pain care fits suitably under the value-neutral-model.

Section 4: Decision Making Framework: The Doctrine of Double Effect

While the previous section attempted to create some much-needed conceptual distinctions to help patients and health-care providers navigate the effects of the opioid crisis, this section gets to the heart of the matter—the various theoretical frameworks that lie behind decision-making processes around opioid prescription. That is, this section concerns the moral and ethical foundations behind withholding opioids; or still prescribing them, despite the knowledge that it has the *potential* to lead to addiction. In continuing on from discussing the CDC's 2016 policy further, I need to look at decision making frameworks. If it is assumed that the interpretation of the policy is what truly caused the collateral damage, then I need to look at how it was interpreted, and the decisions and ethical framework that supported them while interpreting the policy into clinical practice.

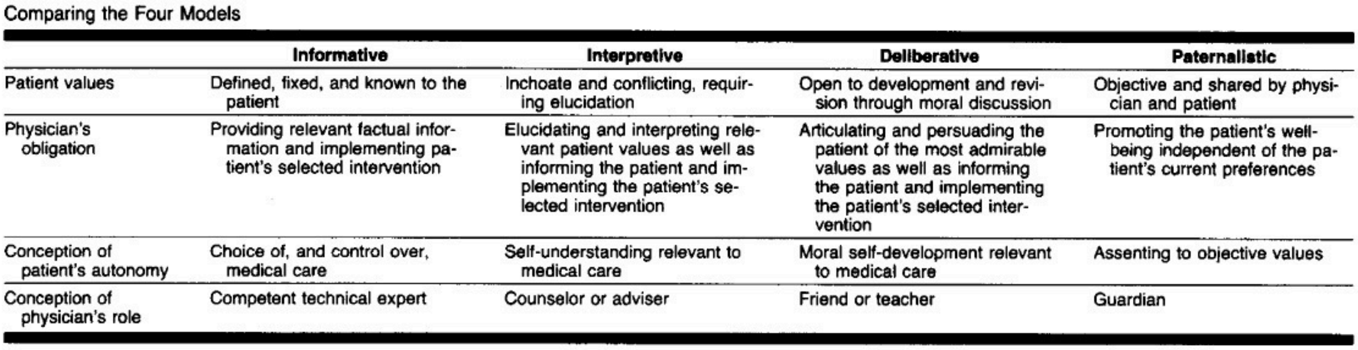
These kinds of decisions demand an ethical framework. There needs to be a structure – a code – to follow because of the latent ethical content at play in all these decisions. And so, in this section, I am going to be exploring some existing moral frameworks which are inappropriate in such a context, and then presenting the framework I consider to be the most effective when it comes to balancing harms in a medical decision-making environment. What a more effective framework requires is an ability to be pragmatically and flexibly applied in appropriate situations. Something more than a blanket policy for the masses, without ethical or moral concern on behalf of the chronic pain community, is needed.

In order to properly evaluate the nuances of a scenario as complicated yet significant as prescribing opioid medications, I first need to look at how those I am arguing against choose to establish (even if implicitly) moral frameworks.

The Four Models of Patient-Physician relationships

According to Ezekiel and Linda Emanuel, there are four models of physician-patient relationships (Emanuel, E, Emanuel, L, 1992) which I am going to use to evaluate the ethical boundaries and compare them as relationship types. It is important that I explore the four types of physician-patient relationship, so that I can explore the necessary ethical framework it takes to uphold boundaries between a doctor and their patient, if one wants to prevent harm to patients by inflicting a doctor's personal beliefs into their treatments. It also allows me to provide examples of what happens when doctors who are vehemently (and *personally*) anti-opioid – the damage they can cause to both thousands of patients, and their own careers.

Below is a comparative example of the four patient-physician models based on the different ways in which they create or ruin boundaries between patients and their physicians. Physician and patient relationships come with rights and responsibilities that go both ways.



Comparing the Four Models

	Informative	**Interpretive**	**Deliberative**	**Paternalistic**
Patient values	Defined, fixed, and known to the patient	Inchoate and conflicting, requiring elucidation	Open to development and revision through moral discussion	Objective and shared by physician and patient
Physician's obligation	Providing relevant factual information and implementing patient's selected intervention	Elucidating and interpreting relevant patient values as well as informing the patient and implementing the patient's selected intervention	Articulating and persuading the patient of the most admirable values as well as informing the patient and implementing the patient's selected intervention	Promoting the patient's well-being independent of the patient's current preferences
Conception of patient's autonomy	Choice of, and control over, medical care	Self-understanding relevant to medical care	Moral self-development relevant to medical care	Assenting to objective values
Conception of physician's role	Competent technical expert	Counselor or adviser	Friend or teacher	Guardian

Figure 10 Comparing the Four Models of Physician-Patient Relationship

Firstly: sometimes called the ‘scientific’ or the ‘consumer’ model, one of the physician-patient relationships is the “Informative Model”. This is largely relative to informed consent (Shah, P 2022). Informed consent being the process of a physician being responsible for giving the patient the full amount of informational available in order for the decision a patient makes to have been with their eyes wide open. The key importance within this model is that fact and value is separate – the patient knows their values and their feelings on decisions and on the things that affect their lives, however what a patient does not have is the medical knowledge and background of each of these choices available to them. The physician’s values and personal opinions do not have a place in the informative model; and the patient is the one in control – their autonomy is upheld. The Emanuel’s describe the physician role in an informative model as a “competent technical expert” – a completely appropriate role for a healthcare provider in the life of their patient.

There is also the “Interpretive Model”, in which the physician-patient relationship interactions are interpreted by the physician to assess what it is the patient wants for their treatment moving forward. This model is also founded within the physician providing all the necessary information to the patient, but further than that, then half the patient work out how they feel about the information provided to them, and look at their life as a bigger picture when looking at how certain treatments or conditions will affect them as individuals, not as though those treatments or conditions are completely isolated within the patient’s life. In this scenario, the physician is denoted as a counsellor or advisor – two positions who inherently have the most caring and considerate of intentions.

The next model is the “deliberative model”, which states that “to help the patient determine and choose the best health-related values that can be realized in the clinical situation.” This model has much more physician-control. The physician in this model acts as a teacher or friend, which have less of an objective and considerate point of view in the life of the patient. Friends, and to a lesser-extent teachers, are able to let their own views and opinions colour the way they advise the patient to make decisions. The physician is meant to articulate and persuade, however is still meant to implement the patient's selected medical intervention.

The last I am going to look at is the "Paternalistic Model". I touched more deeply on paternalism itself in the section above, however this is specifically in application to the relationship between patient and physician. This model is supposed to be so that physicians can choose the treatment options that *they* believe best promotes the patient's wellbeing and health. It "assumes there are objective criteria for determining what's best", and assumption is right – there is no input from the patient as to what they want or believe is right for them. Another disturbing addition of this model is that "Ultimately, it is assumed that the patient will be thankful for decisions made by the physician even if he or she would not agree to them at the time.". If a patient is entirely incapacitated and has no next of kin with power of attorney, or if a patient doesn't have the mental capacity to make decisions for themselves such as late-stages of dementia, then I could perhaps find value in arguing for a paternalistic physician-patient relationship of somewhat having a place in healthcare.

But there is a very specific reason I could argue that a paternalistic model goes against every ethical framework that should be upheld in medical care. Because it goes against the Hippocratic Oath[24] (Lasagne, Louis, 1964). By acting as a "patients guardian" to make choices

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[24] It would be enlightening to explore the full extent of the Hippocratic oath's application to opioid prescribing and the harm done to chronic pain patients as a result, however unfortunately I don't have the time to fully unpack it and it's applications.

"for them, a doctor is inserting their own personal belief system, thoughts, and opinions into their healthcare and treatment. Something which it specifically contradicts three

> "I will respect the autonomy and dignity of my patient; I will maintain the utmost respect for human life; I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing, or any other factor to intervene between my duty and my patient"

One example of an attempt at this paternalistic-model physician-patient relationship is Alfred Clavel Jr. He shared his personal beliefs, ones that dictate a patient's worthiness[25] is what impacts their ability to recover or not, which makes a particularly interesting case-study. Dr Clavel wrote the HealthPartners[26] article (titled "5 ways opioids and their negative side effects make your pain worse" (Clavel, 2002) which includes the particularly problematic claim: "Painkillers don't build our resilience – which is key to feeling better". The way he approaches patient care is akin to social Darwinism – if you're resilient, then you aren't going to experience pain and don't deserve it. If you aren't resilient, then you are fated to experience unimaginable pain – a kind of 'survival of the most resilient'. This is why Clavel's moral framework for his opioid-prescription-related pain care is a form of patient-centred virtue ethics: if a patient shows resilience, then they are not culpable and worthy of not being in pain. Their pain shouldn't be there because they're a resilient individual. He continues that: "For years we wondered why some people become disabled after an injury and some don't. The answer is that some people are more resilient than others." (my italics) Quite explicitly stated here is presented a moral ideal of a 'good patient'. Clavel ignores the possibility that people end up with different levels of injury from the same accidents; or that people's nerves respond

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[25] For more on Dr Clavel see www.healthpartners.com/blog/contributor/alfred-clavel-jr-md/

[26] Clavel is currently the department chair for Pain Management for HealthPartners (https://mhnpc.com/team/alfred-l-clavel/)

differently depending on the patient; or that people have varying levels of pain tolerance; or that maybe people's brains respond to pain signals in an individual way; or even that the same injury on two individuals could damage different nerves, bones or muscles in different ways; or further that a few millimetres one way or another from a bullet near a spine is the 'same injury', and yet is also the difference between walking again or becoming quadriplegic.

In other words, Clavel's moral framework makes a distinction between good patients and bad patients – those who are resilient and are therefore worthy of pain care yet do not even need it because of their resilience. Opioids would infringe on that resilience. And what is clear is this path leads immediately to a blaming of the patient for their own lack of success in reducing their own pain—those patients who lack the appropriate virtues are at fault. At fault for their own pain, and at fault for needing help from their doctors for it. **Clavel even goes so far as to consider pain to be a 'choice'**, when he advises that (2022, Section 3):

> "The first step in moving up [the mood elevator] is to recognise when you are tense and learn healthy ways to relax. This releases chemicals in our bodies that make us feel good, protect us from sickness and help our tissues rebuild." This misleading piece of supposed advice, dressed up in some false utopian dream, implies that patients are just *choosing* to let their pain run riot. That they're being *bad* patients for not relaxing. That their vices and virtues as people are what determines their worthiness of being in pain or not."

A failed paternalistic model of healthcare is inappropriate and is not looking out for the true needs of the patient, and the result is that it impedes the career of the physician, too. Clavel's medical license was suspended needing corrective action in 2010 (Minnesota Board Of

Medical Practice Disciplinary And Corrective Action List, November 2017[27].) The way in which I know that Clavel takes these personal opinions of patients into his healthcare is that his own practice states on their website that “His approach with patient care is simple; they work as a medical team to create the ideal healing state. He believes all patients have the capacity to heal.” (Minnesota Head and Neck Pain Clinic, 2021)

Another form of a catastrophically-damaging, failed attempt at a paternalistic-model physician-patient relationship is the ‘all-patients-are-dupes’ framework used by the very man who assisted in setting the collateral damage done to chronic pain patients in motion. In order to understand why chronic pain patients have been treated as such, we must understand the ethical decision-making hiding behind the policy itself. Using the paternalistic relationship, this framework deems which of their patients are worthy of having a quality of life, and one which believes no patients know what’s best for them because they are all manipulated by the pharmaceutical industry instead of being able to make decisions for themselves doesn’t understand the ‘why’ of ‘why chronic pain patients deserve a quality of life’, or else he would be fulfilling it.

Kolodny’s work also shows an implicit, inappropriate moral framework that informs its judgments on responses to the opioid crisis – even going so far as trying to ignore the contemporary ICD and DSM definitions of addiction or dependency for a more negative perspective in application to those who are not addicted to opioids, but do need them for long-term chronic conditions – to try and further justify his reasoning as to why pain patients do not

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[27] “Denotes Corrective Action Agreement. The Corrective Action Agreement is not disciplinary action, but is a public document setting forth an agreement between the Complaint Review Committee and the licensee. It requires the licensee to take certain remedial action to correct problems identified in the complaint review or licensing process.”

have the intellectual capacity for their right to autonomy: “Addiction is defined as continued use of a drug despite negative consequences. Opioids are highly addictive because they induce euphoria (positive reinforcement) and cessation of chronic use produces dysphoria” (Kolodny, A et al, January 2015). Instead of acknowledging the arguments and experiences of patients and trying to engage with them and respond to them, he takes a very different public approach, gaslighting (Dandaraw-Seritt, 2021) any patients within his field who could oppose such a framework. As Barstein (2020) puts it: “Kolodny referred to the movement countering his stance on opioids as a movement ‘trying to controversialize science.’ He related this controversy to the fossil fuel industry’s attempt to undermine climate science. “There were climate change scientists who were similarly attacked, and their universities stood by them, and I think that Brandeis would stand by science.” According to Kolodny, pain patients on opioids who are angry are real and their emotions are genuine; however, this group of people has been manipulated by the opioid industry (Barstein, 2021).

The basic concept of the framework is that patients have been manipulated without knowing it: *the patients are dupes*. According to Kolodny, patient advocacy groups do not have the capacity for their own autonomy, and cannot think for themselves, since they’ve all somehow been “manipulated by the opioid industry”. To speak on behalf of patients should mean that they do not have the intellectual capacity to think for themselves, but circles back to the physician-patient relationship structured where the physician acts as a ‘guardian’. It is incredibly insulting as a patient to be treated in this way. There seems to be no space here for a patient who is also a philosopher who thinks rigorously. In short, the idea that patients can think for themselves fails to align with the marketing that has surrounded his work as ‘The Opioid Prophet’ (Blaming, 2018):

> “Over the past decade, Kolodny has broken ranks with many physicians by insisting the epidemic is not one of drug abuse but of addiction, borne of the overprescription of extremely addictive painkillers to patients suffering from back and nerve problems, and other kinds of chronic pain. His stance has put him at odds with pharmaceutical companies that manufacture opioids (as well as some pain-patient advocacy groups that receive funding from them), which claim problems with opioids are limited to people who abuse them.”

The logic of this kind of argument is fundamentally that Kolodny is to be considered part of an enlightened messianic elite, who stands above the uneducated masses (among them the pain patients who Kolodny believes are dupes who can be easily manipulated and paid off to shape their own opinions). He has done what no patient has been able to and transcended the pro-opioid ideology which has been plaguing patient’s mental faculties. He has bypassed the false bravado of the opioid trade to a level that others aren’t intelligent enough to. No one can argue with *The Prophet*: he feels justified in speaking on behalf of all patients – with whom he shares no day-to-day experiences. He, the clever doctor, has broken through the evil ideology of opioids and influences policy on behalf of the dupes. Kolodny chooses to take agency away from all patients, not just his own patients; but from (thanks to his significant contribution to the CDC’s harmful ruling) patients right across America – and as a knock-on effect, those all around the world who follow America’s lead, too.

The problem with this Opioid Prophet complex is that a when you become so deep-rooted in your own belief system, it’s as if the counter-argument to your beliefs is just not worthy of notice; it just doesn’t exist as a rational position. Even when the CDC admits its part in unintentional harm caused, the Opioid Prophet is too knowledgeable and righteous to join them. This is how ultimately Kolodny gaslights (Dandaraw-Seritt, 2021) patients, making patients try to believe that a doctor with no experience of what they're going through knows their own mind better than they do. He does this by claiming that their anger and upset is 'justified', yet refusing to give their thoughts as autonomous human beings any credibility. This makes the patients feel as though their upset isn't justified at all, and forces them to believe that they must be acting irrationally, when they have full mental capacity and are the only ones who know what they are feeling or experiencing.

Using this dupes-framework, Kolodny – very similarly to Clavel's above – looks at the patient's worthiness, this time by discrediting the pain that they're experiencing, to justify their own anti-opioid position. Clavel looks at a patients' virtues and how resilient or not they are to determine their value and therefore whether or not they should be in pain or not. Kolodny appears to determine their 'unworthiness' on the basis of their inability to transcend the pro-opioid ideology created by the pharmaceutical companies. In another way both these moral frameworks do absolutely nothing to support the patients who are in pain – opioids or not. They are not suggesting or offering alternatives, not providing resources to cope, and are *not* the ones dealing with these experiences every day.

Care-Based Ethics *versus* Rights Based Ethics

In the midst of a war on opioids, there is going to be a lot of varying opinion within the population. A mother who lost their child to an opioid overdose during the epidemic is more likely to pioneer for all opioids to be removed; whereas a mother who lost their child by suicide because the opioids their child needed to have a quality-of-life worth living were unjustly removed is more likely to campaign for opioids to remain as an option within healthcare. As an academic, I need to be able to justify the answer to my thesis by evaluating the way in which a patient's quality of life is a basic right, and therefore decision-making frameworks should uphold that, even if it might not be the decision that everyone wants. *Healthcare* should have *care* at the heart of it, however it is also important that chronic pain patients are given the same rights as anyone else, too.

Two other options which could be considered viable candidates for ethical frameworks are 'care-based ethics' and 'rights-based ethics'. Care-Based Ethics, which "bases moral notions on the existence of special sorts of human relationships. These relationships come with special moral obligations"; Rights-Based Ethics, which "uses a social contract to distribute rights to members of a community which then define the moral boundaries". (National Education Association).

Instinctually, I feel drawn to care-based ethics for a context involving patient-care: a moral framework that promotes the well-being of others is a particularly important discourse. The importance of quality of life for well-being is significant (as examined in the next chapter). A person's well-being could be said to be significantly improved by their quality of life improving, the two being used interchangeably or in conjunction with each other, particularly from a government perspective such as the Office of Disease Prevention and Health Promotion (ODPHP, 2020), who have a goal and overview of their objective for health-related quality of life and well-being. This is particularly promising as an ethical framework for my stance because it values patients as human beings, and treats them as such; however, it might also be argued that prevention of addiction as a blanket policy is also promoting the well-being of a patient from the perspective of their wellbeing in regards to addiction, even if their pain leaves them in significant suffering and their quality of life deficient as a result. The care-based ethic in its intention is promising – both structurally and morally – in the pursuit of sound patient care; but the outcome of the ethic is too subjective and reliant on the individual or organisation determining the care, and how the body determining care defines well-being in accordance with the definition of quality of life.

The idea of a rights-based ethic is interesting because it doesn't just refer to the patient's right to a quality of life, but it also to a patient's right to autonomy over their own medical care. If a patient is willing to take on the responsibility of using their medications safely and interact with their doctor to keep proper track of the way and amount the medication is being used, then their autonomy as adult, chronic (secondary) pain patients of sound mind, means they have a moral right to decide if they want the pain medication to improve their pain levels, knowing there is a risk of addiction. Taking away that autonomy is yet another way of a *doctor-knows-best* framework. It infantilises the patients, implies they don't know what is best for themselves, and aren't responsible enough to understand the risks of the medication they are taking. A rights-based ethical framework posits that patients have a right to exercise their own autonomy, which is both productive for medical care and lets patients feel in control of their own bodies during a time when they have been controlled by their body for too long. Their body controlling them with pain and chronic illness that they have no choice over. The only *choice* a patient has is to do something about that pain. This doesn't just include opioids, of course. They may choose to meditate, to use heat therapy, to use topical creams and lotions, to use distraction, to use stretches or physiotherapy etc. But it also means they should choose whether or not pain medication is added into that list. As positive and progressive as this framework seems, it would be naïve to trust either side just yet, for it to be put into practice as an ethical structure. Doctors would need to trust their patients enough to let them have autonomy over the choice of taking medications with such severe addiction risks – particularly following the opioid crisis. In comparison, patients would need to trust their doctors enough to go to them if they begin to feel the effects of addiction kicking in, without fear of losing their access to a quality of life. It's a great ethical discourse in theory, but not necessarily suitable for the requirements of reciprocal trust in the current climate that chronic pain care finds itself.

Logistics of Moral Frameworks

The purpose of evaluating moral frameworks is so that there is an ethical justification behind a decision made in a clinical setting, which directly impacts people's lives. Without understanding why we have moral frameworks, doctors can use their own personal belief system when applying healthcare, which diminishes the deserved equal rights of all chronic pain patients. This goes directly to the way in which chronic pain patients deserve to have a right to a quality of life, and the moral frameworks are the tool in which gets the patient and their doctor to that foundation. I am not denying that any moral framework that informs the prescription of opioids needs to include an element of minimisation of harm that the opioid crisis has caused, and minimisation of the risks that could impact potential addiction to opioids. However, *my* responsibility in this argument and in the dissertation as a whole is to the patients who are suffering, but who also deserve a quality of life as much as those who could be impacted by the crisis in other ways, do.

No one's life is worth more than any other—this is a fundamental moral axiom. What possibly gives anyone the right to determine which patients are *worthy* of having reduced pain, and those who aren't. Perhaps this would only apply to patients who participate in sports; or those who have a particular attitude reliant on their mental health status. It could be said to be dependent on how much money they have; on how many languages they speak; or what they believe in politically. Frameworks based on worthiness are impractical, but also disrespect the hundreds of thousands of patients desperately trying everything they can to cope with their pain – to no avail.

Instead, the framework that needs developing to move forward in pain care requires criteria which avoids the pitfalls faced by Clavel and Kolodny. Its criteria will avoid (i) patients needing to have particular characteristics to be worthy of not being in pain; and will avoid (ii) denying patients the autonomy as real human beings who are able to think and possess agency. Key is also criteria which (iii) doesn't diminish the harm that chronic pain does to a person. Kolodny's and Clavel's moral frameworks fall short of the standard that chronic pain patients deserve. There are much more sophisticated ethical frameworks that actually work in the real world.

In this context, I believe there is no better applicable framework than the Doctrine of Double Effect. The medical foundations that have been laid previously emphasise the need for a theory that validates a real-world ethics, in situations where stuttering on moral ambiguity can lead to the loss of lives.

Philosophical theory is often just that – theory. A lot of ethical stances are particularly great in the realm of theoretical injustices and dilemmas, but are merely just feigning the confidence needed to withstand a real-world argument. Included in these is the dangerous and sometimes downright nasty framework of 'patient-centred virtue-ethics' of above.

In contrast, the doctrine of double effect can be applied to all the relevant dilemmas and situations in regards to the prescription of opioids, and chronic (secondary) pain patients' lives. Since a lot of ethical examples and discourses use rare and bizarre examples (e.g., the 'would you torture a terrorist if it got you the solution to saving many innocent lives as a result' argument), they position themselves within a reality that is extremely unlikely to actually happen and is inaccessible to most people. These are scenarios that the individual using the moral framework will likely never have to actually encounter. The chances of having to decide whether it is moral to torture someone in order to save innocent lives is beyond extremely unlikely, (bar the occasional CIA/MI6/Interpol employee). Real world problems (that impact the vast majority of the general population) require real world ethical frameworks.

An ethical framework which provides a robust argument on behalf of those with chronic pain and who those have no voice in the medical community, will need to be the most pertinent, practical*,* ethical structure out of all options available. In order to best represent the chronic pain community, there needs to be an ethical evaluation behind it that works for the day-to-day challenges that they face. This will entail getting rid of the kinds of naïve, ignorant, and uninformed ethical frameworks like those explored above, in exchange for something that upholds the value of all lives: those impacted by the opioid epidemic and those suffering with chronic secondary pain.

Ultimately, a patient's personal virtue should hold no weight whatsoever in the prescription process. At most, it should be weighted on the practicality of it fitting in their lifestyle when seeing which patients are safely compatible with opioid care; but more importantly considered should be the type of pain the patient is experiencing, the levels of pain, the way the pain develops and changes throughout each day and longer-term, and the way pain has stopped them having their best possible quality of life, and so on.

I have already shown in section 1 the necessity of only including *secondary* chronic pain, giving firmer and better-defined boundaries that an ethical theory needs to align with. It is using that science which proves the need for such a pragmatic and developed decision-making tool.

Banning opioids is the wrong way to go about it. Forgetting the very fact that it won't actually solve the illegal trade of opioids into the country – to, ethically speaking, deprive all chronic pain patients of a quality of life when only a small percent ever end up with an addiction[28], which in itself has the chance to go down by confident and careful opioid care, is not proportionate with the moral justification of perhaps preventing a low percentage of the addictions within the crisis.

Instead, if one truly understands the nuances of what chronic pain patients go through and the positive impact of properly-monitored opioid prescribing, then the framework used are going to be fully informed. The empathy of doctors in regards to what their patients are going through can allow for better understanding of pain care, and will allow patients to feel more understood as well. Those who have power to alter access to pain care should be fully informed on the struggles and challenges faced by chronic pain patients – both in terms of the pain that they are experiencing but also in terms of understanding how policy changes have caused harm in their lives – and for instance *not* telling journalists that the patients have been duped into believing there is a problem when there isn't, gaslighting them, and then accusing them of controversializing science whilst invalidating their feelings.

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[28] In reference to calculations in section 1, where I used statistics to calculate that: "between the parameters of 0.32% and 0.72% of those prescribed opioids for chronic pain turn to heroin".

Out of the different moral frameworks available, and in moving as far away as I can from a patient centred virtue ethics, I choose to use a framework that not only upholds the importance of the intentions of an action – but also the integrity of the outcome, as well. Finding a framework that not only made sense with these two conditions, but that also has previous experience of applications in medical ethics case studies, such as euthanasia, and therefore would balance with the medical foundations that I've already laid, lead me directly to the doctrine of double effect.

What is The Doctrine of Double Effect*?*

I am going to be exploring the doctrine of double effect (McIntyre, 2004), also known as the 'principle' of double effect, and the ways it can be applied effectively to the prescription of opioids in cases of chronic (secondary) pain care. This is a moral framework which can be applied in a clinical setting, to uphold the right to a quality of life of a chronic pain patient.

The doctrine of double effect is in principle about the positive outcome of an action, even though there could be a negative consequential impact – with a key emphasis on the *consequential*.

> "According to the principle of double effect, sometimes it is permissible to cause a harm as a side effect (or "double effect") of bringing about a good result even though it would not be permissible to cause such a harm as a means to bringing about the same good end" (McIntyre, 2004).

Though this seems a little like a riddle, what McIntyre articulates in the above can be broken down into two succinct points, which I have also converted into a diagram:

- It *is not* permissible to create the bad outcome even if the good outcome happened as a consequence or side effect.
- It however *is* permissible to create the good outcome with the side effect of the bad outcome as a consequence, as represented in Figure 6 below.

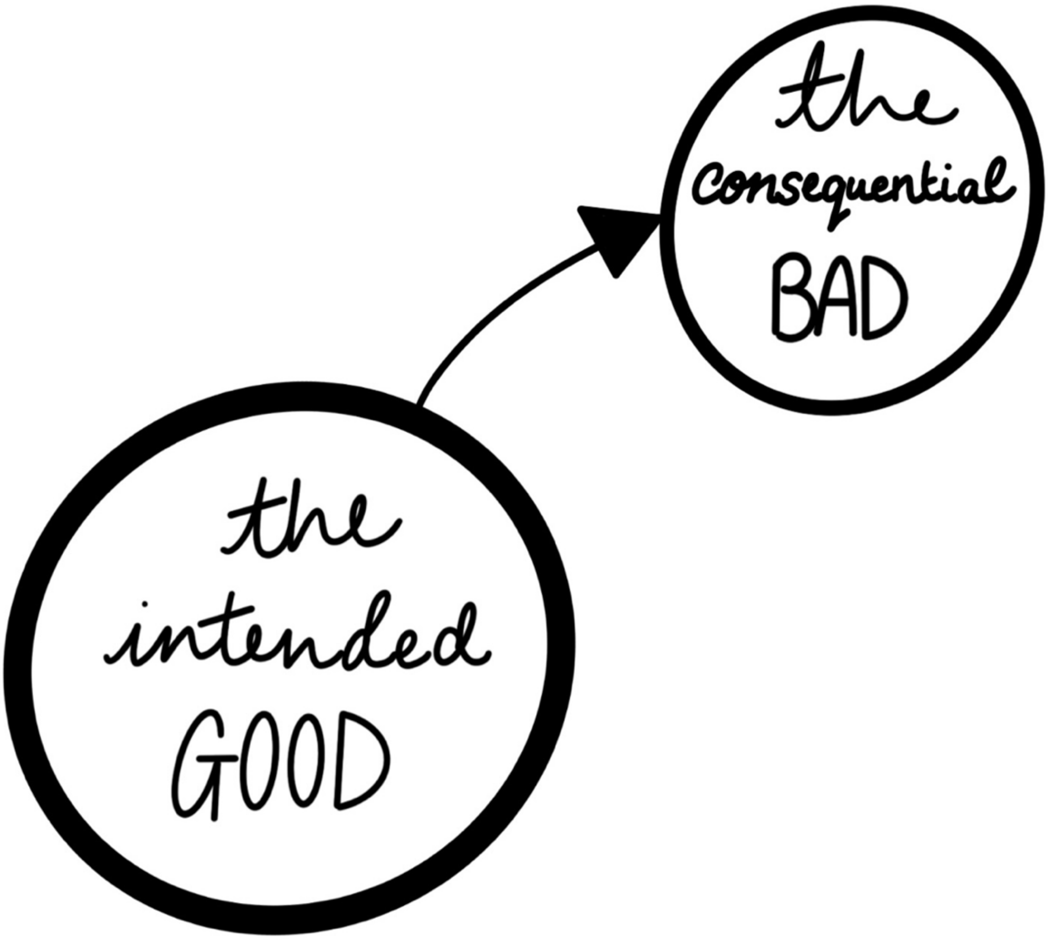

Figure 11 The doctrine of double effect

The important thing to note is that the doctrine of double effect only works one way – *morally speaking*. It's not interchangeable that the good outcome could be a side-product of intending the bad.

The doctrine of double effect works under the implication of there being both a *good* and a *bad* outcome from an action, and the doctrine itself is the moral framework that decides if the good and bad outcome are the correct way round for it to be ethically justifiable – and therefore if the intention is permissible. There are two possible scenarios when operating an ethical decision that contains the same good outcome and bad outcome – however one scenario *is* permissible, and one *is not*.

The scenario that is *not permissible* – is to intentionally create the bad outcome even if the good outcome happened as a consequence or side effect – is not ethically justifiable as a result of both the intention and the outcome being ethically subpar. When one intends a bad effect, even if the intention is to produce the good effect as a side result as well, then the moral behind the decision is still to intend a harmful product, whether or not they overtly care that the good outcome is happening or not. The side product, that's in this scenario the *good* side product, is not causing a problem or interference to the main intention. Therefore, to the individual intending the bad outcome, it doesn't actually matter much if it happens or not, in the sense that, whether or not the individual is encouraging of the good effect, it doesn't influence the success of the bad one. *The intention will always be harm*, whether or not they are hopeful or encouraging of a good effect also happening. Then there is also the way in which the outcome weighs in the morality of the decision. A guaranteed bad effect is the outcome, and no matter if the good effect happens – if it's bigger or better or more significant in its impact of anyone or everyone – it's still a secondary product. It's still morally less momentous in its ethical impact than the bad effect, because the bad effect is *primary* to the good's *secondary* status.

As an outcome, in this scenario ensuring the bad is more important than ensuring the good, and the intention behind it is to cause harm. Together, these are why it becomes morally impermissible by double effect to create the scenario illustrated in Figure 6.

In comparison, the scenario that *is permissible* – to create the good outcome with the side effect of the bad outcome as a consequence – is ethically justifiable because the intention *and* the consequence are both worthy of and ethically justifiable for the principle of double effect. The intention is pure in a way that the good effect is the only desired effect. The individual recognises that the good without the bad would be the ideal scenario. If it were possible to have the good outcome and not need any consideration that there could be a negative result too, then it would be ideal. However, unfortunately, in some situations there need to be a sacrifice – or in regards to the intention of creating good, be willing to concede the sacrifice as well as just having the knowledge it would be (or could be) an option. There has to be an acceptance and an educated, fully-informed understanding when committing a good act for a good consequence, when it is known that something bad may happen as well, as a result. It's a tough decision to make, knowing in advance that your good action means no harm, yet may end up causing it. The good intention – as well as the good outcome – needs to be extraordinarily worth it to the individual. As a consequence, ensuring the good is both the intended and the outcome outweighs the bad, though if someone is intending good then it's also likely they're going to do what they can to minimise the harm – or at the very least make sure not to do anything to maximise it. (If someone were wanting maximum impact of the bad outcome, then their intention switches to bad, therefore meaning it no longer fits as permissible in the criteria for double effect. Therefore, the bad side effect will always be minimised or not interfered with when the principle of double effect is positively identified in an action.)

The Doctrine of Double Effect on Prescribing Opioids for Chronic Secondary Pain.

In application to prescribing opioids for use treating chronic pain, the doctrine of double effect structures the argument as shown in Figure 7. The primary intention is to help the patients. Wanting them to have a better quality of life: one with reduced pain. One in which pain doesn't ruin every part of the individual's life, and they may be able to have a level of functionality that they could have only wished for before.

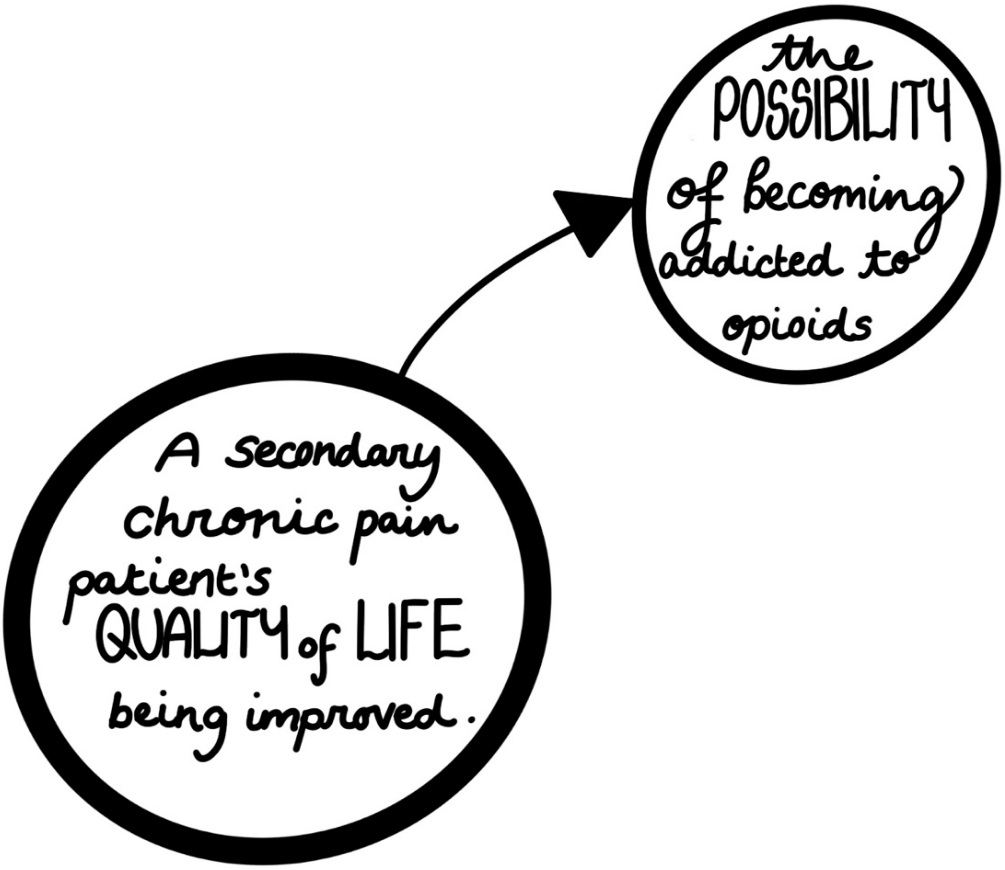

Figure 12 Double effect and opioid use for chronic pain

The *good effect* that is being brought about as primary outcome is: the quality of life of a chronic (secondary) pain patient being improved by the use of opioid based pain relief. The *bad effect* is an unfortunately unavoidable but morally permissible secondary consequences that a low percentage of those who are given the opioid based pain relief will become addicted to them.

From this follows the final important corollary: minimisation. In application to this particular case study, minimising the harm done by opioids can be achieved through understanding the patient's pain more thoroughly, i.e., better patient-doctor relations ensure trust is there if a patient is comfortable enough to approach their doctor if they feel they are in the early stages of becoming addicted without feeling like they are going to be penalised or punished; there needs to be regular check-ins to discuss the progress of their pain care; there could be more options of forms of opioids including buprenorphine which has a ceiling cap on the respiratory depression, meaning one cannot overdose on it (Dr Kunal Sood, private interview, October 2020). Dr Sood also spoke of the ability of using ketamine infusions being used to reset opioid tolerances back to baseline, a view corroborated by Neunhoeffer et al. (2017) in a *PubMed* article, which asserts: "Drug rotation to prevent opioid tolerance is well recognised in chronic pain management." There could be better opioid tracking from the patient themselves, structures to monitor medication use like physical diaries and medication apps; there could even be structures like support groups for patients who are using opioids long-term to give patients a safe place to feel their pain is being taken seriously. Each of which endeavour for the prevention of opioid addiction and misuse, and also the support of patients who rightfully need them.

Minimisation and Proportionality

The reason all these points are so important is that they are all forms of *minimisation* – of keeping the bad outcome still proportionate to the benefits experienced by implementing the good outcome.

The minimisation of harm at stake here isn't a new concept. The thirteenth-century philosopher Aquinas (2006) first discussed the idea of weighing the balance between the bad side-effect and the good outcome in regards to its *proportionality*.

> "And yet, though proceeding from a good intention, an act may be rendered unlawful if it be out of proportion to the end. Wherefore, if a man in self-defence uses more than necessary violence, it will be unlawful, whereas, if he repel force with moderation, his defence will be lawful" (McIntyre, 2004).

This sense of proportionality provides an initial way to measure the bad effect as a consequence of the good, and to ensure they remain within a reasonable measure of each other. The proportion of the bad effect has to be reasonable considering the amount of good being produced, for the bad secondary effect to be deemed permissible.

The above provides one reason why the doctrine of double effect is such a strong ethical framework for moral reasoning in messy, concrete situations. Nevertheless, it is important to recognise that this doctrine is not itself unitary but has changed, evolved and mutated in a number of ways since Aquinas—all these ways however articulate the same basic moral theory and its validity.

This is not to say that the doctrine of double effect is without it's criticisms, though, such as "The Right-Based Criticism of the Doctrine of Double Effect" (Kershnar and Kelly, 2020), who argue that if people have definitive and immoveable moral rights that other individuals cannot infringe on without being immoral, then the DDE cannot work, because even a good intentioned act can infringe on the rights of other people. Therefore, they argue that it cannot be both morally good and morally bad at the same time. However, they also argue that the DDE can begin to infringe on autonomy, using the medical example of a surgeon harvesting a person's organs after they die without their consent with the intrinsically good intention of saving 5 lives from the organs harvested out of the body. The intention would be the 5 lives saved, the secondary by-product being the autonomy of the first patient being disregarded.

To an extent they are right, it could be used to impede on a patient's autonomy if they are no longer able to advocate for their own rights. However, this argument cannot be then applied in exactly the same way to a situation where a patient has the capability to advocate for themself. Also, if a surgeon is making a decision such as that, they are acting with a paternalistic-model physician-patient relationship, which I have already explained the negative implications of.

Furthermore, a lot of their arguments, such as the hypothetical 'framing' of a homeless person to prevent a riot in which 5 innocent people die, they claim that the doctrine of double effect would permit if the primary intention were to save 5 innocent lives. However, there is a very significant flaw in their logic. These examples of the DDE allowing rights to be infringed no are within scenarios that only work morally in hindsight. They cannot work in the real world, because they imply that the application of the DDE is made because one knows the exact outcome with or without the principle (hence how they can allow their preferred morality to be based in consequences, because they apply it in situations where the consequences are guaranteed, already known, or entirely hypothetical

Unfortunately, that's not a luxury we are afforded in real-world medical care. When we cannot know the consequences to base our moral assessment on, then all there is left to apply our moral assessment to is the intention.

What this rights-based criticism proves is that DDE is a fallible ethical framework – all ethical frameworks to an extent are. However, that does not mean that it's not the most rational and beneficial (both in intention for the individual and for the greater good) in application to the context of opioid withholding from chronic (secondary) pain patients.

The Catholic Tradition of the Doctrine of Double Effect

In the post-Thomist Catholic tradition, 4 conditions/criteria were added to the doctrine in order to improve its implementation I am going to be looking at this development of the moral framework, because it shows that the doctrine of double effect is a moral framework which can develop and adapt over time, staying contemporary and relevant throughout periods of history – a timeless moral framework that can adapt and evolve to be as effective today as it was when it was first written about.

The first of these conditions is that:

1. "The act itself must be morally good or at least indifferent."

The nature of ‘indifference’ helps emphasise that the good outcome is intended, and the bad outcome is not a *means* to achieve it, but a by-product that happens as a result. The good act in the particular case study of giving opioids to chronic (secondary) pain patients in the pursuit of a better quality of life—this is a primary, positive result.

2. “The agent may not positively will the bad effect but may permit it. If he could attain the good effect without the bad effect he should do so. The bad effect is sometimes said to be indirectly voluntary.”

This in particular is entirely logical when it comes to real-world application – and its application in the real world is an important part of why I choose to use the doctrine of double effect as a suitable philosophy. This condition is saying that if there is a way to avoid the bad effect, and it was still chosen to achieve the *good* while knowing there is an avoidable *bad*, then it could be argued that the *bad* was *intended*. This condition places culpability on the intention. The balance between good intention and effect, and bad effect is delicate, and is the cornerstone of the very workings of the doctrine of double effect. The current condition defines the need for moral reflection at the level of intention. The following criteria does something similar but in regard to the effect.

3. “The good effect must flow from the action at least as immediately (in the order of causality, though not necessarily in the order of time) as the bad effect. In other words, the good effect must be produced directly by the action, not by the bad effect. Otherwise, the agent would be using a bad means to a good end, which is never allowed.”

The good action cannot happen as a *result* of the bad effect. The bad effect – remaining a by-product – can happen before the good outcome chronologically, but not logically. The good cannot be *caused* by the bad. It's not a sequence of events in which the good can follow the bad. By being a by-product of the good effect, it's reduced to consequential damage – and morally acceptable consequential damage at that.

4. "The good effect must be sufficiently desirable to compensate for the allowing of the bad effect."

The nature of compensation is interesting – though in practical application, or at least in my application to opioid care, I think it's more appropriate to consider if the good effect – such as achieving a quality of life – is *important enough* to make it worth the bad side effect. The importance of 'desirability', which in practice is the importance of having a quality of life, is of course a very desirable quality.

These four features formulated by the Catholic tradition not only improve the sturdiness of double effect because of their presupposition of minimising the bad consequential damage, but reinforce the need for intent and effect to both be good, and in proportion, as Aquinas intended it to (McIntyre, 2004). It also highlights the significance of the importance of the good effect.

Joseph Mangan

Joseph Mangan (1949) followed this Catholic tradition, but provided four additions, as opposed to adjustments, requiring that (McIntyre, 2004):

1. "That the action in itself from its very object be good or at least indifferent;
2. That the good effect and not the evil effect be intended;
3. That the good effect be not produced by means of the evil effect;
4. That there be a proportionately grave reason for permitting the evil effect."

Again, what is stressed is that the bad needs to be *proportional* to the good and this essentially tells us that when applying the doctrine of double effect to a practical, real-world scenario, the key question is: *'is it worth it?'* Specifically, is the quality of life being intended for a chronic (secondary) pain patient worth it? Is the good-intentioned effect worth the harm or the destruction that is going to happen as a result? Essentially, is the bad side effect going to cause a much more significant impact than the previous state of affairs?

While there is going to be certain level of subjective difference in answering these questions, the use of 'proportional' implies objective perspective — but in the application to 'real world' problems is an objectivity that is too rigid, and therefore cannot be reduced to logical interpretation.

There is also a particular final factor to bring into consideration. McIntyre (2004) explains that:

> "It is reasonable to assume that agents who regret causing harm will be disposed to avoid causing the harm or to minimise how much of it they cause. This assumption could be made explicit as an additional condition on permissibly causing unintended harm: 'that agents strive to minimise the foreseen harm."

Minimising foreseen harm is particularly interesting. Unforeseen harm is collateral that cannot be planned for – only *reacted to* – whereas placing a condition on the principle of double effect allows for some sort of feeling of control over then bad outcome.

Minimising harm is directly correlated to minimising the side effect. Technicality isn't the core of the principle of double effect – the core is the good intent leading to the good outcome, and as far as the potential fallout is concerned, bygones be bygones as a result. And part of that good intent is about not intentionally causing the bad outcome.

It could be posited that by letting the bad outcome be bigger than it possibly needs to be, then ethically the bad outcome is intentional. It is intentional to not minimise the harm done, therefore the bad outcome becomes inflated.

I take the position that quality of life for chronic (secondary) pain patients (the intended good), through the provision of properly monitored opioids, is proportionally worth the chance that a small percentage of those may develop the illness of addiction, and become addicted to those opioids. [29]

Ultimately, though, pain – just as with concern for the destruction caused by addiction – will vary infinitely between individuals, and therefore the concept of it being 'worth it' in regards to the patient's own determination of their wellbeing and quality of life being achieved, cannot be scaled down to numbers. All that can be evaluated, without devaluing the harm of opioid addiction, is that (i) being addicted to opioids is bad, and (ii) chronic pain is bad; but that in this particular application the addiction of opioids is both (i) not purposely intended; and (ii) only has a small chance of occurring and is certainly not guaranteed, only a possibility.

The doctrine itself recognises the consequential damage of the bad effect. It doesn't brush it aside, nor does it negate the significance of the harm done by the opioid crisis itself. It insists

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[29] And, yes, it could be said that if this was the ethical framework to justify the harm caused by the policy, it would have allowed the harm to chronic pain patients as a by-product. However, it also requires the minimisation of the bad effect. That *did not* happen with the policy. The harm was not immediately mediated when it became foreseen, allowing the 'bad effect' of chronic pain patients suffering to not be proportionally considered in the intention of preventing opioid addiction. There was foreseen harm *not* minimised, as well as unforeseen.

on the minimisation of harm, and that intention and outcome of an ethical framework should be morally good.

Section 4 Conclusion and Philosophical Application

When it comes to a case study as important as this, with real lives hanging in the balance, the need for a more suitable framework becomes that much more significant. Ethical frameworks that not only contribute to the diminishing rights of chronic pain patients but actively encourage it, prevent patients who are worthy of a quality of life from attaining it.

The concept of gaslighting (Tremain, 2020) is important when looking at the philosophical application of ethical framework to the case study of chronic pain and opioids. Pure theoretical understanding of philosophical approaches isn't enough when harm is being done to real people, it fails to recognise the consequences on an individual's mental and physical health when they are being gaslit by their medical professionals, i.e., *the consequences of this type of medical abuse* (Frasier, 2021). A 'doctor-knows-best', paternalistic attitude isn't just insulting and patronising; it makes patients who are incredibly vulnerable question themselves and their own experiences; makes them feel like they're alone; as though one is listening to their experiences and therefore feel unworthy of being listened to; like their feelings and opinions are invalid; like they're unimportant in the world; and it causes a rift of distrust between doctor and patient (a key factor to moving forward in safer opioid care). Patients suffer the cost of a doctor wanting to have the power over someone else.

I have concluded that the doctrine of double effect is a morally robust framework because it requires upholding ethical integrity of both the intention and the outcome, and is practical within the real world. It doesn’t use a ‘patient-centred-virtue-ethic’ nor a ‘patients-are-all-dupes’ ethical framework. In short, it consists of four main pillars which work for this case study:

1. Proportionality.
2. Morality of intention.
3. Importance of the good outcome.
4. Minimisation of the bad outcome.

The ethical framework leans on these four pillars to uphold both the intention and the outcome – a significant balance in philosophical reasoning, especially one being used in real-world application. This is a beginning in providing an alternative medical ethics model for pain patients when it comes to the prescription (or not) of opioids.

Section 5: Consequences (if the current analysis and response remains unchanged)

It may seem a little disjointed to go from two paragraphs with productive models on solving a problem to another reiterating the harm said problem has done – but it was of the utmost importance to me to truly drill home the ultimate consequences should we not change the way things are happening at the moment; and gains more insight into the case study in application to the philosophical frameworks – as opposed to the other way around. This is particularly important to look at in response to my thesis question, because it is a direct answer to how chronic pain patients became collateral damage of the response to the opioid crisis. The consequences are very literally *the* collateral damage.

Without understanding the consequences, the scale and magnitude of the impact that these policies had can't be fully processed; and I owe it to the chronic pain patients who have been suffering, and to those who have died as a result, to make sure that their legacy is in helping other chronic pain patients moving forward.

Chronic pain has a fervour unlike anything else. It is adaptable, manipulative, and invincible. Even when someone is just as adaptable, are alert to its manipulation, and never gives up – it'll always win. It lasts there through the sorrow and the joy; it's there for when you lose your faith and it's still there when you find hope. Whether on the days it's just a background noise, or when it feels like the loudest thing in the room – it'll always be there.

Patients with legitimate medical necessities are currently stigmatised as drug-seekers, as addicts, **as burdens on the medical system.** When what they truly need the most is support from the medical community. As I have reiterated repeatedly in this paper: if there were better, less dangerous, less addictive, and yet just as effective options available on the market, then I would wholeheartedly plea doctors to refrain from opioid prescribing. But medical and scientific care isn't there: the magical alternative doesn't exist. If we can create options that don't put patients at risk, which also support their quality of life and functionality – then they can replace the option of opioid care and begin to give patients the safe support they deserve.

There are current versions of opioids already in distribution which carry fewer risks than the traditional morphine or oxycodone. Dr Kunal Sood (private interview, 2018) informed me of an opioid which is becoming more available and accessible, called buprenorphine (NHS, 2020. Buprenorphine has a ceiling cap on the respiratory dysfunction that opioids can normally cause. One of the major symptoms of opioid overdose is respiratory arrest (Boom, 2012) cascading into respiratory failure. Buprenorphine has a ceiling (Walsh et al. 1994) that respiratory depression can reach, meaning it cannot surpass that level of dysfunction and the patient taking it cannot overdose on it in the traditional sense, since an opioid overdose (WHO, 2021) implies respiratory arrest as a result of too many units of opioid drugs. By new and less harmful drugs being created for the market, more options become open to chronic pain patients to reduce their suffering without as much of a risk. This being without sacrificing the quality of life they were getting on their older treatment, just with less harm as a consequence.[30] Unfortunately, buprenorphine – as revolutionary as it is in the prevention of overdoses – is still an opioid drug, and therefore carries the *addiction* risks that all opioids do even with reduced *overdose* risk. It

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[30] That's not to say buprenorphine is 'new', per se; one of the articles on its ceiling cap was published before the most recent opioid crisis even happened. But what is 'new' is it's appropriate application and use with a newfound purpose, and the sheer potential it has in over growing its uses, and developing new objectives for it in the helping of patients.

is, however, a perfect example of how new innovations in medicines and pain-relief products can begin to change and evolve to become safer and more productive. This means that frameworks and structures such as the doctrine of double effect are less depended on in medical decision making, because the bad outcome as a result of the good intention and action will be minimised.

For too long, both profit and medical politics have been put ahead of the well-being of patients. In the late 90's, Purdue Pharma put their profit margin before integrity and the care for patients they supposedly wanted to help. They exploited the hope of patients who needed their support, promising to have the next big thing in pain care innovation – and let patients put themselves at risk when they were taking medications promised to be far less harmful than they were. And now, profit still remains driving pharmaceutical companies, however medical politics and wanting to distance from the harm Purdue did has now contributed to swinging the pendulum in the other direction. Doctors don't want to prescribe opioids at all anymore, due to doctors 20 years ago prescribing too many.

There are also clinical commissioning group (CCG) decisions here in the UK that aren't as positively productive to pain patients as they could or should be. For example, lidocaine patches, which carry no side effects or risks in the way that opioids do and which can be bought over the counter in many, many other countries are only available under a select few CCG's for prescription at all in the UK, and can only be prescribed for inpatient care elsewhere (NHS 2020). They're topical and wear off after 12 hours, yet help some patients relieve their pain patient as much as opioids do. Logically, the positive progression for pain patients to not need to take as many opioids is to prescribe something like lidocaine with very minimal risk. However medical politics of each CCG having its own list of allowed medications for doctors within the county to be allowed to prescribe is standing in the way of that. By making unilateral decisions in a paternalistic way in situations such as this, the choices for patients to make autonomously regarding their own health has been illogically taken out of their hands, leading to frustration and even more distrust between doctor and patient.

Suicide Rates Amongst the Chronic Pain Community

Suicide rates amongst the chronic pain community are dramatically higher than in the general population. Unfortunately, this section is discussing the most severe and devastating collateral damage of all: those who have lost their lives because of it. Harvard T.H. Chan School (2018) discussed a study done on the CDC's records, looking at the information on 123,181 suicides. The study found that 1 in 10 of the suicides on record were people who had chronic pain of some sort. The article went on to report that:

> "Michael Barnett, assistant professor of health policy and management at Harvard T.H. Chan School, said in a September 10, 2018, Reuters article that the findings of the study don't shed light on the state of chronic pain management in the U.S. He did, however, say that "there aren't any medications that seem to be particularly effective for chronic pain.""

We know how much more common suicide is amongst those with chronic pain, so as a medical community we need to be moving forward with pain care – not restricting it. Options for pain-reduction need to be being added onto the 'table', not being taken off of it. By trying to move forward with anything less than the best of intentions to support chronic pain patients is equivalent to telling them their pain doesn't matter – their life doesn't matter as much as others' do. Ethically, not treating chronic pain patients as equals is about more than them being given the same treatment as anyone else – it's a case of importance in giving them the support to have equal opportunities in life than their healthy counterpart may have access to. The 1 in 10 suicides being of people experiencing chronic pain isn't the only damning statistic in this case. Relative to abled/healthy control subjects, risk of dying by suicide as a chronic pain patient nearly doubled the general average; and the amount of chronic pain patients who have suicidal thoughts (Tang and Crane, 2006). By not having frameworks in place such as double effect, opportunities to improve their quality of life and therefore reduce the risk of suicide are not as common as they need to be to save lives. It emphasises the dire need for better ethical structuring in policy care, because of the severe consequences.

Heartbreakingly, in 2021 the deeply feared consequence of reducing opioids for chronic pain patients was reported as having happened. In 2017, just one year after the CDC introduced the new policy to minimise opioid prescribing and prevent access to them – a patient in Florida died by suicide (Joseph, 2021), citing his lifeline of opioids being denied to him as the catalyst in the suicide note left to his wife. Brent Sloane had been on opioid medications to keep his unbearable pain at bay for 6 years, when his prescription was withheld and he ran out. He did everything from tracking down medical records, to calling his pain clinic again and again, and even showing up at the door. The script had been denied, without even tapering him off which would have been the safest thing to do. The 40-year-old pain patient sent his wife a text on the afternoon of the 12th of September 2017, saying "they denied script I'm done love you" shortly before he killed himself.

His wife – in an unprecedented but revolutionary legal case – sued the pain clinic for such irresponsible pain care. In result, the jury agreed that the pain clinic's care (or should I say lack of pain care) was reckless, and ultimately endangered Sloane. His suicide was a direct result of the denial of his medication, and wouldn’t have happened if not for the carelessness and flippancy that the pain clinic acted with when handling an opioid prescription. The clinic’s decision was made without giving any autonomy or consideration to the patient and his own declaration of his needs – and caused his death as a result.

Opioids – particularly in high doses – can’t be stopped at the whim of a doctor just wanting one less of their patients to be on opioids. Opioid dependency builds up for a long time, and especially in high doses, to stop them suddenly can shock the body into a withdrawal, a very serious medical situation which can be fatal in itself, let alone the suicide risk it lead to in this particular case.

> “Slone’s case is notable because it appears to be the first time a jury sided with a patient whose opioid medication was, in their eyes, improperly withheld. It is a sign of the growing recognition that after a reckoning over the damage wrought by prescription opioids, the pendulum swung too far back in certain cases and left another group of people with chronic pain at risk” (Joseph, 2021).

The concept of a ‘reckoning’ that happened in the pursuit of ending the opioid crisis with rash decisions and no regard to the patient’s quality of life is a particularly apt way to describe it. Paying penance for the sins of the opioid crisis, however, isn’t the pharma conglomerates – but is the pain patients who had no responsibility in the crisis whatsoever.

Beth Darnall (2021), a psychologist and the director of the Stanford Pain Relief Innovations Lab, points out the inadequacy of the belief that all opioids are bad, and that everyone needs to be off of them as soon as possible. “There is this rush, almost a panic, to decrease doses rapidly under the guise of patient safety, but the irony is these rapid changes expose patients to greater risk" (quoted in Joseph, 2021).

Patients wanting to go ahead on the journey of reducing their opioids are doing an extraordinary thing. Their bodies have to learn how to re-function amongst new neurobiological changes; they will experience the gruelling effects of withdrawal (though with slow and low tapering hopefully this can be avoided mostly); and the pain that they are enduring to be on the opioids in the first place will come back with a vengeance unless the patient who is being tapered has found an alternative pain reliever that maintains their quality of life. Unless someone is at serious risk of overdose or is allergic to an opioid that is used, then there is no other valid or viable reasoning for not tampering an opioid dose level over time. The shock-change with irresponsible care is doing far more harm to the patient than the opioid does, and is negligent.

'The Opioid Prophet' (Blaming, 2018) claims that the suicides among chronic pain patients aren't of people who've been abruptly taken off of their opioids. Such a significant figurehead in opioid policy and care seems to be gaslighting patients who desperately need support but instead are being told that their lives aren't important enough to dignify with validated feelings. Barstein (2020) writes:

> "On a larger scale, many critics of Kolodny believe that he is responsible for an epidemic of suicides of pain patients who have been denied opioids. "With any good lie, there's usually some kernel of truth," Kolodny said. If an individual who is physiologically dependent on opioids is abruptly taken off of them, it is true that withdrawal can be so physically and psychologically debilitating that people feel as if they are going to die. However, the claims made against Kolodny with regards to

> suicide do not involve patients who are abruptly taken off opioids, Kolodny explained."

$7 Million in compensation and a unanimous jury in the Sloane case (creating an entire legal precedent) would have to disagree.

The 'epidemic of suicides' that Kolodny is painting as some big conspiracy against is not sourced, giving no evidence of such inflated accusations, and is a gross exaggeration of the allegations against him. Many are calling for an acknowledgement that suicides have been happening, of which there *is* evidence of and since 2017 is also legal precedent of. Instead, the choice to gaslight patients and families of victims at their most vulnerable with accusations of being conspiracy theorists, as reported by Barstein (2020) is a complete denial of his responsibility in the (unintended) harm that the CDC has already openly admitted to. By taking credit for his actions when it suits (Blaming, 2018), and refusing to take blame for the consequences of those actions (Barstein, 2020), care for the patients takes a back seat to the needs of the policy makers. It's an unsustainable ethical framework to try and maintain, resulting in invalidation and disintegrating trust between patients and those who are meant to be supporting them. A framework like this cannot last long-term because any positive progress in chronic pain care will be disregarded as hypocrisy, stagnating the branch of medical care.

'Crip Theory' and Infantilisation

'Crip theory' is the colloquial term used for critical disability theory (Hall, 2019), the philosophical approach at the cornerstone of disability ethics. I need ot discuss crip theory and infantilisation because the way in which chronic pain patients were thrown to the side as unimportant collateral damage has also contributed even further to the infantilisation – and therefore the dehumanisation – of chronic pain patients. This also includes their human right to a quality of life. It focuses on ideologies of society, and their impact of limiting disabled people as opposed to the philosophy of the individual subjects themselves.

> "Julie Avril Minich argues that critical disability theory involves the "scrutiny of normative ideologies [that] should occur not for its own sake but with the goal of producing knowledge in support of justice for people with stigmatised bodies and minds." For this reason, thinkers should "recommit" to "social justice work" (Hall, 2019)."

As a social justice theory at its core, if the perspective of critical disability theory were to consider the application of the harm done to chronic pain patients as a result of withholding opioids, they would be appalled at the way society is treating chronic pain patients, who are being vilified and punished for a crisis they had no part in creating. Society doesn't acknowledge the nuances of the times opioids are being used validly and safely, they only know what the media tells them and of the drastic problems with illicit opioids causing havoc, which get generalised into one opinion on opioids, be them therapeutic or otherwise. Opinions like that Kolodny has presented perpetuate the patronisation of chronic pain patients as dupes who don't know what is best for themselves, infantilising them (Barstein, 2020). It is also not socially just to gaslight patients when claiming that the 'outcry' of patients desperate to be heard is just a conspiracy theory. Kolodny's attitude, shown in the following passage, is utterly insulting in more ways than one, and goes against every socially constructive or supportive philosophy for patients, just as social justice theories try to prevent.

> "Although Kolodny said Steinberg has ties to the opioid industry, he acknowledged that the rest of the protestors genuinely believe his stance causes harm to people suffering with chronic pain. Behind this sentiment, he said, "is a mixture of fact and fiction, or

> fact and conspiracy theory, even." One conspiracy theory Kolodny rejected is that he and Physicians for Responsible Opioid Prescribing secretly wrote the CDC guideline calling for more cautious prescription of opioids. Kolodny is the executive director of PROP, an advocacy and educational group pushing for responsible prescription of opioids" (Barnstein, 2020).

The first insult to critical disability theory is that The Opioid Prophet (Blaming, 2018) entirely invalidates anything that the protestors and patients are feeling in regards to the way they have been treated. He acknowledges that the patients 'believe' that he is causing harm – not that he is doing so. He then adds injury to said insult when he then proceeds to accuse patients of mixing facts with fiction and conspiracy theories. It's easy to spin the story of doing what's best for patients when the patients who are getting hurt haven't had the voice or platform to rebuttal. Furthermore, the only evidence of this supposed conspiracy theory even existing in society is of Kolodny's claims against it, not in the affirmative.[31] Social justice theories such as critical disability theory centre around the *respect* for those who are suffering at the hands of society. Having respect for chronic pain patients who have suffered at the hands of a policy is to treat them with dignity. Treating the patients with dignity means both (i) not lying to them in regards to information that affected their lives, and (ii) not gaslighting them when they enquire if they're being lied to. In this example of gaslighting, Kolodny denied he was behind the CDC guideline: "Kolodny brushed aside many of those concerns and instead focused on deflecting attention away from PROP" (Anson, 2021).[32] When the CDC eventually released details of the process behind the creation of the guideline (which took the threat of a lawsuit by the Washington Legal Foundation and threat of congressional hearing) it was discovered

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[31] I would love to read these specific claims against him to see what the exact accusations are, and could get a broader understanding of how PROP's involvement which has been misinterpreted as 'writing' the guidelines. It seems probable that if he had actually written the guidelines, he'd have taken the credit for it from the start.

[32] Anson's article includes the YouTube video of Kolodny's most recent interview (Kolodny, 2021).

that not only was PROP involved in the creation – but *five* of its board members were. As of March 2021, he still only admits to *three* members involvement (Anson, 2021). [33]

As a case study, it is extraordinary that someone should be so adamant in not admitting their involvement in something that caused harm, even if it was made with the best of intentions. The longer Kolodny denies any part in harm caused unintentionally, by gaslighting patients and significantly infantilising them, then in accordance with social justice theory he is continuing to harm more patients. Unlike the *unintended* harm of the policy, this time the harm is a continued *active choice* opposing the people implicated in cultural practice. He seems happy to take credit for what PROP has achieved with the withholding of opioids when he wants to be hailed; and seems happy to say it's a conspiracy theory when he wants to avoid the blame and consequences. In regards to Critical Disability Theory, what Shelley Tremain (2020) calls the 'structural gaslighting and [epistemic] injustice' means that patients "increasingly doubt their own observations and conclusions, especially their observations and conclusions about their own circumstances and statutes of affairs surrounding them". When someone is already in a vulnerable place, such as a person who is in debilitating pain all of the time, they are easier to manipulate. Making someone in a vulnerable situation question their reality around them makes them feel even more isolated than they already are. They begin to lose faith in themselves, and can fall into the control of the person who wants to make them believe they have none.

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[33] "PROP President Jane Ballantyne and Vice-President Gary Franklin were members of a key advisory panel; David Tauben was on the guideline's peer review panel; and Kolodny and David Juurlink were on a stakeholder review group. While technically true that PROP did not write the guideline, PROP had input and key relationships within the CDC. Dr Roger Chou, one of the guideline authors, has collaborated with PROP members on several occasions, such as writing an op/ed with Ballantyne that encouraged doctors to consider tapering "every patient receiving long term opioid therapy" (Anson, 2021).

To emphasise, the guideline that the CDC produced isn't gaslighting patients: the gaslighting is what happens when even the CDC themselves have recognised that (unintended) harm was caused by the policy, but when an individual remains doing interviews and lectures claiming that the claim of harm is all just a conspiracy theory created by pharmaceutical companies, and therefore patient's feelings are invalid because they have been manipulated into feeling that way. The gaslighting of patients does nothing to support victims of the opioid crisis, does nothing to prevent further victims of it, and is at its foundation a purposeless medical-abuse (Dandraw-Seritt, 2021) of chronic pain patients. The infantilising that often goes with it is relevant beyond just ethical capabilities, but clinically too, since if patients are being assumed to be dupes who aren't able to make their own decisions, then it brings back into question patients' mental capacity; and philosophically begs the concept of responsibility into question altogether (an issue which space precludes my exploring in full here).

In combating the horrific opioid crisis, unilateral moves were consequently made on behalf of chronic pain patients who were entirely capable of giving their full and balanced consent, it they had been fully informed in order to make their decision. The opioid crisis saw infantilisation contribute towards harm – be it the harm to those who became addicted, or harm to chronic pain patients themselves. When Purdue Pharma took away the true and correct information needed, as a result they intentionally withheld the ability for patients to give consent (Purdue Pharma, 2021), taking away their right to make decisions for themselves. Then, when the pendulum swung too far in the other direction, the doctors who used the CDC opioid guidelines too severely *also* took away the ability for informed consent, because even if a patient was fully informed about the risks and hazards that come with taking opioids, they took that decision out of their patients' hands and decided that they knew what was best for them.

Long-Term Conditions Need Long-Term Solutions

When dealing with long-term conditions, as well as looking at the long-term risks we also need to be looking at long-term solutions. This may be ironically the most important part of my collateral damage section, because it’s the slight glimmer of hope that there is a way out of it. That things can change, and if we learn why chronic pain patients deserve a quality of life, and how they became collateral damage of a crisis that was of no fault of their own, then maybe we can prevent further damage and learn from our mistakes. But this also means taking responsibility for trying to do the right thing and minimising the risks to the public of opioids, however unfortunately that risk now weighing out with the reward in the lives of those who are ow suffering as collateral damage.

Risks (in this context) are things to be prevented by making choices that minimise harm; solutions are the progression of moving forward. For example, finding a solution for patients whose long-term chronic secondary pain means a requirement for long-term pain management medications – in a way that reduces and minimises addiction risk and won’t perpetuate the harm already done by the opioid crisis.

A long-term solution looks like using Ketamine infusions to both prevent hyperalgesia (the condition of extra pain and sensitivity from opioid use) and prevent opioid tolerance getting too high, and therefore being able to keep dosage levels low even though there may need to be people using opioids– sustaining long-term opioid use safely.

A long-term solution looks like patients being treated as individuals – not letting a blanket policy make prescription decisions for everyone and just hoping that as many people as possible fall in that category.

A long-term solution looks like pain patients who are already on opioids having access to more regular support, such as check-ins with their doctor to make sure the opioid they're using is remaining the most effective opioid for their pain, and that they know about all the other options available for them. Checking that their dosage is still effective, and if it isn't, investigating in an unbiased manner whether that is due to tolerance, hyperalgesia, or is simply a progression in the condition which is causing an increase in the pain source.

Philosophy is only useful when it can be used as a tool to solve *real-world problems*; and we need ethics with a framework which values patient's lives to sustain advancements such as these going forward in chronic pain care, and in the use of opioid treatments. Using philosophical principle to create and sustain long-term solutions will help to combat the crisis for both those who have fallen victim to the opioid crisis, and those who are suffering debilitating chronic pain and deserve a quality of life. Using better and more sturdy ethical frameworks can make sure that in moving forward, there is as little un/foreseen fallout of collateral damage as possible.

Section 5 Conclusion and Philosophical Application

Opioid care needs more stable ethical framework in order to progress in both the long-term and the short term of pain treatment. Chronic pain patients are already at much higher risk of suicide than the general public (Harvard T.H. Chan, 2018). They need more support from the medical community, not to be dropped like they're burdens on the system and burdens to their doctors. Heart-breaking cases like that of Brent Sloane are the extreme – but *have* been happening as a result of withholding opioids (Joseph, 2021).

Critical disability theory is a school of philosophy already rigorously fighting against social injustice that chronically ill and disabled patients, with one pillar being the humanisation of disabled and chronically ill people. Remaining on course would continue to see chronic pan patients being infantilised, controlled, and manipulated when it's deemed necessary by people who don't have the firsthand perspective of living in excruciating permanent pain. The current format of coping with the opioid crisis is dehumanising for chronic pain patients. A paternalistic indoctrination approach that has been the response to the opioid crisis up until now is insulting at best, and harmful at standard. A philosophy that upholds the values and the legacy of both opioid crisis victims and chronic pain patients, by not letting the pendulum swing too far in either direction this time, is one that will hold the most potential for longevity and at treating people like the human beings with rights that they are. Thankfully, the CDC has begun proposing altering their guidelines on opioid prescribing to try and prevent unintended harm caused by it; and though it can't erase the damage to pain care,[34] or bring back the lives

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[34] This damage would have not been necessary if the CDC had not been put in the position of having an opioid crisis to solve. Blame for the damage caused to pain care is the ultimate responsibility of the pharmaceutical company that caused the opioid crisis two and a half decades ago.

lost by suicide as a result of wrongfully withheld prescriptions, it can change the future of pain care and give back to patients their right to a quality of life.

Conclusion

The first time that a doctor questioned *my* medications because of a crisis happening on the other side of the planet, I knew I needed to do something to help those around me that it was happening to, as well. I'll never be able to reiterate enough that I'm not here to promote opioid care, nor am I here to promote *overzealous* prescribing – even in chronic secondary pain patients. I'm here to frame the need to respect a chronic pain patient's right to a quality of life.

Their right to a life worth living.

As I started writing this conclusion on a flight home from Ibiza in September 2022, I began talking to the lady next to me on the plane, who told me that just three nights ago she was sitting on her balcony in so much pain that she thought about just throwing herself off, because she had been managing her pain with opioids for over 10 years, and in this past year has had them withheld. Her pain was un-liveable, un-bearable, and un-treated to the best of the capabilities that modern medicine has. And it nearly cost her life, just three days before I crossed paths with her. I tell this story to illustrate that it isn't just happening in rare cases found deep in the internet. There are patients all around us who are silently suffering – some nearly to death – as a consequence.

That is why I fight so hard for patient care to improve with the use of sturdy philosophy, and for those who disrupted it to take responsibility for the unintended harm they caused. Without taking responsibility, in this post-CDC-admittance era, then continued denial in any unintended harm is simply the choice to gaslight patients (Tremain, 2020), now causing intended harm.

My first section explored the medical and historical background of both the Opioid Crisis and Chronic Pain, because the distinction between different types of chronic pain is vital in exploring the utility and validity of opioid use. Chronic *(Secondary)* Pain (WHO, 2015) – the pain I have been referring to – involves a primary physiological condition, to which the chronic pain is secondary. This is important because if opioids are being used as a resource to target pain, then they need to be effective, and to be effective they need to be able to interrupt nerve signals by attaching onto/activating the opioid receptors. The effectiveness of opioids is entirely reliant on it being able to intercept those signals in the nerve cells, and the pain signals sent with chronic (primary) pain are different (NICE, 2021), so therefore respond to opioids differently, too.

The history of the opioid crisis was also key to explore in order to see the lasting damage done by the *response* to the opioid crisis, as well as the crisis itself. One harm does not invalidate the other, nor do they override each other. Both are tragedies which have led to harm and death. The CDC categorises the most recent opioid crisis into 3 waves of progression. Each wave was a new chance for policy intervention, preventing further harm in both the crisis and to pain patients. Instead, 20 years into the crisis meant a blanket policy trying to help everyone, but while harming those in its path (National Vital Statistics System Mortality File, 2019). The 2016 CDC guideline (Dowell et al., 2016) was published in the hope of preventing *over-prescribing* of opioids by pain doctors; however even the CDC themselves have now admitted in hindsight that the policy has caused ‘unintended harm’ – swinging the pendulum in the opposite direction – even if some outright claim that said pendulum apparently hasn’t (Kolodny, 2021, 7:24). These were important to explore within the first section – not only because they provide the foundations for my entire thesis – but also because they lay the foundations for 'how' chronic pain patients have become collateral damage of a response to an epidemic, allowing me to explore the 'why'.

The second section is about 'why' chronic pain patients have become collateral damage of a crisis they had no part in creating: concluding that there is currently not a sufficient or clear enough distinction between *the psychological illness* of addiction and *the physiological medication-side-effect* of dependency. This section helps explore the neurobiosocial, behavioural, and textbook definitions of the two terms; and creates a clear-cut line between the two. Opioid dependency is a biological guarantee of opioids, it's an unavoidable side effect of taking the medication; whereas addiction is an illness within itself that those who take opioids could develop as a consequence – but those who don't take opioids can have it as well. It needs to be distinguished, so that chronic pain patients who have retained their capacity to make decisions about taking the medication will stop being incorrectly categorised as addicts, because it has been altering their pain treatment even when there is no alteration to the condition. This lack of distinction is one of the key reasons in why chronic pain patients became implicated in the opioid crisis in the first place. There is minimal ethics behind letting actions be taken on indistinct and unclear information – like if a sergeant gave orders while acting on bad intel.

The third section is the cornerstone of the ethical analysis within my exploration. After evaluating the ethical structures which are currently surrounding the opioid crisis and its impact on chronic pain patients – unfortunately also finding the ways in which these currently exploit patients, infantilise them, and interrupt their opportunities to access the care that they have a right to – I present my argument for the doctrine of double effect. Evaluating the doctrine of double effect as a framework serves the important purpose of showing how allowing opioids to be used long term for certain individuals with chronic secondary pain is ethically sound – even if the risks were to unfortunately fall true. Ethically, there is a way to move forward in which the approach is unprejudiced and considers all eventualities and outcomes in comparison to one that lets pain patients suffer. It's objective, unlike one which unfairly puts the weight of the world on the shoulders of someone who doesn't deserve it, by letting patients be pseudo-punished for the crisis that they had no hand in creating.

It allows us to see that there *are* ways in which we can positively move forward, and allows for patients to be treated as the individuals they are, whilst being objective enough to create a fair and balanced ethical framework that protects them and their doctors in a secure way.

The penultimate section is one devoted to both the implications of quality of life versus quantity of life, and that of quality of pain versus quantity of pain. A quality of life is paramount in this discussion – just like any other human being, a chronic pain patient has the right to the best quality of life that modern medicine can assist them to. If that can be achieved in any other means possible (and safer) than opioids then it should be strived for, however if that ability is not there then the intrinsic right to the quality of life for the patient has not been altered as a result. Regardless of how the medical community can help to achieve it, a chronic patient has an inherent right to have a quality of life – one which is well categorised by the WHOQOL (2021); and which I have proven is impacted by chronic pain in every single possible way. Chronic pain has such a significant hold over the ability to achieve a quality of life, that any reduction in the pain will improve the life's quality. I also explained how understanding, and being able to better explain, the quality of a patient's chronic pain and not just the quantity of it is benefiting chronic pain patients globally already. When I created my chronic pain scale, the way it was received by the chronic pain and medical community so vastly baffled me. But it's utility goes beyond helping patients communicate their needs, and feel validated and understood; with better understanding of the pain that patients are enduring, opioids can be prescribed in only the appropriate situations for them, whereas alternatives such as muscle relaxants and NSAIDS may be determined as more useful that opioids. As a consequence, making opioid prescribing safer. The charts of comparison between a patient's preference in their quality and quantity of life and pain also help patients and their doctors understand their priorities in the use of pain relief. Ultimately, allowing for more responsible prescribing as well. Philosophically, the importance of patients being able to better communicate is not just in the validation of the patient – but it allows doctors to be morally responsible for their decisions while knowing the clearest information from their patient. A better patient-doctor relationship will lead to more trust, and trust is an invaluable resource in pain care – particularly when opioids are added to the relationship.

None of which I would have needed to assess, of course, if chronic pain patients *weren't* being treated as collateral damage in the clean-up of a crisis that happened for greed and profit (Van Zee, 2009).

The final section of my thesis looks at the heart-breaking consequences of the 'unintended harm' that the response to the opioid crisis caused. As Kolodny (2021, 7.00) rightly pointed out, the idea of a 'suicide epidemic' is an over-exaggeration[35]. No specific data has been collected of whether suicides of chronic pain patients were consequent on a withholding of their opioid medications. However, there are documented cases, including one that has set legal precedent in the US. (Joseph, 2021). One life lost because of irresponsible patient care as a result of a guideline that did not show ethical consideration is a life too many. Long-term

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[35] Though I have found no evidence thus far of anyone making this over-exaggerated claim.

conditions need long-term solutions to help solve them, and thankfully the CDC have begun making the changes that although can't undo the unintended harm – can hopefully prevent more of it in the long-term.

My thesis doesn't seek to apportion the blame; it's not intended to be a 150-page accusation at the CDC, nor a witch hunt for those behind the policy. Quite the opposite: it's about those who are responsible taking accountability for the unintended harm that their actions caused – even though they were without malice – and then all moving forward positively to improve pain care. It's about acknowledging the harm caused *with enough respect for those hurt* to want to recognise the shortcomings of the policy, and caring enough about the patients suffering to do something about it in the future. By not only refusing to acknowledge the harm that has been done to the chronic pain community, even now that the CDC themselves have, but actively trying to discredit and alter the perception of those who are fighting for the right to not suffer more than they have to, is philosophically equivalent to standing by and watching while knowing that more harm is to come. "Standing by and doing nothing while a sin is committed is as bad as committing the sin itself" (Tripathi, 2012). The CDC have acknowledged that unintended harm has been caused. All that can be done now is to work progressively to prevent more harm being done, particularly with the new proposal for changing the guidelines – while ensuring we do not negate the travesty and devastation of the opioid crisis. It'll be a long process, and there is a lot of work that needs doing – but I fight on behalf of every patient who can't.

The pendulum needs to swing back into balance. Chronic pain patients have a right to a quality of life, and should never have become collateral damage in a war on opioids that they had no hand in causing.

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