

The Assisted Dying Bill: an Analysis

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legislative drafting
 close readings
 parliamentary counsel
 bills
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 assisted dying
 legislation



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§ 1 Introduction

NYONE following the news of late will have seen the major debates emerging over the Terminally Ill Adults (End of Life) Bill, introduced as a Private Member's Bill by Ms Kim Leadbeter MBE MP (Lab, Spen Valley). The bill is a matter of considerable passions both for and against it. Those seeking a case in moral philosophy, theology, practical ethics, or any similar field for or against assisted dying will not find it here.² Rather, as a student of legal writing, I wish to examine how the bill is written. My principle is that, while there is intense disagreement on the question of whether assisted dying is moral in

- 1 Published on introduction as Bill 12 , hereinafter 'Bill'
- 2 For the sake of convenience, I will use the term 'assisted dying' throughout this Note rather than 'assisted suicide', 'aid-in-dying', 'euthanasia', 'compassionate release', 'legal killing', or any other of the euphemistic and dysphemistic terms proponents and opponents use. No philosophical implication is meant by this; I merely find the term 'assisted dying' convenient and in common parlance.

any circumstances (with good and coherent arguments on both sides of that point), no one sensible would say that enabling assisted dying is moral in all circumstances. There are clearly circumstances where a lax regime leads to assisted dying becomes immoral and dangerous. The regulatory environment and legislative specifics make an enormous difference. In this Note, I will examine closely and critically the text of the Bill, highlighting a series of what, to me, are clear flaws in its drafting which render it unworkable short of major amendment. My point is not about the entire question of assisted dying generally—there are more qualified people than I commenting on this matter. Rather, it is the question of drafting—is the bill fit for purpose? On the basis of the following analysis, I firmly answer, 'no'.

§ 2 Mental health against capacity

The most prominent and, in my opinion, most clearly fatal error in the bill occurs in cl 3, which ties the inquiry into whether or not a person is allowed to make the decision to end her life solely to the Mental Capacity Act 2005. This is a grave and serious error, because it elides, either intentionally or by incompetence, the major distinction between mental capacity under the 2005 Act and the notion of mental health under the Mental Health Act 1983. The grave consequence, which must be justified by the Bill's proponents, is that someone may have capacity for a decision to obtain assisted dying notwithstanding judgment partially impaired by a mental disorder.

While it might seem to the layman that 'mental capacity' and 'mental illness' are synonymous, they decidedly are not. While someone can fall under the ambit of both acts, many people are in one but not the other. For example, someone with severe cognitive disabilities will likely fall under the Mental Capacity Act 2005, because in some regards 'unable to make a decision for himself', due to these disabilities.³ This person, however, does not fall under the 1983 Act because he does not have a 'disorder or disability of the mind',⁴ as the 1983 Act makes explicitly clear that such cognitive disabilities are *not* a mental health condition unless they are 'associated with abnormally aggressive or seriously irresponsible conduct on his part.'⁵

Conversely, someone who is very depressed or has suicidal ideation can and will very much still have capacity for almost all decisions under the purposes of the 2005 Act. As the Baroness Hale of Richmond noted, the 2005 Act continued the common law presumption of capacity and the rule that the 'the threshold for capacity is not a demanding one.' The consequence of the use of capacity but not mental health in the thresholds is that except where a mental health disorder directly prevents someone from making healthcare

- 3 Mental Capacity Act 2005, s 2(1)
- 4 Mental Health Act 1983, s 1(2)
- 5 Mental Health Act 1983, ss 1(2A), 1(4)
- 6 MH (by her litigation friend, the Official Solicitor) v Health Secretary para [2006] AC 441, para 26, HL per the Baroness Hale of Richmond

decisions (as about assisted dying), someone with a mental health disorder can simply breeze through the process legally, as the doctors and judge will have to certify him if he has legal capacity, disorder notwithstanding.⁷

To be clear, there are numerous cases where a mental disorder will render a person incapacitate under a 2005 Act, but the fact that the Bill does not deal with the substantial portion of cases where the two do not go together means that an unknown swathe of people are left in a gap. Those who might think that a desire to end one's life by someone with depression is inherently an impingement on capacity are wrong. Where depression and a terminal illness are co-morbidities, a person may merely be making an 'unwise' decision, which is not a sign of being incapacitate. The Court of Appeal has made clear that the 2005 Act requires a 'statute requires there to be a clear causative nexus between mental impairment and any lack of capacity'; where someone is both depressed and suffering a terminal illness, that causative nexus is much less clear. Furthermore, the 2005 Act analysis does not allow the outcome of the decision to be determinative of capacity, meaning that the decision resulting in death is not sufficient to indicate incapacity where a mental disorder is present. To

This is already capable of illustration under existing law. In *King's College Hospital NHS Foundation Trust v C*, MacDonald J considered a patient who wanted to discontinue her life-extending dialysis treatment because, *inter alia*, she 'felt she did not have the mental health to continue with the treatment', and was not satisfied with living merely a 'tolerable' life. The examining doctor suggested (in a tentative diagnosis limited by the patient's ill-health) a personality disorder was present that interfered with her capacity. His Lordship was not persuaded by submissions from doctors that the patient was not solely deciding things by the catastrophic interpretation of events potentially resulting from her mental health; rather, Macdonald J saw many factors (of which this might be one) at work. The 2005 Act required strict causation and it would be difficult to establish the line between a personality disorder and being a 'strong willed, stubborn individual with unpalatable and highly egocentric views' (the patient potentially being both). Consequently, MacDonald J, while acknowledging that the patient's potentially irrational decision 'will alarm and possibly horrify many, hovertheless found capacity.

My purpose here is not to criticise MacDonald J, but to illustrate how fine the lines can be. This is more tolerable in a system of refusing life extending treatment than in one in

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The issues of discretion are discussed further infra.

Mental Capacity Act 2005, s 1(4)

York City Council v C [2014] Fam 10, para 52, HC per McFarlane LJ ibid, paras 53f

[2015] EWCOP 80, para 72, per MacDonald J

ibid, para 79

ibid, paras 41–46

ibid, paras 70 et seq

ibid, para 93

ibid, para 97
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which the government and health services are causing the deaths by active intervention. The obvious point to avoid this danger would be to draft to consider mental health as well as capacity.

California's assisted dying law, in fact, does exactly that. The End of Life Option Act in that jurisdiction, as codified, provides in this regard as follows (emphasis added):

California Health & Safety Code

§ 443.5 Prerequisite determinations by physician

- (a) Before prescribing an aid-in-dying drug, the attending physician shall do all of the following:
 - (1) Make the initial determination of all of the following:

(A)

- (i) Whether the requesting adult has the capacity to make medical decisions.
- (ii) If there are indications of a mental disorder, the physician shall refer the individual for a mental health specialist assessment.
- (iii) If a mental health specialist assessment referral is made, no aid-in-dying drugs shall be prescribed until the mental health specialist determines that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder.

The California drafting has two essential components which the Bill lacks. First, any indication of a mental health condition, even as a co-morbidity, stops the process at once and diverts the patient to a full mental health assessment. This occurs regardless of capacity. The Bill contains no such 'brake' provision. In fact, it appears to expressly *bar* such inquiries by only permitting psychiatric referrals for doubts about capacity,¹⁷ a much lower threshold than for mental illness impairing judgment.

Just as importantly, the assessor will consider not only the question of capacity, but also the question of whether judgment is impaired by a mental disorder. This means that cases where someone might have a mental disorder as one of a number of factors influencing a choice of assisted dying is not eligible. It prevents someone, like the patient in the case of C, who has judgment influenced by a mental disorder but retains legal capacity, from being helped to die.

This drafting analysis makes an implicit moral assumption—viz, that a prudent system with proper safeguards (such as the Bill's proponents say they desire) would not risk the chance of someone with a mental health disorder impairing judgment access treatment

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17 Bill, cl 9(3)(b)
18 n 9
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to end her life, capacity notwithstanding. A cautious system should always lean towards denying treatment where there is any doubt. This is not analogous to any other case of existing medical treatment. It is not, in fact, treatment. It is the provision of death. The standards should be stricter.

One would think that the drafters of the Bill would have read models from jurisdictions often cited as successful, such as California. Had they done so, they would have seen the simple drafting that prevents a grave risk to the integrity of the safeguards in an assisted dying system. If the drafters are not reading and citing other jurisdictions (both as examples to follow and models to avoid), then that is immensely concerning and may explain why the Bill has so many flaws. Conversely, if the drafters read the Californian legislation, and chose not to follow it, that is also a bad sign. It indicates the safeguards are intentionally not as robust as international comparators.

Either way, this is a matter of immense concern. The absence of references to mental health in the sense of the 1983 Act is so disturbing that I consider it sufficient reason, absent future amendment, to reject the Bill.

§ 3 A dearth of discretion (except when doctor shopping)

The Bill purports to have three levels of safeguards, *viz*: the assessment of a first doctor, ²¹ a second ('independent') doctor, ²² and then by a judicial officer of HM High Court of Justice. ²³

This seems rather robust. For all the flaws of the judiciary, it is hard to pull the wool over a High Court judge's eyes. However, on examination, the Bill presents a thread that unravels the entirety of its case for safeguards. It is the word 'must'.

In all three cases (two doctors and a judge), the role of the inquiry is limited to verifying if a checklist of factors are met, of which the most important are the person being terminally ill, having capacity, and a settled and informed wish to end her life.²⁴ If these are met,

- 19 I will be citing California throughout this Note in part because it is—ignoring the moral questions over if this should ever be allowed, at all—to my mind a successful system inasmuch as its safeguards appear robust in theory in practice. There are other jurisdictions which are cited in this regard, but the only 'successful' one with which I am familiar to a sufficient degree to cite in comparative analysis is California.
- 20 Or, that of any other jurisdiction with similar safeguards.
- 21 ibid, cl 7
- 22 ibid, cl 8
- 23 The Bill does not specify that the judge in question must be a High Court judge, as opposed to a deputy High Court judge or a master; I presume that the intent is that a full judge of the High Court is intended, but presuming things is a dangerous game here.
- The factors differ slightly between each safeguard, mostly due to verifying earlier steps in the process. For the first doctor, see *ibid*, cl 7(2)(a-g). For the second doctor, see *ibid*, cl 8(2)(a-e). For the judge, see *ibid*, cl 12(3)(a-h).

the safeguard has no discretion and must grant it.25

This robs the process of any safeguarding validity. Context is everything in the law.²⁶ In everything from sentencing to child custody, there is a recognition that discretion means that there will be scenarios where a default assumption must be parted with; the only notable crime with a sentence absolutely fixed by law is murder's mandatory life sentence, which in practice achieves variation by both partial defences and differing tariffs. The reason for this is that the human being does not fit neatly into cells on a spreadsheet. There are always unforeseeable scenarios that require a judge or decision maker to use her discretion to approach in a way that is both consistent with the law and reflective of the circumstances at hand. There are scenarios where justice might require a homicide might walk free and a first-time thief is sent to prison.²⁷

One of the reasons that judges of HM High Court of Justice are given life tenure until the statutory retirement age is that they are trusted in their experience, wisdom, and judgment to be able to carefully consider the factors that make cases difficult to decide. The same is true of the position of trust and power (such as to prescribe) which medical doctors hold in society. Yet, under the Bill, these professionals are reduced to clerks. A patient who checks every box yet over whose decision the doctor or judge feels grave doubts *must* be sent on to die. That ignores the fact that a choice may be legally voluntary yet also morally compromised (such as by financial pressure).²⁸ What, then, is the point of the judge and the doctors if they cannot apply their professional judgment? The forced checklist approach reduces humanity to a series of yes/no questions. It is not an approach that anyone would advise in any area of the law and is especially ill-suited to one involving people being killed.

The result is that the process seems to be a Potemkin safeguard, in which the three voices are there mainly to give authority to a decision. It is here useful to compare it to a policy recognised as failed. Prior to the Mental Health Act 1959, judicial officers would issue 'reception orders' for the detaining of lunatics in asylums. These arrived in court on the basis of a written petition by someone familiar with the alleged lunatic (preferably by the alleged lunatic's husband or wife) and two medical certificates; on the basis of these papers alone, the judicial officer was permitted but not required to issue the order, without ever having seen the alleged lunatic.²⁹ This process gave considerably more discretion to the judge in whether or not to detain the alleged lunatic than is given to the High Court judges here,

- 25 For the first doctor, see *ibid*, cl 7(3). For the second doctor, see *ibid*, cl 8(5)(a). For the judge, see *ibid*, cl 12(2)(a).
- 26 Cf Stack v Dowden [2007] 2 AC 432, para 69, HL per the Baroness Hale of Richmond
- 27 I think these are very rare scenarios, but in a population of sufficient size, very rare scenarios will with some regularity pop up once in a while.
- 28 Consider, for instance, that the law recognises consent to sexual relations as voluntary even where motivated only by a need for money on the part of one of the parties. This may be fine for sex (I have no more qualification nor desire to speak on the morals or policies of sexual regulation than on assisted dying), but is rather more permanent with regards to death.
- 29 Lunacy Act 1890, ss 1-9

whose decision is dictated by a checklist. Yet, as one might expect, judges under the 1890 Act were viewed as nothing more than 'a "rubber stamp" of little practical value in challenging the decision to detain.'30

There is no reason to think that under the Bill judges, given less discretion than under the 1890 Act, will be anything but more constrained. The judges are further able to find facts only through inquisitorial proceedings, as no advocate is appointed for the case against assisted dying;³¹ English judges have many skills but are not examining magistrates (notwithstanding the occasional description of some family court processes as inquisitorial).

The same can be said of doctors; we would be horrified if told some old lunacy legislation required a doctor to recommend sending someone to an asylum based on a default checklist rather than an organic analysis. Yet, the 'must' here does precisely this. It again raises the question: what is the point of these careful opinions if professional judgment is circumscribed?

It is not a point in the Bill's favour that the one area where significant discretion is granted is in the field of doctor shopping. A patient desiring to end his life is able to pick at his discretion a first 'co-ordinating' doctor. The Bill does not provide that a patient can shop for a number of doctors until she gets a positive decision on the checklist, but it also does not forbid it and, as far as I can tell, would allow for an unlimited number of first declarations given the complete discretion on cancellation.³² The first doctor then refers to the 'independent doctor' (presumably 'independent' here being used to indicate that the second doctor is independent of the first, although ideally both doctors would also be independent of the patient). If, even given the strict checklist circumscribing discretion, the independent doctor rejects the patient as failing the checklist, there is an express allowance for the first doctor to make another (though only one) referral and try to find another doctor who will say 'yes' this time.³³ Combining the two provisions (the ability to cancel declarations and re-make first declarations alongside the first doctor's ability to shop), it seems that the patient and the first doctor have quite a lot of discretion in finding someone whose reading of the checklist leads to 'yes'. Why is there wiggle room here and only here? It reads like the Bill is trying to make the safeguards consistently lead to one outcome—in favour of the provision of assisted dying.

Again, the California law provides an instructive comparison, as it also involves two doctors (though not a judge). It requires of multiple checklists prepared by the Medical Board of California as a prerequisite,³⁴, as well as a number of verifications by the first and second physicians,³⁵ as *prerequisites*. Thus, the doctors are not mandated to prescribe based on the fulfilment of these standards. Only when these conditions are fulfilled, including a

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30 MH (n 6), para 26, per the Baroness Hale of Richmond
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³¹ There is a case that the Bill would benefit from a King's Proctor taking that role.

³² Bill, cl 14

³³ *ibid*, cl 10

³⁴ Cal Health & Safety Code § 443.22

³⁵ ibid, §\$ 443.5 & 443.6

re-verifying before the time of prescription that the (more stringent than the Bill) criteria on an informed decision remained met, *may* the first doctor issue the prescription.³⁶

That line between 'must' and 'may' is crucial. So long as the Bill goes with 'must', it must be rejected.

§ 4 The ouster provisions

It is always striking when a statute ousts appellate jurisdiction. As a general rule, unless legislation involves the creation of specialist tribunals and specialist appellate hierarchies, it is a bad idea to put in place special rules limiting judicial scrutiny in a specific case. The general judicial scepticism and academic dislike of ouster clauses is quite well-known, with a long history (which starts well before *Anisminic*,³⁷ despite that case often being cited as the general origin of judicial resistance). Attempts to make decisions unappealable have faced judicial resistance in the past decade most notably in the case of *Cart*.³⁸

It is thus worrying that the Bill contains at least one and possibly two ousters. First, the decision of the High Court is appealable only where the High Court has declined to send the patient on to assisted death.³⁹ The fact that appellate scrutiny is available only where the decision is against assisted dying is an effort to weigh the scales, which again undermines the ostensibly strong safeguard of the High Court. Why is there no appeal in the other direction? It might be objected that this is an *ex parte* application with no other party to appeal, but that could easily be solved by appointing some office (like the Official Solicitor or King's Proctor) with the ability to appeal where some aspect of the proceedings underlying it is unsatisfactory or worrying. Instead, the Bill once again awards discretion only to the extent that it is likely to result in the outcome of assisted dying.

Then, at the Court of Appeal, there is again no discretion; if the checklist is met, assisted dying must be authorised.⁴⁰ At this point, the Bill becomes oddly silent. There is no mention of appeal to the Supreme Court. Is the UKSC ousted? The Bill appears to desire this, inasmuch as it explicitly states appeal is allowed in some circumstances (by saying a person 'may' appeal denial in the High Court to the Court of Appeal)⁴¹ and is silent about any further appeal. The textual inference is supported by the fact that the power to make a declaration allowing assisted dying is expressly granted to the High Court and Court of Appeal,⁴² but no express language awards such power to the UKSC. These textual inferences are mitigated against by the general presumption against ouster, such that it is possible courts may interpret into the text an *Anisminic* fudge to find Supreme Court

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36 ibid, § 443.5(b)
37 Anisminic Ltd v Foreign Compensation Commission [1969] 2 AC 147, HL
38 Cart v Upper Tribunal [2012] 1 AC 663, SC, effectively overturned by the Judicial Review and Courts Act 2022, 8 2
39 Bill, cl 12(8,11)
40 ibid, cl 12(9)(a)
41 ibid, cl 12(8)
42 ibid, cls 12 & 13
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review. Yet, that is a silly basis on which to pass ouster clauses.

The Bill cannot be supported so long as it contains these ousters, particularly the onesided partial ouster of the Court of Appeal. Appellate jurisdiction should, as far as possible, proceed by neutral rules of general application.⁴³

§ 5 Sunrise but no sunset

The California statute to which I have been periodically referring is also notable for having a sunset clause, meaning it automatically self-repeals in 2031.⁴⁴ This is a sensible provision. Legislation which is controversial, experimental, and potentially dangerous should not be left to inertia. Rather, the future legislature should have to affirmatively confirm it is working rather than risk that other things occupying parliamentary time leave it another failed Act clogging the statute book due to a lack of parliamentary bandwidth.

By contrast, the Bill envisions permanency. It not only lacks a sunset clause but also has what I shall call a 'sunrise clause' which forces commencement of all uncommenced provisions, notwithstanding the will of the Secretary of State, after two years.⁴⁵ This is unusual. It is well-known that a minister cannot indefinitely ignore or disregard an obligation to consider if an Act must be commenced,⁴⁶ There is a delicate constitutional dance regarding commencement, in which the Secretary of State lacks complete discretion but also has considerable power to respond to the conditions that may make an Act difficult to implement.

It is not beyond imagining that it may take considerably more than two years to prepare, with proper consultation, the regulations, frameworks, and supervision involved in rolling out a scheme of this magnitude. If things are not ready and delay is needed, the Secretary of State has no options to prevent it either than a new Act of Parliament. That is very unwise. Presumably the bill's drafters were worried that the Secretary of State in office at the time of the Bill's implementation might be opposed to it and try to avoid implementing it; this may be further influenced by the fact that the present Health Secretary, the Rt Hon. Wesley Streeting MP (Lab, Ilford North), is an opponent of the Bill. If so, this is very shortsighted. It is already unlawful for a Secretary of State to take efforts to permanently block the future implementation of legislation passed by Parliament.⁴⁷ Furthermore, Parliament can always take further steps to force commencement if a majority support implementation at that time. In any case, the risk of obstruction pales in comparison to the risk of forced commencement before things are ready. It is essential in bringing into force complex legislation that the Secretary of State have the discretion to account

⁴³ This is also a value-based assumption of mine, but I think, if I may be permitted some self-congratulation, an eminently reasonable.

⁴⁴ Cal Health & Safety Code § 443.215

⁴⁵ Bill, cl 42(4)

⁴⁶ See generally R v Home Secretary, ex p Fire Brigades Union [1995] 2 AC 513, HL

⁴⁷ See ibid

for the delays, mistakes, and problems that beset all government projects.⁴⁸ Otherwise, provisions risk coming into force without the necessary voluminous body of secondary regulations to supplement the skeletal framework.

Given the sensitivity of this legislation, there is also a case that the Bill should, in addition to being without a sunrise clause and having present a sunset clause, have special procedures for approval on commencement. The Easter Act 1928, an uncommenced law for changing the date of Easter,⁴⁹ provides that the commencement can only occur with the commencement order being approved by resolutions of both Houses of Parliament.⁵⁰ Without diminishing the importance of Easter to practising Christians, it strikes me that the sensitive nature and risk of an assisted dying legislation have a rather more pressing case for requiring commencement approval.

The absence of sunset and forcing of sunrise are another reason I regard the Bill as untenable.

§ 6 Wills

This is (selected from a number of minor points I find worrying), but one which is telling as to the general sloppiness I find in the method of drafting of the Bill. First, the Bill prevents the doctors involved from being involved in the process if they 'know or believe that they are a beneficiary under a will of the person.'51 Clearly, it is good that neither doctor is a beneficiary of the will, but why, precisely, is it dependent on knowledge or belief? One can all too easily imagine an unscrupulous doctor insisting he did not know he was in his client's will.⁵² In many cases, it might be quite difficult to spot and distinguish cases of a doctor exercising hidden undue influence from cases where a grateful patient adds the doctor secretly to his will as a beneficiary (which seems likely to happen in many cases).

The sensible point would be to have an independent solicitor or other authorised legal practitioner execute a will with the patient prior to the first declaration and attest at each stage that the doctors who eventually sign on are not beneficiaries. As a corollary, the patient would be barred from amending her will or executing a new will after the first declaration and independent solicitor attestation. This would stop a doctor from using the excuse of being unknowingly added to the will and prevent the possibility of undue influence and abuse being disguised as being a surprised recipient of the patient's testamentary gratitude. This would be quite simple and sensible. It is the thing that, I imagine, anyone

- 48 There are many areas in which government could be more efficient and competent, but I doubt that will change in the next few years, sadly.
- 49 The Act is highly unlikely to be commenced absent œcumenical agreement on changing the date of Easter, but, in theory, His Majesty in Council have a continuing duty to check if the global Christian consensus has approached a unified date of Easter which would justify commencement.
- 50 Easter Act 1928, s 2(2)
- 51 Bill, cls 5(3), 7(6)(f)
- 52 Most doctors, of course, are quite scrupulous, but there are always those few who seemed to have neglected to acquire scruples in the course of their medical training.

reviewing this Bill would spot. I can only wonder if anyone carefully reviewed this Bill prior to introduction, or, if safeguards were antithetical to the vision set out by this Bill.

Another element of concern, in my eyes, was the fact that the Bill allows for assisted dying by 'approved substances', which encompasses both 'drugs' and also 'other substances' as approved by the Secretary of State.⁵³ These approved substances must presumably be capable of self-administration (ingestion or other means) by the patient as required by the Bill.⁵⁴

There are two elements to this, a minor one and a major one. First, the minor one. 'Drug' is an odd choice of term. The general legislative term in the context of healthcare (rather than, say, cocaine) is 'medicinal product', which is used throughout the Medicines Act 1968,⁵⁵ as well as the Human Medicines Regulations 2012, whose definition of 'medicinal product' would seem to by definition apply to anything used to end a patient's life.⁵⁶ This has little meaning in terms of construction; the ordinary meaning of 'drug' here is clear enough. Yet, it again suggests a certain sloppiness. Why use a term at odds with the Act and Regulations that are the framework governing medicines in Britain? A bill drafted with care would avoid these little things and assisted dying should be legalised, if at all, only by a bill drafted with care.

The second, much more important, aspect to this point relates to the administration of approved substances. In particular, the administration of approved substances which are not drugs and thus cannot be done by simple ingestion, such as gas. As gas is a tricky thing to administer fatally (or so I gather), absent creation of a new and morbid industry, require the doctor to exercise the Bill's authority to invent a medical device to allow the patient to self-administer the gas.⁵⁷

That authority ought to give everyone pause. The idea of doctors creating special vessels for gas administration is worrying because, while a talented few are both physicians and engineers, most doctors are not particularly skilled at advanced engineering. More generally, what is all this about doctors suddenly being able to invent custom medical devices and use them, apparently untested, on patients?

The term 'medical device' is only mentioned in the clause allowing the doctor to invent one. On its face, this would involve giving doctors the power to design and use medical devices, outside the normal regulatory framework for approval, strikes me as odd. Surely any device for such administration ought to go through the standard practices for medical

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53 ibid, cl 20
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⁵⁴ ibid, cl 18(6)(c)

The Act makes reference to 'drugs' in the context of medicines, rather than control of illegal drugs, only in s 74K(1), which refers to pharmacies dealing in drugs, medicines and appliances; otherwise 'medicinal products' is predominant throughout the many, many other provisions.

⁵⁶ Human Medicines Regulations 2012, reg 2

⁵⁷ Bill, cl 18(6)(b)

devices? At least one physician has already declared his desire to import his untested gas administration pod to Britain if this is legalised;⁵⁸ this provision on devices may lead to many more doctors trying their hand at engineering for which they are not qualified.

The fact that the medical device is intended to bring about death does not change the fact that it needs to be checked for safety. Yet, the Bill, once again showing signs of sloppiness, just drops a power to invent medical devices which appears to circumvent existing processes.

The natural rejoinder here is that the Secretary of State can surely make additional regulations on the devices for administration. Yet, a careful reading of the Bill shows that there is a massive lacuna in this regard. Let us review the powers for secondary legislation regarding approved substances. Clause 20(1) provides that the Secretary of State must specify at least one drug or other substances by regulations. Clause 28(1) provides for the power to make, in relation to approved substances, regulations about the 'prescribing and dispensing', 'transportation, storage, handling and disposal' and records relating to the foregoing. None of this deals with the matter of administration. In Clause 30(1)(d), we see that a code of practice may be issued by the Secretary of State governing ') the arrangements for providing approved substances to the person for whom they have been prescribed, and the assistance which such a person may be given to ingest or self-administer them.'

A code of practice under the bill is not binding but merely something a practitioner must 'have regard to'. ⁵⁹ Breach of a code of practice is not, by itself, capable of being an offence; the Secretary of State has no discretion to create offences for breach of the codes. ⁶⁰ This is a lower level of binding than one might want for a power to create bespoke medical devices for patients. Furthermore, what good is general guidance for inventing a new device? No code can anticipate the best way to use a new invention. As such, the medical devices in the Bill seem, I suspect again from sloppiness, to be left in a dangerously unregulated state.

Proponents of the Bill might point to the fact that the wording in Clause 18(6) is 'prepare a medical device', not 'invent'. Is 'prepare' distinct? Perhaps, but I would strongly prefer that things do not rest on a 'perhaps'. To my mind, the ordinary meaning of 'prepare' can encompass creating bespoke medical devices and reading it as covering creating an essentially new device accords with the intent of the provision to allow patients with particular disabilities, including limited mobility, to administer the substance. Proponents of the Bill might also note that the riskier fears here involve the use of gas, which may well not be approved by the Secretary of State for use. That is true, but, once again, I would really prefer not to leave things to the chance of secondary legislation.

The odd language about approved substances belies a sloppiness which is revealed by a close examination of the lone reference to medical devices. The lack of a clear regulatory framework for such devices is another point against the Bill.

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58 Janet Eastham, "I'll bring death pods to Britain if assisted dying law passes", The Telegraph (24 Nov 2024).
59 ibid, cl 30(6)
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⁶⁰ ibid, cl 30(7)

§ 8 Conclusion

I have been bemused by how much of the debate on the Bill is on the substantive principles and philosophical wrestling. I recognise that this is how most people view things, but this publication has always been very clear that style matters as much as substance. My reason for opposing the Bill is not because I think it is philosophically or morally wrong; I have not felt any need to carry out such an analysis. This is because it fails at the first hurdle—the numerous glaring errors in its drafting. These errors may be accidental or deliberate; it is irrelevant. This is an important and delicate matter which deserves a Bill with careful safeguards, scrupulous drafting, and a generally high standard of care. Yet, here, the drafters of the Bill seem not to have put much care into writing it save to tilt the scales in some places against safeguards. This is no fit basis for a major change in English law. If another bill were proposed to legalise the same thing, my first response would be the same as here—to read it carefully and closely and see if it is fit for purpose. After the close reading involved in this Note, my firm conclusion is that the Bill is decidedly *not* fit for purpose.



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