**MEDICINAL CANNABIS PRESCRIBING:**

**A STUDY OF BOUNDARY WORK AND MEDICO-LEGAL RISK[[1]](#footnote-1)**

**ABSTRACT**

In November 2018 the prescription of ‘unlicensed’ cannabis-based medicines was legalised. This paper adopts a ‘boundary work’ analysis of the post reform guidance issued for doctors, revealing a discourse which frames the prescription of medicinal cannabis as a matter for clinical judgement, but also as fraught with medico-legal hazard. Making visible the boundary work which underscores the messaging of medico-legal hazard, this paper highlights a triad of rhetorical devices comprising the ‘last resort’ principle, ‘personal responsibility’ and the randomised controlled trial as an exclusive measure of ‘safety and efficacy’. Having identified a pronounced signalling of medico-legal risk which is likely to have a chilling effect on prescribing, the paper explores how the *Bolam-Bolitho* formulation of the legal standard of care in negligence litigation might respond to this new domain of prescribing. This paper concludes with observations about the compatibility of innovative prescribing of unlicensed cannabis medicines with the standard of care in negligence law, notwithstanding the extreme caution inherent in the interim prescribing guidance.

**Keywords – medicinal cannabis – prescribing – boundary work – medical negligence -standard of care**

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**INTRODUCTION**

In 2018 the prescription of unlicensed medicinal cannabis products was legalised in the United Kingdom, largely as a result of activism by those caring for children with rare and intractable epilepsies.[[2]](#footnote-2) These conditions can cause over a hundred seizures a day[[3]](#footnote-3) and have a significant mortality rate.[[4]](#footnote-4) Cannabis had substantially improved the quality of life of a number of these children (and their families), including by dramatically decreasing the number and severity of seizures, reducing the frequency of hospitalisation and even enabling their children to start school[[5]](#footnote-5). The reforms were effected by ‘rescheduling’ cannabis based medicinal products (CBMPs) under the Misuse of Drugs Regulations 2001[[6]](#footnote-6), a move accompanied by a requirement that use of the unlicensed product must be in accordance with the prescription or direction of a specialist medical practitioner.[[7]](#footnote-7) The explanatory memorandum to the 2018 regulations states that reforms aimed to ensure that access is provided where medically appropriate, whilst ‘minimising the risk of harm, misuse and diversion.’[[8]](#footnote-8)

This new domain of prescribing was not confined to cases of intractable childhood epilepsies[[9]](#footnote-9), but could also be used to potentially transform the lives of many adults with chronic health conditions.[[10]](#footnote-10) Over 18 months after the reforms however, patients (including the same desperate families, whose cases had triggered the Government’s review of cannabis as a medicine) had resorted to crowd funding[[11]](#footnote-11), petitioning Westminster[[12]](#footnote-12) and court action to push for funded prescriptions for medicinal cannabis.[[13]](#footnote-13) In March 2020, when Teagan Appleby’s family could no longer afford her private prescription for medicinal cannabis, she was admitted to hospital in a critical condition[[14]](#footnote-14) during ‘lockdown’, a situation which undoubtedly risked prejudicing her health even further. Issues of access for adults are also ongoing and similarly revolve around finding a practitioner willing to prescribe, and affordability.[[15]](#footnote-15) Although the cost of private prescriptions for most adults (as opposed to the quantities needed for intractable epilepsies) are usually lower[[16]](#footnote-16), they are still higher than many can afford, and patients often resort to the black market or ‘medical exile’ to access this medicine.[[17]](#footnote-17)

When the 2018 reforms were followed by an absence of NHS prescriptions[[18]](#footnote-18), Matt Hancock (Secretary of State for Health and Social Care) appeared to blame doctors for their unwillingness to prescribe.[[19]](#footnote-19) In parliamentary debates on the issue of access,[[20]](#footnote-20) the medical profession’s ‘interim guidance’ to doctors was identified as a key barrier to prescribing.[[21]](#footnote-21) A House of Commons Select Committee explained the reluctance to prescribe in terms of ‘evidence’ and spectres of medico-legal risk:

‘[D]octors must be satisfied that there is a sufficient evidence base for prescribing the unlicensed product. If there is an insufficient evidence base, doctors are reluctant to prescribe knowing that they are *taking personal responsibility* for doing so and that there could be *serious professional and legal consequences* if there are adverse outcomes for their patient.’[[22]](#footnote-22)

As explored later in this paper, the National Institute for Health and Care Excellence (NICE) guideline published late in 2019 did little to improve matters for those seeking increased access. While the reforms had been concerned with *unlicensed* products, the NICE guideline on ‘*Cannabis Based Medicinal Products*’ (CBMPs[[23]](#footnote-23))[[24]](#footnote-24) virtually ruled out prescription of these unlicensed medicines, endorsing only the use of three already available *licensed* products in relation to four very specific conditions.[[25]](#footnote-25) The rush for reform has been followed by a gulf between the promise of access and reality.[[26]](#footnote-26)

The medicinal cannabis reforms were bound to agitate deeply embedded norms in modern medicine on many levels. First, there are claims that the possible applications of CBMPs could have significant potential to disrupt established thinking on accepted treatments for a wide range of conditions.[[27]](#footnote-27) Second, the pharmacological effects of these substances depend on the ‘endocannabinoid system,’ a subject which is largely absent from training[[28]](#footnote-28) and medical school curricula in the UK. Thirdly, evidence based medicine treats high quality double-blinded randomised controlled trials (RCTs) as the gold standard of generating evidence on the safety and effectiveness of medicines[[29]](#footnote-29), whereas relatively few randomised trials have been conducted on these products.[[30]](#footnote-30) Finally, a group we might describe as the ‘first wave’ of likely patients for medicinal cannabis, who self-identify as potential candidates for a prescription[[31]](#footnote-31) (e.g. by registering with a cannabis clinic or asking their doctor), create a challenging dynamic which may be an unfamiliar and uncomfortable ‘reversal’ of the ‘usual structural inequality’ in doctor: patient relationships.[[32]](#footnote-32) Internet use had already ‘changed forever’ the relationship between ‘empowered possessor and dispenser of technical information and the dependent patient’.[[33]](#footnote-33) This shift is even more pronounced in the case of many cannabis patients[[34]](#footnote-34). They will often have prior experience of cannabis used therapeutically (whether with a prescription or without), and like the self-taught patient envisaged in the Supreme Court judgment in *Montgomery v Lanarkshire Health Board,* will no longer be ‘wholly dependent upon a flow of information from doctors’[[35]](#footnote-35) having researched the application of CBPMs for their condition (or that of their child[[36]](#footnote-36)) extensively.

The legal changes which unleashed this cumulative assault on traditional evidence-based medicine, generated demarcation strategies (discussed below) from a profession and its regulators adjusting to a new landscape they had little notice of or input into. The drawing of new and sometimes artificial boundaries is typical of the ‘boundary work’ which occurs when ‘two or more rival epistemic authorities square off for jurisdictional control over a contested ontological domain.’[[37]](#footnote-37) Boundary work involves a process of ‘demarcation’ ‘driven by a social interest in claiming, expanding, protecting, monopolising, usurping, denying or restricting the cognitive authority’ of the rival camps.[[38]](#footnote-38) This paper blends ‘boundary’ work scholarship with medico-legal jurisprudence to examine the recently legalised domain of prescribing unlicensed medicinal cannabis products. First, the paper draws from the original ‘boundary work’ thesis of Thomas Gieryn[[39]](#footnote-39) and the later work of Lancaster[[40]](#footnote-40), Zolotov[[41]](#footnote-41), Zarhin[[42]](#footnote-42), Sobo[[43]](#footnote-43) and others to observe how ‘medicinal cannabis’ has been constructed in the context of the UK’s 2018 reforms. This analysis is then extended in a new direction by mining the proliferation of guidance issued by professional bodies, government agencies and royal colleges, to reveal a discourse which frames ‘prescribing’ as a medico-legally hazardous activity. In making visible the boundary work which underscores the messaging of medico-legal hazard, this paper highlights a triad of rhetorical devices comprising the ‘last resort’ principle, ‘personal responsibility’ for prescribing and the randomised controlled trial as an exclusive measure of ‘safety and efficacy’. The article concludes that whilst these constructs are grounded in legitimate concerns with managing known and unknown health risks, these boundary mechanisms may also have the effect of deterring innovation preserving medical authority, and risk compromising the reform objective of *balancing* patient access with safety.

The focus of the paper then shifts to examine some of the realities of medico-legal risks of prescribing. The legal standard of care in negligence liability has been chosen for analysis because it provides a space in which these ‘boundary sites’, particularly of judgements about the safety and efficacy of medicines and medical practices, can be negotiated, sustained, further embedded, or sometimes reframed. The paper examines how the *Bolam-Bolitho* formulation of the standard of care in the context of allegedly negligent medical treatment might be applied to innovative prescribing of unlicensed medicinal cannabis products in a way which is more permissive of innovative prescribing than the guidance would suggest, and which (again, contrary to much of the guidance) enables the values and preferences of the patient to be given real weight in clinical decision making.

1. **BOUNDARY WORK AND MEDICINAL CANNABIS**

Gieryn’s original boundary work thesis[[44]](#footnote-44) described scientists’ attempts to defend their professional autonomy by marking out their terrain from non-science. Much like science, medicine is a ‘negotiated practice defined by the boundaries it draws between itself and other realms,’[[45]](#footnote-45) and it involves the continuous playing out of disputes over what constitutes acceptable medical practice and the legitimate role of medicine. Where references to Gieryn’s ‘boundary-work’ feature in legal scholarship, two distinct approaches might be identified; ‘introspective’, studies seeking to unpick the origins of law’s boundaries and their precepts or operative assumptions,[[46]](#footnote-46) or studies which ‘look out’ to how actors go about the business of applying the law, examining how professionals find ‘workable solutions’ in contested or conflictual areas[[47]](#footnote-47) and how law’s boundaries become enmeshed with the interests of those tasked with applying those distinctions.[[48]](#footnote-48) Zarhin et al’s study of the system for accessing medicinal cannabis in Israel noted that[[49]](#footnote-49) authority to ‘demarcate’ had been assigned to the Ministry of Health which translated ‘rhetorical boundary work’ (from policy and debates) into ‘regulatory boundary work’, in the form of regulations and guidance limiting access. In the UK context, the regulations themselves say little about the boundaries of prescribing,[[50]](#footnote-50) impliedly delegating much of the boundary work to formal and informal regulatory networks. The General Medical Council (GMC), the only body tasked by statute with providing guidance to the medical profession,[[51]](#footnote-51) has said little on the issue (see below), therefore the boundaries embedded in professional guidance from royal colleges and other bodies on medicinal cannabis prescribing have assumed substantial importance. This delegation of boundary work to post-reform publications from a mix of regulatory and non-regulatory bodies has resulted in a slew of guidance, but a regrettable lack of coherence.

The present study ‘looks out’ at the role of post-reform professional guidance in the contested field of medicinal cannabis, exploring tension points in this new domain of prescribing. First, however, ideas about boundary work and the construction of both ‘medicinal cannabis’ and the act of ‘prescribing’ are formulated in the context of the UK reforms.

*A. ‘Medicinal Cannabis’ as a contested object*

As in other jurisdictions, ‘medicinal cannabis’ as an object has emerged as a complex, contested entity.[[52]](#footnote-52) The label ‘medicinal cannabis’ implies a single, discrete object: however, cannabis ‘is not one medicine but a family of medicines’[[53]](#footnote-53) (a plant with two very well-known isolates (cannabidiol (CBD) and tetrahydrocannabinol (THC)) and over 100 potentially medically useful components[[54]](#footnote-54)); and it manifests in many physical forms (including tinctures, purified oils, pills, oral sprays, dried flowers, a vaping product and edibles). Further, whilst the impetus for reform in the UK centred around the experiences of young children with intractable epilepsies, medicinal cannabis products are reported as providing therapeutic benefit for a diverse range of conditions. A 2018 review by Dame Sally Davies (then Chief Medical Officer for England), concluded that these products did indeed have medicinal value for patients with nausea/vomiting caused by chemotherapy, spasticity in multiple sclerosis and chronic pain (adults), in addition to intractable epilepsy.[[55]](#footnote-55) This was despite the current absence of positive Randomised Controlled Trial evidence and against a background of some well-known risks (particularly mental health disorders and addiction[[56]](#footnote-56)). More broadly, it has been claimed that medicinal cannabis is helping patients with fibromyalgia, anxiety and depression, the rigidity and tremors associated with Parkinson’s disease, Tourette’s syndrome, Alzheimer’s disease, chronic fatigue syndrome, cancer, the distress experienced by patients receiving palliative care and it has even been named as a possible treatment for Covid-19.[[57]](#footnote-57) There is, however, either ‘limited evidence’ or ‘no conclusive evidence’ that medicinal cannabis is an effective therapy for these other conditions.[[58]](#footnote-58)

As a broad legal term, ‘medicinal cannabis’ can be used to refer to a range of products which are subject to divergent regulatory boundaries, including: (1) a small number of ‘licenced medicines’ derived from the cannabis plant (in the UK these are currently, Epidiolex®[[59]](#footnote-59) and Sativex®), (2) licensed *synthetic* cannabinoid medicines (such as Nabilone and Dronabinol) and (3) *unlicensed* cannabis based medicinal products which can now be accessed through exceptional procedures[[60]](#footnote-60) in the UK, although they may be regularly prescribed in other jurisdictions.[[61]](#footnote-61) It is this third category of ‘unlicensed CBMPs’ which is the main focus of this paper as these are what the 2018 reforms sought to enable patients to (safely) access.

Of course, these ‘legal’ or potentially ‘legal’ manifestations of ‘medicinal’ cannabis do not capture ‘self-medication’, that is, where a cannabis plant or cannabis-based product is obtained and used for therapeutic purposes, absent a prescription.[[62]](#footnote-62) The cultivation, possession or use of cannabis or cannabis products containing more than 0.2% THC remains a criminal offence.[[63]](#footnote-63) In 2000, an independent inquiry into drug policy set up by the Police Foundation recommended that a special defence for therapeutic use should be created.[[64]](#footnote-64) To date, there has been no change in the law to protect persons who know that cannabis helps them to cope with their condition but are unable to obtain an NHS prescription or fund a private prescription. Crown Prosecution Service (CPS) guidance on when it is ‘in the public interest’ to prosecute someone for possession of a small amount of cannabis does now refer to ‘Evidence demonstrating that the cannabis is being used to alleviate symptoms associated with a chronic medical condition’ as a mitigating circumstance.[[65]](#footnote-65) However, this applies to possession offences only and not to cultivation or supply, and it has certainly not halted the prosecution of therapeutic users.[[66]](#footnote-66)

*B. The Functional Significance of Prescribing*

The act of prescribing is multi-functional and potentially transformative for both doctors and patients. It can be regarded as a communicative device[[67]](#footnote-67), in that it is, for example, an acknowledgement of the patient’s suffering, legitimation of the situation as deserving medical attention[[68]](#footnote-68), a fulfilment of the therapeutic relationship[[69]](#footnote-69) and a device for managing medical uncertainty in diagnosis and treatment and for providing hope.[[70]](#footnote-70) The ‘ritual’ of prescription can be used as an efficiency manoeuvre, replacing lengthy and inconclusive explanations,[[71]](#footnote-71) or is sometimes used (or experienced as) an act of ‘dismissal,’ bringing the time-constrained doctor: patient consultation to a close. In the context of encounters between the patient seeking a cannabis prescription and their specialist, a consultation that ends without such a prescription will undoubtedly be experienced as a disappointment.[[72]](#footnote-72) This will particularly be the case in cannabis clinic settings, if the clinic has positioned itself as providing access to cannabis medicine, which will inevitably result in an expectation of prescription.

The act of prescribing can also have its own cultural and symbolic meaning,[[73]](#footnote-73) beyond its potential to offer improved outcomes for the patient. Prescriptions for medicinal cannabis in particular are ‘transitional objects’[[74]](#footnote-74) in that they can symbolise a transition for the subject of the prescription from ‘criminal’[[75]](#footnote-75) to ‘patient’,[[76]](#footnote-76) and a recasting of the object of the prescription from illicit, recreational substance to approved medicine. This transition is rendered visible in the case of Lezley Gibson, an MS sufferer, prosecuted for cultivating her own cannabis plants for therapeutic reasons. In January 2020 the prosecutor withdrew on the grounds that prosecution was no longer in the public interest, seemingly because Mrs Gibson had redeemed herself by obtaining a legal (private) prescription for medicinal cannabis.[[77]](#footnote-77)

The status of cannabis based medicines has historically been compromised by the widespread use of cannabis as a drug of pleasure and, consequently, the object of ‘medicinal cannabis’ remains ‘inextricably intertwined’ with the object of ‘recreational cannabis.’[[78]](#footnote-78) The fluidity of this boundary can mean that patients are marginalised; being or feeling that they are the subject of moralistic judgements and treated as manipulative malingerers,[[79]](#footnote-79) or that legitimation of medicinal use through reform, helps to de-stigmatise recreational use.[[80]](#footnote-80) In the UK it is clear that a significant amount of boundary work in policy papers, debates and professional guidance focuses on keeping medicinal cannabis distinct from the object of ‘recreational cannabis.’ The 1998 House of Lords Select Committee observed ‘slippery slope’ styled arguments which construed legalising for medical use as a ‘stalking horse’ for legalising recreational cannabis use.[[81]](#footnote-81) In the Committee’s view however, legalising the prescription of cannabis would only fortify the boundary, as it would: ‘create a clear separation between medical and recreational use, under control of the health care professions. We believe it would in fact make the line against recreational use easier to hold.’[[82]](#footnote-82)

Beyond these functions, prescribing is also an exercise of medical authority and jurisdiction, as it remains largely (although not wholly) the preserve of registered medical practitioners.[[83]](#footnote-83) Both regulators and professional bodies engage in boundary work to defend their claims to territory as a trusted profession or source of authority, and some members of the medical profession may be understandably resentful that they have seemingly been gifted the ‘dirty work’[[84]](#footnote-84) of maintaining the line between recreational and medicinal uses, preferring the clinical realm of judging whether thresholds of safety and efficacy have been met.[[85]](#footnote-85)

Added to all of these dynamics, the prescription itself has particular medico-legal significance, for the signature on the prescription identifies where legal responsibility for the prescribing lies.[[86]](#footnote-86) The act of prescribing unlicensed cannabis products has been associated with possible reprisals from the medical community[[87]](#footnote-87), and unknown risks of liability for the doctor, and their interpretation of this legal risk will be heavily informed by the proliferation of regulatory and professional guidance issued in the aftermath of the 2018 reforms. ‘Prescribing’ in particular has been identified as a ‘battleground’ where the clinical autonomy of the medical profession is defended.[[88]](#footnote-88) However, the emergent boundary work has constructed a landscape which rules out routine prescribing, whilst saying little about the interests of individual patients. Its terms have likely contributed to a broader failure to deliver the balance of access with safety promised by the 2018 re-scheduling legislation.[[89]](#footnote-89)

**II. MIXED MESSAGES AND THE PROLIFERATION OF GUIDANCE ON MC PRESCRIBING**

This section advances the previous section’s boundary work analysis, exploring the emergence of key guidance, including the NICE guideline, ‘default’ General Medical Council (GMC) guidance on prescribing unlicensed products (but not CBMPs specifically) and more recent guidance from the royal colleges and medical associations.[[90]](#footnote-90) Much of this guidance acknowledges the possibility that prescribing might be appropriate, thus preserving clinical autonomy, whilst simultaneously being laden with warnings against it. Crucially, the guidance says nothing of access, only of risk. A tone of extreme caution prevails, combined with refrains of ‘personal responsibility’, prescribing as a ‘last resort’ and insufficient evidence of ‘safety and efficacy’, which the author argues work together to convey an indeterminate threat of medico-legal ramifications. These three prominent boundary devices will be examined and key points of tension in the guidance highlighted in the pages that follow. First, however, the boundary between publicly funded and privately funded care is scrutinised, as it is this boundary which possibly represents the most fundamental barrier to increased access to medicinal cannabis.

*A. The NHS/Private Health Care Boundary: a two-tier system*

The NHS/private health care boundary is hugely significant in medicinal cannabis prescribing, and represents the next frontier for patient activism. Thus far, prescriptions have occurred largely in the private sector and NHS prescribing has been virtually non-existent.[[91]](#footnote-91) The scarcity of publicly funded prescriptions is likely (at least in part) a result of: i) the impact of the 2019 NICE guideline and ii) the fact that in the NHS, a specialist’s prescription of an unlicensed CBMP must still be approved by local governance arrangements, usually a prescribing group within the NHS trust or Clinical Commissioning Group (CCG).[[92]](#footnote-92)

*The NICE Guideline*

For those working in the NHS, guidance from NICE has special status when it comes to the standard of care.[[93]](#footnote-93) The NICE guideline on CBMPs was published in November 2019[[94]](#footnote-94) and, whilst it endorses the medicinal value of cannabis for some conditions, it does so in very narrow terms. Essentially it only enables prescribing on the NHS for three (already licensed) products[[95]](#footnote-95):

i) tetrahydrocannabinol (THC): cannabidiol (CBD) spray (currently Sativex®) which should be ‘offered’ on a four-week trial basis for spasticity in multiple sclerosis;[[96]](#footnote-96)

ii) Epidiolex® which should be recommended for two rare forms of treatment-resistant epilepsy;[[97]](#footnote-97) and

iii) Nabilone (the generic name for a synthetic cannabinoid), which should be ‘considered’ for the treatment of, and for adults with intractable nausea/vomiting associated with chemotherapy.[[98]](#footnote-98)

Whilst prescribers in many countries clearly *do* prescribe medicinal cannabis for chronic pain[[99]](#footnote-99), NICE steers prescribers away from considering this option, instructing doctors to ‘NOT offer’ unlicensed CBMPs[[100]](#footnote-100) and ‘NOT offer’ CBD for chronic pain in adults, unless as part of a controlled trial.[[101]](#footnote-101) The recommendation regarding chronic pain was based on there being ‘some evidence’ of ‘modest’ effectiveness[[102]](#footnote-102), but given the large number of people who might benefit (sic), medicinal cannabis was not cost effective as a treatment option.[[103]](#footnote-103)

The prescribing guideline is very narrowly drawn; virtually prohibiting prescription of unlicensed medicinal cannabis products, and only endorsing the use of specific named, licensed products in relation to four very specific conditions. The recommendation in relation to spasticity *only* in MS is of particular interest, as many MS sufferers claim that Sativex® helps with both their pain *and* spasticity.[[104]](#footnote-104) Clearly, endorsing its use for pain in MS, would risk breaching the embargo on the use of medicinal cannabis for chronic pain, and this artificial distinction functions to preserve the regulatory boundary between authorised use (spasticity) and unauthorised use (pain).

Whilst the prescribing of unlicensed CBMPs on the NHS is virtually non-existent, there are nevertheless at least two means by which private prescribing might ultimately ‘spill over’ into the NHS: i) as experience builds in the private sector, consultants who are employed there, or specifically in medicinal cannabis clinics, frequently have NHS roles too,[[105]](#footnote-105) and over time their accumulated experience may mean that they seek to prescribe in their NHS capacity; and ii) a prescription might be initiated in private healthcare, but then be handed over to the NHS via ‘shared care’ arrangements.[[106]](#footnote-106) Under ‘shared care’, a patient who is doing well on a prescription of CBMPs may seek access to follow up services, including monitoring appointments or even further prescription, under the direction of the initial (probably private) prescriber, but locally with their GP.[[107]](#footnote-107) The NICE guideline specifically envisages ‘shared care’ as a way forward, providing guidance on how a ‘shared care arrangement’ might work in this setting. Presumably, once private healthcare has determined that the treatment is working for this patient, then this should affect the cost benefit analysis which NHS prescription requires or which might otherwise prevent NHS funding, and could open the door to funded prescribing. However, this pathway from privately funded trialling of the medicine to publicly funded of a tried and tested medication has not thus far been a reality for the families seeking cannabis medicines for their children.[[108]](#footnote-108)

*B. Beyond NICE: the Emergence of Professional Guidance*

When the 2018 reforms were introduced enabling the prescription of unlicensed medicinal cannabis products, ‘interim’[[109]](#footnote-109) guidance to the profession was published by a number of professional and regulatory bodies, to include: the Royal College of Physicians (RCP)[[110]](#footnote-110), British Paediatric Neurology Association (BPNA)[[111]](#footnote-111), Royal College of General Practitioners (RCGP)[[112]](#footnote-112), Association of British Neurologists (ABN)[[113]](#footnote-113) and the Care Quality Commission (CQC)[[114]](#footnote-114). ‘Position statements’ were also prepared by the Royal College of Psychiatrists[[115]](#footnote-115) and British Pain Society,[[116]](#footnote-116) and NHS England produced a review accompanied by ‘Frequently Asked Questions’.[[117]](#footnote-117)

Only the General Medical Council (GMC), however, is tasked by statute with providing guidance to medical practitioners[[118]](#footnote-118), consequently the GMC is generally regarded as the predominant source of ethical guidance.[[119]](#footnote-119) Detailed advice from the regulator on prescribing medicinal cannabis or dealing with requests for medicinal cannabis has not been forthcoming.[[120]](#footnote-120) Whilst the GMC perhaps takes the view that it is not part of its role to provide advice on prescribing specific medicines, the medicinal cannabis reforms raised special ethical issues. Not least of these were that these reforms have been felt across a range of specialties *and* general practice (as reflected by the proliferation of guidance from different royal colleges), that the patient’s prior experience of the active ingredients may fundamentally disrupt the usual doctor:patient dynamic and that the reforms and media attention more broadly had ramped up patients’ expectations of access to cannabis based medicines. Arguably, these issues would benefit from more direct input from the regulator. Instead, doctors are directed to[[121]](#footnote-121) the GMC’s 2013 generic guidance on the prescription of unlicensed medicines, found within *Good practice in prescribing and managing medicines and devices* (hereafter referred to as the ‘GMC’s default guidance’).[[122]](#footnote-122) This default guidance states that prescribing decisions should also take account of ‘the clinical guidelines published by NICE and devolved equivalents, and by ‘medical royal colleges and other authoritative sources of specialty specific clinical guidelines.’[[123]](#footnote-123)

The proliferation of (sometimes conflicting[[124]](#footnote-124)) guidance, outlined above, has spawned a ‘fragmented discourse’,[[125]](#footnote-125) a position which risks quite opposite stances being ethically justified by the extant guidance and the result becoming one of regulatory vacuum.[[126]](#footnote-126) For example, whilst (as we shall see) the interim professional guidance features three pronounced themes of RCTs as the exclusive measure of safety and efficacy, use of unlicensed products as a last resort and personal responsibility, these are far less prominent in the GMC’s generic guidance on prescribing unlicensed medicines.

**III. ANALYSIS OF ‘INTERIM’ PROFESSIONAL GUIDANCE: FRAMING PRESCRIBING AS MEDICO-LEGALLY HAZARDOUS**

*A. Prescribing CBMPs - a last resort?*

Professional guidance and guidelines can have rhetorical force, the term ‘rhetorical’ used here not in a pejorative sense, but to convey that one of their functions is to persuade[[127]](#footnote-127) practitioners to behave (or conform) in a certain way. The tenor of interim professional guidance on medicinal cannabis is deeply cautious, envisaging that prescription of unlicensed cannabis products is to be undertaken with ‘extreme caution,’[[128]](#footnote-128) is unlikely to be medically appropriate and is only to be used as a ‘last resort’.[[129]](#footnote-129) Exacting applications of last resort rhetoric can be viewed as a grudging acceptance of cannabis as having a place in modern medicine, but only in cases of desperation where nothing is working, all bets are off and there is little left to lose. From a patient’s perspective they must prove themselves deserving of an exceptional exercise of compassionate prescribing by showing that they have tried all conventional treatments on offer, but have not found them to be effective or tolerable.

Despite the publicised success stories of unlicensed medicinal cannabis products in the treatment of a number of children with intractable epilepsies[[130]](#footnote-130), the BPNA recommends using unlicensed cannabis-based products for children with intractable epilepsy only as a ‘last resort’. The ‘last resort’ theme is underscored by the BPNA’s preference for brain surgery[[131]](#footnote-131) over the use of unlicensed CBMPs and the recommendation that patients who have been using cannabis products with more than 0.2% THC content (albeit that they may have improved dramatically) should be ‘transitioned to’ pure CBD.[[132]](#footnote-132)

The BPNA is not alone in its ‘last resort’ stance. Reluctance to recognise a place for unlicensed MC products in prescribing is more pronounced in NHS England FAQs, which does not apply only to children. According to NHS England it:

‘expects that cannabis-based products for medicinal use should only be prescribed for indications where there is *clear published evidence of benefit* or UK Guidelines and in patients where there is a clinical need which cannot be met by a licensed medicine and where established treatment options *have been exhausted.*’[[133]](#footnote-133)

If taken literally, NHS England’s stipulation that access should be contingent on having ‘exhausted’ all conventional treatment options could be extremely onerous, as it may involve trying any number of options first, many of which will have far from benign risk burdens. It will also take a substantial amount of time to verify whether each drug is or is not working adequately. All of this is made the more burdensome by current waiting times to see specialists.[[134]](#footnote-134) A further problem with the language of last resort in the interim guidance is that it encourages doctors to view ‘unlicensed’ status as a proxy measure of unacceptable risk, and to automatically privilege licensed alternatives regardless of their benefit: harm ratios. Yet, licensed medicines for serious health conditions, such as AEDs (anti-epilepsy drugs), opioids, benzodiazepenes and NSAIDS (nonsteroidal anti-inflammatory drugs) are frequently incumbered with formidable side-effects and risk profiles, including, for example, renal and cardiac risks, blindness, stroke, organ damage, gastro-intestinal bleeding and dependence.[[135]](#footnote-135)

There is, however, a real distinction between the fairly restrictive ‘last resort’ stance advocated in some of the interim professional guidance and the more liberal ‘default’ GMC guidance. The GMC’s guidance on prescribing unlicensed medicines generally,[[136]](#footnote-136) states that the prescription of unlicensed products is ‘common’ in some areas of medicine,[[137]](#footnote-137) and may be ‘necessary’, for example, where licensed medicines ‘do not meet the patient’s needs’.[[138]](#footnote-138) There is no ‘last resort’ provision stipulating that the patient must have tried all other available medicines first (although it is perhaps implicit in the wording used that they should at least have been ‘considered’ first), and there is no further definition of ‘need’ in the GMC guidance. ‘Need’ could arguably justify prescription where the patient or their carer has a strong preference for avoiding the usual, licensed treatments because of their known side-effects. We know, for example, that many patients prefer cannabis over licensed opioids because of the latter’s daunting side effect profile. This is referenced in many court judgments both here and in other jurisdictions[[139]](#footnote-139), including *R v Brown*[[140]](#footnote-140) with the defendant arguing he was taking cannabis unlawfully out of ‘necessity’, as it represented an effective and low risk analgesic for the pain associated with his MS, when compared with the available prescription drugs which carried adverse side effects.[[141]](#footnote-141) As the GMC’s identification of situations where prescription of unlicensed medicines might be ‘necessary’ is non-exhaustive,[[142]](#footnote-142) potentially there is room for a doctor deeming a prescription ‘necessary’ where the patient is currently using cannabis to effectively control their symptoms, but is otherwise compelled to obtain it from the black market, an experience described by the Ontario Court of Appeal in *Hitzig v Canada* as ‘dehumanising and humiliating’ and entailing poor quality control, a lack of protection from adulteration, consorting with criminals and unpredictability of supply.[[143]](#footnote-143)

The Medical Cannabis Clinicians Society (MCCS), an association led by a team including experts in cannabis-based medicine, issued its own guidance to doctors considering prescribing.[[144]](#footnote-144) Aligning itself with the GMC’s default guidance on unlicensed medicines, the MCCS document offers a further counter-discourse to strict applications of the last resort approach. For example, with regard to epilepsy, the MCCS guidance states that whilst it does not recommend cannabis products as ‘first line treatment’, equally ‘[cannabis medicines] are not necessarily medicines of last resort’, it being ultimately for the prescriber to determine whether use of the CBMP is ‘reasonable’ with regard to the evidence ‘and the circumstances of the individual patient.’[[145]](#footnote-145) This would seem to be in line with the default GMC position, in privileging the best interests of the patient over any particular stance on prescribing medicinal cannabis.

Of course, there is not *necessarily* any incompatibility between the GMC’s guidance appearing to be more liberal on the prescribing of unlicensed medicines in general, and guidance from other sources on specific unlicensed medicines being more restrictive.[[146]](#footnote-146) There will be some unlicensed medicines where a lot is known about the relative risks and outcomes, and others where the risk profile remains very uncertain. What is clear however, is that the guidance specific to cannabis medicines takes a more restrictive stance on prescribing, and that in the case of NHS England in particular, appears to adopt wording which implies that *all* available options ought to have been tried first (rather than just considered).

*Reserving Prescribing for Specialists*

The ‘last resort’ stance is underscored by the 2018 regulations’ reserving of the act of prescribing in the first instance to specialists (consultants).[[147]](#footnote-147) Thereafter, prescription can be continued by others, provided it remains under the direction of the specialist.[[148]](#footnote-148) This is distinct from the position for some other unlicensed medicinal products which can be prescribed by specialists, General Practitioners (GPs), ‘dentists; independent nurse and pharmacist prescribers and, in some circumstances, supplementary prescribers (who can be a pharmacist, nurse, midwife, community nurse, optometrist, physiotherapist, radiographer, or chiropodist/podiatrist)’.[[149]](#footnote-149) It is clear therefore that not all unlicensed product prescribing is restricted to consultants. It seems unlikely that a GP would prescribe any medicine that they had not satisfied themselves was appropriate for their patient to try in light of current evidence on its potential risks and benefits. There are reported instances of GPs being willing to continue to prescribe an unlicensed medicinal cannabis product for their patient, when prescription is initiated by a consultant, but that the law prevents them from doing so.[[150]](#footnote-150) Excluding GPs from initiating an unlicensed CBMP prescription, reduces the pool of (initial) prescribers by more than half.[[151]](#footnote-151) It may therefore be viewed in part as a rationing measure, whilst also functioning to corroborate the message that concerns around safety and efficacy place these drugs beyond the competence of GPs. It is clear that families are continuing to make long monthly journeys to consultants, despite the intention that ‘shared care’ would remove this burden.[[152]](#footnote-152)

*B. At your own risk*!

Article 5(1) of the Medicinal Products Directive 2001/83/EC enables the prescribing of unlicensed medicines, on a named patient basis (sometimes known as ‘specials’) ‘for use by an individual patient under his [the prescriber’s] ‘direct personal responsibility.’ The meaning of ‘direct personal responsibility’ is unclear, but the UK regulations on prescribing unlicensed medicines translate these words into a requirement that prescribers must only prescribe these medicines for those ‘*for whose treatment [the prescriber] is directly responsible* in order to fulfil the special needs of that patient.’[[153]](#footnote-153) This transposed wording implies a certain relationship between the prescriber and the named patient, that is, that prescribers may only prescribe unlicensed products for those they would describe as their patients and whom they already owe a duty of care to – it communicates little, however, about the content of any liabilities (an issue dealt with in further detail below, with specific reference to key standard of care principles generated by the judgments in *Bolam, Bolitho* and *Montgomery*[[154]](#footnote-154)). The GMC’s default guidance makes no specific reference to direct responsibility other than to underline the ordinary duty of care of the prescriber with an emphasis on monitoring, saying that doctors prescribing unlicensed medicines must: ‘*take responsibility*for prescribing the medicine and for overseeing the patient’s care, monitoring, and any follow up treatment.’[[155]](#footnote-155)

In other places, however, the wording ‘direct personal responsibility’ has been seized upon as of grave significance for the prescriber, hinting at enhanced and unidentified liabilities. NHS Trust policies on prescribing unlicensed medicines frequently discourage such prescribing on the vague premise that the prescriber takes on the liabilities of the drug manufacturer or becomes a ‘producer’[[156]](#footnote-156) and becomes strictly liable[[157]](#footnote-157) for any product defects. Interim professional guidance on medicinal cannabis emphasises that the act of prescribing is fraught with risk for the prescriber. The wording of the BPNA guidance on prescribing unlicensed CBMPs is opaque on the matter, stating that ‘the responsibility for the prescribing *and potential adverse effects of a CBPM prescription will remain with the prescribing clinician.*’[[158]](#footnote-158) Guidance from the Care Quality Commission also adopts the language of responsibility ‘remaining with the prescriber,’[[159]](#footnote-159) and even the MCCS notes that prescribers of unlicensed medicines’take full clinical responsibility for any consequences of the prescription and might not be covered by professional indemnity insurance.’[[160]](#footnote-160)

Case law does indeed recognise that all off-licence prescribing or prescribing of unlicensed medications is to some extent at the prescriber’s risk,[[161]](#footnote-161) as the prescriber cannot refer to the product’s market authorisation in order to justify either their decision to prescribe or their advice to the patient regarding dosage. However, the main problem with ‘at your own risk’ messaging and ‘responsibility remaining with the prescriber’ is that it is unclear, and there is no attempt to explain the ambit of this ‘responsibility’. In the absence of such an explanation, clinicians may assume the worst, including perhaps that any liability will be personal and not covered by any indemnity or insurance or that liability would be, ‘enhanced,’[[162]](#footnote-162) strict[[163]](#footnote-163) or even absolute, regardless of any reasonable care exercised by the prescriber. Policies on prescribing unlicensed medicines frequently state that the ‘prescriber may be called upon to justify his actions in the event of an adverse reaction,’[[164]](#footnote-164) yet this is the case for *any* therapeutic intervention a doctor recommends. Despite the fact that the prescription of unlicensed medicines is widespread[[165]](#footnote-165), there has been little sign that the threat of ‘personal responsibility,’ other than through the ordinary mechanisms of negligence, has become a reality. What we can say with certainty is that the standard of care is enhanced as the result of prescribing a medicine about which less is known when compared with its conventional counterparts. This could mean that the prescriber should be particularly alert to the risks of unknown side-effects, should monitor the patient for signs of complications and should take reasonable care to bring the possibility of unknown risks to the attention of the patient.[[166]](#footnote-166)

*C. Safety and efficacy – preserving the authority of the RCT?*

In evidence based medicine, a triptych of ‘safety’, ‘efficacy’ and an insistence upon RCTs[[167]](#footnote-167) to demonstrate these, are frequently used as gatekeeping devices,[[168]](#footnote-168) and it has been suggested that ‘evidential uncertainty’ can sometimes provide strategic means for defending professional boundaries or for the rationing of healthcare resource.[[169]](#footnote-169) The interim guidance on medicinal cannabis prescribing is filled with references to the absence of evidence on the safety and efficacy of these drugs and a resolution not to use them in the absence of positive RCT evidence.[[170]](#footnote-170) This insistence on RCT evidence is most pronounced in the BPNA’s guidance on treating epilepsies in children. Its provisions recommend that the only cannabis-based medicine to be considered for children should be Epidiolex® (a licensed product containing no THC and one of the few cannabis based medicines to be the subject of recent RCTs supporting its use for intractable epilepsies in children).[[171]](#footnote-171) *NHS England* adviceechoes these sentiments, foregrounding concerns about the impact of THC on the young: ‘…currently there is no good evidence that products that contain THC are either safe or efficacious and there is a concern about the effect of THC on the developing brain.’[[172]](#footnote-172)

The ABN’s interim guidance (which would apply to adults with epilepsy or other neurological conditions) takes a slightly less prescriptive approach, stating that there is only ‘published evidence of efficacy’ of cannabis for Dravet’s Syndrome and Lennox-Gastaut Syndrome,[[173]](#footnote-173) therefore ‘extreme caution’ must be used before considering MC for other epilepsies. It is not true to say that evidence in relation to other epilepsies does not exist[[174]](#footnote-174), it is rather that the ABN’s guidance equates ‘published evidence of efficacy’ with an exclusive subset of RCTs. That same rigid insistence on RCT evidence is also seen in relation to chronic pain (with RCP guidance claiming that there is: ‘no *robust* evidence for the use of CBPM in chronic pain and their use is not recommended’[[175]](#footnote-175)) and in NHS England’s advice:

‘…*whilst individual patients may perceive benefit*; this hasn’t been fully tested in comparative randomised controlled trials in large numbers of patients. Potential harms of using cannabis-based treatments for medicinal use in the long term have also not been studied’.[[176]](#footnote-176)

Aside from NHS England’s disqualification of the patient from being able to identify whether their medicine is benefitting them, similarly to other interim guidance documents, NHS England also flags concerns about the absence of reliable evidence regarding the *effects of long-term use.*[[177]](#footnote-177)The interim guidance stance on RCT evidence is clearly less liberal than the GMC’s default 2013 guidance on prescribing unlicensed medicines. The latter says that doctors must ‘be satisfied that there is sufficient evidence *or experience* of using the medicine to demonstrate its safety and efficacy’.[[178]](#footnote-178) The guidance does not elaborate on what is meant by ‘experience’, but in this context it could be construed as fulfilled by a clinician’s experience either of prescribing cannabis generally, or the specific cannabis product. This juxtaposition of ‘evidence’ and ‘experience’ suggests a far more generous approach to determining whether trying a medicine is appropriate than the rigid insistence on RCT evidence seen elsewhere, raising questions of how a court might resolve the tension between these two approaches (see further below on this provision, and particularly on the possible meaning of ‘experience’).

As detailed above, the interim guidance communicates a clear, exclusive preference for RCTs, to the point that they are assumed to represent the *only* type of evidence which will satisfy the concerns of ‘evidence-based medicine.’ Yet it is clear that there are real and justifiable concerns with assuming that data generated by RCTs is supremely reliable and that prescribing decisions in the absence of positive RCT evidence cannot be made. For example, there are suggestions that the coverage of medicines by RCTs is ‘lopsided’, being distorted by industry’s research agenda[[179]](#footnote-179) and that which medicines become the subject of RCTs may serve commercial interests rather than the health and wellbeing of the population.[[180]](#footnote-180) In some cases RCTs have compared single drugs against a placebo or a ‘poor comparator’[[181]](#footnote-181), and may tell us little about how the drug performs in real-world settings,[[182]](#footnote-182) where patients taking the medicine will often be suffering from co-morbidities and already be taking multiple other medications. Moreover, insistence that RCT evidence is the only way of gauging safety and efficacy neglects the fact that modern medicine clearly embraces practices which are not supported by RCT evidence, including; the number of drugs which have been licensed without positive RCT evidence[[183]](#footnote-183), ‘off licence’ prescribing of medicines for children,[[184]](#footnote-184) administering multiple medications for co-morbidities or intractable conditions and surgery (where progress tends to be iterative, on a ‘trial and error’ basis with only an estimated 24% of the currently used surgical therapies being supported by the results of RCTs[[185]](#footnote-185)).

The emphasis of the unknown nature of *long-term effects* of taking CBMPs risks evident in interim guidance also risks applying a ‘double standard’.[[186]](#footnote-186) Even where RCT evidence is available, trials often only test new medicines for a relatively short period,[[187]](#footnote-187) and licensing occurs well before data about long-term use is available. For example, the RCTs which formed part of the evidence base for licensing Epidiolex featured a 14-week treatment period.[[188]](#footnote-188) Further, any evaluation of long-term effects in RCTs tends to be based on ‘surrogate outcomes’ which can be unreliable for predicting long term risks.[[189]](#footnote-189)

It should be stressed at this point that the author is not attempting to suggest that some lesser evidentiary standard ought to be used for prescribing CBMPs, but rather that the relative reliability of the evidence generated by RCTs is sometimes overstated, and that an approach which recognises the importance of RCTs whilst also drawing from other sources of good quality evidence may be preferable. As Nutt et al have recently suggested, ‘patterns of evidence’ made up of databases detailing patient reported outcomes, robust observational studies, ‘N of 1’ trials can be used to build a picture of the relative safety and efficacy of medicinal cannabis for some conditions.[[190]](#footnote-190) Interim guidance and default GMC guidance endorse different routes to making these judgements on safety and efficacy. Given that RCT evidence is far from a perfect proxy for measuring safety and efficacy of medicines in individual cases, it is argued that the GMC’s generic guidance may in some instances be far more consistent with achieving a suitable balance between safety and access.

**IV. PROFESSIONAL GUIDANCE, THE STANDARD OF CARE AND MEDICO-LEGAL RISK IN CBMP PRESCRIBING**

There are at least two compelling reasons for examining how prescribing unlicensed CBMPs might be received by the legal standard of care, focusing on hypothetical situations where an adult patient[[191]](#footnote-191) came to harm as a result of taking these medications.[[192]](#footnote-192) First, the risk of being sued in negligence has been cited as a key factor in studies of why doctors do not feel confident to prescribe,[[193]](#footnote-193) and whilst professional guidance is visible and accessible to medical practitioners, standard of care jurisprudence is not. It is true (albeit perhaps overstated[[194]](#footnote-194)) that a failure to exercise reasonable care in prescribing work or in the aftercare of the patient can result in negligence liability where recognised harm results[[195]](#footnote-195) or may trigger fitness to practise concerns.[[196]](#footnote-196) Whilst fear of liability is far from being the only barrier to wider access to medicinal cannabis, there is value in examining how the standard of care might respond to what can currently be regarded as ‘pioneering’ prescribing that goes against the weight of the interim guidance explored above. Secondly, the ‘standard of care’ provides a space in which these ‘boundary sites’, particularly of judgements about the safety and efficacy of medicines and medical practices can be negotiated, sustained, further embedded or sometimes reframed, as the key issue in standard of care adjudication is frequently, ‘the level of acceptable risk.’[[197]](#footnote-197) It is argued that despite the constructs of last resort, personal responsibility, safety/efficacy and the strongly held preference for RCT evidence in the interim guidance, standard of care jurisprudence creates a generous space for innovative prescribing. The *Bolam-Bolitho* formulation of the legal standard of care affords room for achieving a better balance between providing access to patients and maintaining patient safety than might otherwise be thought, and the Supreme Court judgment in *Montgomery v Lanarkshire Health Board* invites consideration of the patient’s values when making treatment decisions.

*Prescribing unlicensed CBMPs and the ‘Bolam-Bolitho’ standard of care*

The *Bolam* test assures doctors that their conduct is not negligent provided it is accepted as proper by a ‘responsible body of medical opinion.’[[198]](#footnote-198) As the prescribing of CBMPs on the NHS is virtually non-existent, doctors may feel confident that a decision to *not* offer a prescription of a cannabis based medicine is always legally safer than a decision to prescribe, as it would appear to have the support of the majority of medical opinion in the UK. However, we know that the parameters of the standard of care in relation to medical treatment can accommodate substantial differences in clinical judgement. A court presented with divergent expert opinions on whether prescribing was appropriate or inappropriate may *prefer* a view which rules out prescribing CBMPs on the particular facts, but the court’s preference would not suffice for a finding of negligence.[[199]](#footnote-199) Further, the fact that the practice of CBMP prescribing represents a niche minority amongst clinicians is not treated as an indicator of negligence; even a very small proportion of the specialty concerned can constitute a responsible ‘body’ of medical opinion.[[200]](#footnote-200)

The *Bolam* approach to fixing the legal standard of care, and its reliance on expert evidence from members of the medical profession, famously led to a state of affairs in which doctors could too easily call upon the support of their peers as a means of escaping liability.[[201]](#footnote-201) In *Bolitho,* however, the scales were at least theoretically rebalanced. For an expert’s view to satisfy the ‘responsible body of medical opinion’ threshold, it must be capable of withstanding the judge’s ‘logical analysis’.[[202]](#footnote-202) The extent to which this has truly recalibrated the doctor’s legal standard of care remains a moot question.[[203]](#footnote-203) What is clear, however, is that whilst *Bolitho* ‘logicality’ was initially treated as another way of asking whether the body of opinion supporting the defendant was ‘responsible,’ recent post-*Bolitho* jurisprudence appears to separate out ‘responsibility’ and ‘logicality.’ In *C v North Cumbria University Hospitals NHS Trust[[204]](#footnote-204)* Mr Justice Green sought to clarify the methods by which courts must now assess expert evidence in clinical negligence cases. His speech, now a mainstay in modern medical negligence judgments,[[205]](#footnote-205) seems to envisage three components of *Bolitho* reasoning. If the defendant’s practice is a) supported by a body of ‘*appropriate* expert opinion,’ that opinion will be given ‘substantial weight.’[[206]](#footnote-206) Courts should not delegate the decision to the defendant’s expert, however, and must assess whether that evidence is b) given in good faith, is *‘responsible*,’ ‘competent’ and ‘respectable,’[[207]](#footnote-207) and c) whether the opinion itself is reasonable and *logical*. In determining logicality, the court must assess expert opinion against the other evidence presented in the case and check for internal consistency.[[208]](#footnote-208) These three components of ‘appropriateness, ‘responsibleness’ and ‘logicality’ shape the following analysis of how the standard of care might be assessed for pioneering prescribers.

*A. Identifying the support of an ‘appropriate body’ of opinion*

First, how easy would it be to find an ‘appropriate body’ of opinion to express support for prescribing unlicensed CBMPs without positive RCT evidence, against the backdrop of interim guidance which is steeped in the language of ‘last resort’ and safety and efficacy concerns? As the standard of care is fixed according to the specialty being exercised at the time of the alleged negligence,[[209]](#footnote-209) and prescribing is in the main restricted to consultants,[[210]](#footnote-210) we would expect the ‘appropriate’ expertise to come from other consultants in that field of medicine who work with patients with similar conditions. However, it can be argued that truly ‘appropriate’ expertise should also be sourced from those with expertise in medicinal cannabis prescribing specifically.

Cannabis medicine is a developing field and as the prescriber is expected to be neither ‘polymath’ or ‘prophet’[[211]](#footnote-211), hindsight bias should be avoided. The past two years has seen the opening of a number of private clinics in the UK employing the services of consultants in rheumatology, chronic pain and neurology who are trained, experienced and willing to prescribe medicinal cannabis in appropriate cases.[[212]](#footnote-212) It therefore seems likely that consultants could readily be identified through clinic webpages who would support its use in a variety of conditions. A condition of clinics obtaining Care Quality Commission registration for providing access to medicinal cannabis,[[213]](#footnote-213) is that they use a governance mechanism equivalent to those in NHS settings, for example, multidisciplinary committees (MDCs), to approve prescribing decisions.[[214]](#footnote-214) Given therefore that decisions to prescribe should already be approved by MDCs or similar, this may go some way towards providing the support of an ‘appropriate’ and ‘responsible’ body of medical opinion. However, it is questionable whether doctors working for the same clinic would be capable of furnishing the court with the ‘support’ needed for *Bolam* purposes, given the potential for conflicts of interest. Nevertheless, the courts may place some secondary weight on the view of the multidisciplinary team working with the defendant when assessing whether the defendant’s conduct was ‘reasonable’.[[215]](#footnote-215) Given that practitioners will be judged on the basis of standards of care at the time of the alleged negligence and not with hindsight[[216]](#footnote-216), the pool of experts who can give evidence on standards at this time is likely to be small, as legal provision for prescribing is still new. A related difficulty then, is that the community of prescribers remains ‘niche,’ and the expert may be known to the defendant through this community, even though the expert is from outside the employing organisation. This could also raise questions of conflict of interest, diminishing the weight to be attached to their evidence.[[217]](#footnote-217)

In addition to the problems generated by prescribing being confined to a small, and possibly close-knit community of specialists, the newness of the field will likely mean that at present many prescribers would have had a fairly short period of time in which to have built up their expertise. Indeed, some refer to themselves as ‘self-taught’ or ‘self-proclaimed’ experts.[[218]](#footnote-218) These potential preliminary issues should not however prevent the identification of an ‘appropriate’ body of opinion. Litigants could always turn to experts from jurisdictions who can claim 10+ years experience, to seek their opinion on the relative safety and efficacy of these medicines. In *R v Beren,* for example, the Supreme Court of Canada was presented with an array of experts who were agreed ‘that cannabis is safer than many existing prescription drugs and some over the counter medication.’[[219]](#footnote-219) Evidence from Health Canada provided assurance that whilst the risk profile of cannabis was not completely benign, the adverse effects were ‘within the range tolerated for other medications’.[[220]](#footnote-220) There is perhaps doubt whether the evidence from an expert who practices outside the UK would have the same weight as an expert from the instant jurisdiction, but in areas where little expertise exists there is certainly evidence to suggest that a court would not discount the opinion of an expert who practices overseas.[[221]](#footnote-221)

*B. ‘Responsible’ experts & ‘logicality’: unlicensed status and the absence of positive RCT evidence*

One key question may be whether expert evidence supporting the prescription of unlicensed CBMPs in the absence of positive RCT evidence can satisfy the ‘respectable’ and ‘logicality’ thresholds embedded in the *Bolam-Bolitho* configuration of the standard of care. Before a judge can accept expert opinion as being ‘responsible, reasonable or respectable’, they must be satisfied that the experts have ‘directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion.’[[222]](#footnote-222) ‘Medical hubris’ must not overtake ‘clinical judgement’[[223]](#footnote-223), and for an expert giving evidence to satisfy a judge that they are ‘responsible,’ they should recognise the limitations of their knowledge. These issues concern the framing of the expert opinion, whether it makes the necessary concessions[[224]](#footnote-224), the source of expertise (e.g. whether that expertise draws from years of relevant clinical experience and remains current and whether it is contextualised in terms of relevant professional guidance). The expert evidence, if departing from such guidance, must show carefully reasoned arguments for such departure (on which, see section C below).

On ‘withstanding logical analysis’, first, it is clear that both the prescription of unlicensed medicines and the ‘off-label’ prescription of licensed medicines, are accepted constituents of modern medicine.[[225]](#footnote-225) Although the scale of these prescribing patterns is not known, doctors should be assured that prescribing an unlicensed medicine is not regarded as prime facie negligent. Indeed, the existence of the GMC’s guidance on this subject envisages that such prescribing can be entirely consistent with a doctor’s duties.[[226]](#footnote-226) Further support can be derived from *Jones v Taunton & Somerset NHS Foundation Trust[[227]](#footnote-227)* where Mr Justice Stewart was tasked with deciding whether, in 1995, the use of Nifepidine (a drug used to avert pre-term labour) was to be regarded as a breach of duty to the patient or whether it defied logical analysis given its unlicensed status. The judgment made it abundantly clear that use of a drug despite the absence of positive RCT evidence was not indicative of negligence.

Key to this discussion is the fact that in *Jones* the drug, although vindicated in later NICE guidance, had still not been the subject of RCTs twenty-five years later. Referring to the GMC’s 2013 guidance, Mr Justice Stewart stated that the fact that a drug was unlicensed was merely one factor to consider, and not a strong factor in light of the other evidence, such as the practices of other units and medical literature on the subject at the time of prescribing.[[228]](#footnote-228) In assessing the usefulness of published papers, the judge made reference to the reputability of the journal[[229]](#footnote-229) (although of course ‘reputability’ offers no guarantee of the reliability of published papers[[230]](#footnote-230)). This would be consistent with court judgments which suggest that whilst a clinician’s view which is founded solely on clinical experience without regard to published research is unlikely to be regarded as ‘logical’,[[231]](#footnote-231) a commitment to evidence-based medicine does not preclude a role for clinical judgement and received wisdom.[[232]](#footnote-232)As argued earlier, there are many reasons for disputing a dogmatic insistence on RCT evidence for prescribing. There are plenty of studies and literature occupying the position between anecdote and double-blind RCT which could be relevant in informing opinion, including ‘N of 1’ studies, registry data, case studies, observational studies and cross-sectional studies. Whatever the shape of interim guidance, the standard of care clearly *does not* insist upon RCT evidence to support clinical decision making.

All of the above also raises questions about the liability of a GP who through ‘shared care’ arrangements undertakes to issue repeat prescriptions for the patient under the direction of the specialist. The standard of care already recognises that doctors may fall below the standard of care by failing to spot a ‘barn door’ error of another doctor, however, they are *usually* entitled to assume that the decisions of other members of the medical team are non-negligent.[[233]](#footnote-233)

*C. ‘Guidelines not tramlines’: deferring to guidance in the legal standard of care*

A further pertinent question concerns the extent to which the interim guidance discussed above determines the prescriber’s standard of care. In *C v North Cumbria* Green J indicated that when assessing expert evidence on whether the defendant’s practice was negligent, that evidence had to be tested against ‘other sources of evidence’, to include relevant professional guidance.[[234]](#footnote-234) We know that professional guidance is frequently heavily relied upon in fixing the standard of care, and indeed in *Montgomery v Lanarkshire Health Board,* the Supreme Court appeared to formally align the legal standard of care with current professional guidance (specifically GMC guidance) on what should be disclosed to a patient regarding proposed treatment.[[235]](#footnote-235)

Closer examination of case law reveals that the standard of care affords significant latitude for the clinical judgement of the doctor in the individual patient’s case. First, the courts refuse to equate the standard of care with the content of professional guidance and they leave considerable scope for professional autonomy of clinicians in the use of innovative treatments.[[236]](#footnote-236) In *Price v Cwm Taf[[237]](#footnote-237)*, the claimant failed to persuade the court to view a departure from NICE guidelines as ‘prima facie negligence,’ the judge preferring to say that: ‘a clinical decision which departs from the NICE Guidelines is likely to call for an explanation of some sort. The nature and degree of detail required will depend on all the circumstances.’[[238]](#footnote-238) In the context of NICE guidelines it should also be noted that these guidelines relate not just to safety and effectiveness, but also to cost. The guideline which states that doctors should NOT offer cannabis-based products for chronic pain, for example, is largely based on cost and has little to do with safety and effectiveness. After an extensive review of the evidence, NICE conceded that there was ‘some evidence’ of ‘modest’ effectiveness for chronic pain, but given the limited effectiveness and potentially large number of people who might benefit, medicinal cannabis was not *cost* effective as a treatment option.[[239]](#footnote-239) This is clearly a rationing based decision and departure from this guideline should therefore not be cited as a reason for finding a doctor’s prescription to be negligent. This is another reason why great care is needed before branding a departure from NICE guidance ‘negligent’, as the standard of care vis a vis patients is largely concerned with safety and effectiveness compared to other available treatment options and cost considerations are unlikely to be relevant.

Secondly, even where there seems little distinction between the legal standard of care and the contents of professional guidance, much of the guidance itself acknowledges a role for clinical judgement that the usual rule should be departed from. NICE guidance does not profess to define the standard of care – its contents are ‘guidelines not tramlines’,[[240]](#footnote-240) and its recommendations do ‘not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient’.[[241]](#footnote-241)The House of Commons Select Committee report in 2019, underlined this saying: ‘If a clinician believes that prescribing a medicinal cannabis product will help their patient, they should not be discouraged by the guidance from doing so.’[[242]](#footnote-242) This is repeated by the BPNA which said of its guidance that it: ‘should not be a barrier to prescribing and is only advisory. Specialist clinicians *should use their own judgment*, along with the evidence, when judging whether prescribing CBPMs would be in the *best interests* of their individual patients.’[[243]](#footnote-243) Further, a letter from the Department of Health and Social Care following the 2018 reforms clarified the status of interim professional guidance saying that the guidance ‘does not remove or replace the clinical discretion of the prescriber in accordance with their professional duties.’ Doctors are to work with their patients/carers to agree the best treatment for them, ‘in accordance with normal clinical practice.’[[244]](#footnote-244)

The GMC’s guidance on prescribing unlicensed medicines has already been noted as leaving more room for clinical autonomy.[[245]](#footnote-245) Whilst licenced products are usually to be preferred over unlicensed ones, this is not an absolute rule and with reference to unlicensed medications, rather than insistence on RCT evidence found elsewhere, doctors should instead ‘be satisfied that there is sufficient evidence *or experience* of using the medicine to demonstrate its safety and efficacy’.[[246]](#footnote-246) Similarly, in terms of eligibility, the GMC supports prescribing an unlicensed product on the basis that licensed medicines do not meet this patient’s ‘needs’ or that it is otherwise considered ‘necessary’ in this case, both being open textured provisions allowing significant margin for discretion. These provisions clearly envisage a balancing exercise to be undertaken when determining whether trying this medicine is ‘necessary.’ As long as the doctor has considered the guidance, has conducted the balancing exercise and reasonably concluded that such prescribing would address the patient’s need or was otherwise ‘necessary’, then such conduct will presumably not be regarded as negligent.[[247]](#footnote-247) Aside from these gestures towards clinical judgement and a patient’s best interests as trumping the content of guidance in appropriate cases, a ‘logicality’ threshold would surely acknowledge that any guidance should be subject to qualification and interpretation in light of the particular experiences and profiles of individual patients. Co-morbidity and polypharmacy represent growing problems in modern medicine,[[248]](#footnote-248) whereas RCTs and professional guidance tend to focus on a single condition and/or treatment. This leaves doctors to determine in many instances what is appropriate where the patient has multiple morbidities and requires a cocktail of medications.[[249]](#footnote-249) Thus it seems that there is some consensus that the available ‘guidance’ will always necessarily be subject to prerogative of the practitioner to act in what they reasonably regard as the patient’s best interests. This is most clearly expressed in the MCCS guidance which adopts the stance that the best interests standard is the ultimate guide to decision making after balancing the available evidence.[[250]](#footnote-250)

All of the above shines a very different light on professional guidance and speaks to a space for clinical judgement, albeit one which is rarely examined or tested in the courts. Doctors and experts called in their defence must be able to justify decisions to prescribe with reference to the available guidance and evidence, but are free to come to a decision that their patient’s needs are best served by trying these unlicensed products.[[251]](#footnote-251)

*How are tensions between GMC default guidance and interim guidance to be addressed?*

One particularly thorny issue arises out of the fact noted above that the GMC’s 2013 guidance on prescribing medicines differs in key respects from the interim guidance issued around CBMP prescribing. How would a court decide on the relative status of these two thresholds for the purposes of fixing the standard of care, or, for that matter, if the court had to choose between the GMC’s guidance on prescribing unlicensed medications and the far less liberal interim guidance of the BPNA? NHS England advice and the other interim guidance has been drafted specifically with reference to medicinal cannabis and therefore might be regarded as more ‘applicable,’ to the context of prescribing cannabis-based medicines than the GMC’s general prescribing advice. But there are reasons for thinking that GMC guidance should be considered more authoritative – as mentioned above.[[252]](#footnote-252) Its guidance has been highly influential in fixing the standard of care,[[253]](#footnote-253) and it is widely regarded as the predominant source of ethical guidance to the profession.[[254]](#footnote-254) For example, in *An NHS Trust v Y*, Lady Black noted that GMC guidance in particular (as compared with, for example, RCP guidance) had a very important part to play given its ‘special role in providing guidance for the medical profession.’ [[255]](#footnote-255)In fact she went further, commenting that the statutory backdrop to the GMC’s advice giving role meant that the GMC’s guidance could be singled out as ‘undeniably part of the established regulatory framework.’[[256]](#footnote-256) The positioning of GMC guidance as part of the regulatory framework provides strong support for saying that there should be a preference for GMC guidance for standard of care purposes when there is perceived to be a difference of approach between its provisions and guidance from other sources.

*D. The ‘first wave patient’ and calibrating risk to include reference to patient values and experience*

One final but crucial question, particularly in the context of the first tranche of cannabis patients, is to what extent the standard of care allows patient values and experience to legitimately inform the clinician’s calibration of acceptable risk? As already intimated, some of the factors that marks out this newly legalised domain of prescribing as antagonising conventional medical norms include that ‘first wave patients’ are likely to self-identify as potential candidates for a prescription,[[257]](#footnote-257) will often have prior experience of cannabis used therapeutically and will have researched the application of CBPMs for their condition extensively.In many instances they will be an embodiment of the patient envisaged by the Supreme Court in *Montgomery v Lanarkshire,* who, rather than ‘placing themselves in the hands of their doctors (and then being prone to sue their doctors in the event of a disappointing outcome)’ are :

‘…capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.’[[258]](#footnote-258)

Whilst setting the standard of care for risk disclosure, *Montgomery* also specified that the patient’s consent should be made up of information about material risks, the benefits of the proposed treatment, the alternative treatments and meaningful dialogue regarding the same.[[259]](#footnote-259) These four facets of informed consent *per Montgomery* reflect a shift in the values driving clinical decision making from the clinician to the patient,[[260]](#footnote-260) with the role of patient values in decision making as a ‘connecting thread throughout the judgment.’[[261]](#footnote-261) Herring goes further, suggesting that *Montgomery’s* move to a patient-centred test of which risks are material for the purposes of disclosure ‘privileg[es] patient assessments of how risks are to be valued over professional ones.’[[262]](#footnote-262) Whereas the interim guidance analysed above makes little reference to such matters, it is argued here that informed consent and taking into account the values of the patient can legitimately be used by the clinician to calibrate the acceptability of risk. On this, the *Mongtomery* judgment makes reference to:

‘a fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.’[[263]](#footnote-263)

This stratification of the doctor’s roles in *Montgomery* indicates that, resources aside, the patient’s autonomy is always bounded by the doctor’s prior decision as to which treatments should be suggested for the patient to choose between. However, patient choice is illusory if ‘other actors control the parameters of the choice,’[[264]](#footnote-264) and whilst some control of available options is inevitable, it is argued that consideration of the patient’s values should not be confined to the doctor’s assessment of which risks are ‘material’ when advising the patient of the risks associated with recommended treatment. Patient values should also be relevant at the stage of selecting treatment options for the patient to choose between. Whether a doctor follows a strict application of the ‘last resort’ policy may determine whether unlicensed cannabis medicines are selected as one of the options for discussion. We should note, however, that *Montgomery* does not suggest that the doctor’s role in choosing acceptable treatments is *limited to* clinical considerations,[[265]](#footnote-265) or that patient values cannot legitimately be taken into account in framing those choices.

Of course, there are dangers in moving too far towards a ‘patient-led’ approach when calibrating the relative risks of available treatment options, not least the dangers associated with the patient’s vulnerabilities. Patients with chronic conditions or diseases may be physically and psychologically vulnerable. Simpson, who explored the relationship between hope and vulnerability in healthcare contexts, identifies hope as generating additional hazards (including of disappointment), and as creating sensitivity to information, both positive and negative, relating to what is hoped for.[[266]](#footnote-266) Dresser agrees, noting the vulnerability that stems from a willingness to listen to stories or details that fuel hope and filtering out ‘cautionary tales’ and ‘negative results.’[[267]](#footnote-267) This compounded vulnerability stemming from a patient’s condition and their hopes for better therapeutic options can also increase the risks of exploitation, and the possibility that promoting patient autonomy may be used as a screen for self-serving commercial interests[[268]](#footnote-268) should not be overlooked. Private or consumer medicine can be ‘breeding grounds’ for false hopes,[[269]](#footnote-269) and providers may consciously or unwittingly exacerbate those false hopes because of their fears of losing patients or of bad reviews[[270]](#footnote-270) if they refuse access to the ‘hoped for’ medicine.

Aside from these vulnerabilities, there are other reasons to qualify a patient led approach to the calibration of risks when prescribing. Patients have no right to demand specific treatment,[[271]](#footnote-271) and doctors must not allow themselves to be led by their patients into prescribing medicine which goes against their own clinical judgement[[272]](#footnote-272), otherwise there is a risk that the doctor might be ‘duped’ or manipulated into a transaction which is either not in a patient’s best interests or which creates a risk of diversion. There may also be broader concerns which may go against giving patient preferences significant weight in this context, such as, that increases in prescription of unlicensed medicinal cannabis products will undermine the very clinical trials that are so desperately needed in this field. Understandably, many patients would rather be permitted to try a new medicine under their doctor’s supervision, than enrol in a trial where they may unknowingly be allocated to the control group. Consequently, the trials themselves may become unviable due to a shortage of willing volunteers, particularly where the unlicensed medicine is used for a very rare condition and the pool of potential volunteers is already small.[[273]](#footnote-273) The potential impact of increased prescribing of unlicensed medicines on the feasibility of clinical trials is an important and sobering consideration, but it is unfair to expect patients with chronic conditions to bear the burden of waiting for a suitable trial, rather than be able to access a treatment which is already legally available. With rigorous monitoring of outcomes in place, their treatment can still contribute to the data availability on the safety and efficacy of the medicine for their condition.

In light of the above concerns, the question then becomes whether an appropriate body of medical opinion, would ‘responsibly’ and ‘logically’ support taking into account the specific patient’s values when calibrating the risk of using an unlicensed CBMP? A key step in safety netting against liability for a failure to disclose will therefore be advising the patient fully and candidly of known potential risks and benefits.[[274]](#footnote-274) Account needs to be taken, for example, of the fact that both prescriber and patient may be affected by optimism bias.[[275]](#footnote-275) It is probably advisable, therefore, to ensure ‘that the patient realises s/he is effectively rolling the dice’ as the risks cannot be clearly defined.[[276]](#footnote-276) GMC guidance on ‘Consent’ requires that dialogue with the patient pursues ‘a shared understanding of the expectations and limitations’ of the available treatment options.[[277]](#footnote-277) It will therefore also be important to ensure that the patient knows that the drug may take some time to work, that these drugs are not a cure, but may offer means for managing the symptoms of disease and disorder, that current supply chains may mean there could be a break in supply, that the drug may not work at all (so that the patient is prepared for disappointment), that the prescription is an innovative treatment,[[278]](#footnote-278) that it is ‘unlicensed’[[279]](#footnote-279) and what that means,[[280]](#footnote-280) and that it is not supported by positive RCT evidence, that as with any new treatment the long term risks and benefits are not yet clear[[281]](#footnote-281) and, possibly even, that it departs from professional guidance.

In addition to patient values, *patient experience* also has an important place in this area of clinical decision making. Reference to ‘experience’ in the GMC’s default guidance could be interpreted as supporting a prescriber who relies in part on a *patient’s* experience (e.g., in this context, of using cannabis) to support their clinical judgement, and there have been suggestions that some doctors would indeed consider this.[[282]](#footnote-282) The courts have recognised that evidence generated by scientific studies represents generalities, the average effect of a particular medicine, and that doctors must then apply their clinical judgement to transpose this into a decision which takes account of this specific patient’s circumstances.[[283]](#footnote-283) Those circumstances may, in this context, include the fact that the patient has taken cannabis based products in the past and it has helped them to manage their condition. If an NHS consultant knows her patient has been accessing a cannabis product privately, and it has had a marked reduction in symptoms of increased quality of life, there is surely an argument for saying that the consultant should at least consider pursuing such a prescription on the NHS.[[284]](#footnote-284)

Thus far, however, there is little sign that a path to NHS funding is opening. Even though a patient’s journey through private healthcare may have demonstrated evidence in their case that a form of medicinal cannabis is tolerably safe and effective, or at least relatively so when compared with other treatments, NHS prescriptions remain unavailable.[[285]](#footnote-285) The Advisory Council on the Misuse of Drugs reported in late 2020 it was ‘strongly presumed’ that less than 5 NHS prescriptions had been issued for unlicensed CBMPs since the 2018 reforms.[[286]](#footnote-286) Further research is needed into how much concerns about opaque medico-legal risks contribute to this picture.

**CONCLUSION**

In 1998 a Select Committee advised that if prescription of unlicensed medicinal cannabis was to be legalised, ‘professional bodies should provide firm guidance on how to do so responsibly.’[[287]](#footnote-287) The reforms which occurred twenty years later, have been accompanied by a proliferation of guidance in which the emphasis is on *avoiding* prescribing, rather than prescribing responsibly and which emphasises risk but says little about patient access. The reforms themselves challenged fundamental norms of established medical practice; they came at a time of educational and training deficit, the evidence base for these medicines did not conform to ‘gold standard’ RCTs and the characteristics of the first medicinal cannabis patients were likely to disrupt some of the usual structural inequality in doctor: patient relationships. The reforms were also characterised by a delegation of the detail to professional bodies and regulators. This article has presented a boundary work analysis of the guidance generated by these reforms, highlighting a repertoire of rhetorical devices which if taken together appear to underscore messaging of heightened medico-legal risk. The prominence of the ‘last resort’ position, particularly as endorsed by NHS England, creates a formidable barrier to access, requiring other options to have been exhausted and privileging licenced products regardless of their benefit: harm ratios. This messaging is accompanied by opaque hints of enhanced and unidentified liabilities which ‘remain with the prescriber’, despite a lack of evidence that the threat of personal responsibility for prescribing unlicensed medicines is a reality. Finally, interim guidance flags concerns about the absence of published double-blind RCT evidence on the safety and efficacy of these medicines and the effects of their long-term use. Yet, the evidence generated by RCTs is often a poor reflection of their performance when prescribed in real world settings and is inevitably weak on the evidence of long-term effects. On all three fronts this author has noted variance between the GMC’s default guidance on prescribing unlicensed products and the interim guidance on medicinal cannabis prescribing, creating further layers of uncertainty. Medico-legal uncertainty is a powerful device for constraining practice, and serves in this instance to exacerbate uncertainty as to whether and when prescribing might be consistent with a prescriber’s standard of care whilst also furthering a covert rationing agenda.

The second part of this paper examined how the standard of care might respond to prescribing of these newly available medicines, identifying significant room for innovative prescribing practices in contrast to the very restricted space for prescribing suggested by the interim guidance. Identifying an ‘appropriate’ body of medical opinion may present problems if prescribing remains niche and confined to a small community of clinics, but if problematic, expertise could reliably be sourced from overseas. Case law tells us that the ‘unlicensed’ status of a drug is one factor amongst many to consider when assessing the logicality of prescribing it, and the standard of care is a long way from insisting on RCT evidence to justify a prescribing decision. Other factors against which ‘logicality’ is judged include the professional guidance itself, but despite the tone of extreme caution noted in this guidance, this still leaves significant room for prescribing consistently with the law’s standard of care. First, GMC guidance is markedly liberal in its stance on prescribing unlicensed medicines and it is GMC guidance which has traditionally been favoured by the courts because of its position as part of the regulatory framework. Secondly, standard of care jurisprudence leaves room for departure from applicable guidance. Whilst departing from guidance is not to be equated with negligence, clinicians prescribing in situations not envisaged in the guidance should nevertheless be advised to document their rationale for prescribing in detail, [[288]](#footnote-288) and generally ‘safety net’ even more assiduously than usual, including when researching possible contraindications, taking detailed histories from their patients, consulting and taking account of the views of other doctors[[289]](#footnote-289) and recording the results of this, and taking time over obtaining the informed consent of their patients, so as to be able to justify their decision on clinical grounds. Finally, in the context of the first wave of adult patients there is real scope for patient values and experience with cannabis to be given weight in prescribing decisions. Nevertheless, the apparent inconsistency between the BPNA and NHS England on the one hand and the GMC and MCC’s thresholds for prescribing these unlicensed products is troubling, as is the almost impossibly high threshold that prescribers would seemingly have to meet according to NHS England advice. A clearer steer from the GMC could be a welcome step towards facilitating responsible access, as there are sufficiently unique characteristics in this field of medicine to make it deserving of a profession-wide set of guidance.

1. This paper is connected with another project with University of Liverpool ethics approval to interview and survey medical practitioners on their experience and understandings of the legal requirements around medicinal cannabis prescribing (approval no 7495). [↑](#footnote-ref-1)
2. A. Schlag et al, ‘Medical cannabis in the UK: From principle to practice’ (2020) *Journal of Psychopharmacology* (online first), 1. [↑](#footnote-ref-2)
3. Alfie Dingley, who went from 150 seizures a week, to 300 days of being seizure free when using cannabis oil - (Health and Social Care Committee, *Drug Policy: Medicinal Cannabis* (2019) at [61]). [↑](#footnote-ref-3)
4. E.g. Sudden Unexpected Death in Epilepsy (‘SUDEP’). All epilepsies carry an increased risk of death. Dravets Syndrome, a rare intractable form of epilepsy carries a 10-15% chance of SUDEP before the age of 10: [www.dravet.org.uk](http://www.dravet.org.uk). [↑](#footnote-ref-4)
5. Above at n.2 and see Vera Twomey’s book, *For Ava* (Mercier Press, 2019). [↑](#footnote-ref-5)
6. I.e. moving them from Schedule 1 (controlled drugs considered to have no medicinal value) to Schedule 2 (controlled drugs acknowledged to have medicinal benefits): Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (E.W.&S) Regulations 2018 (SI 2018 No.1055) inserting a new Regulation 16A into the Misuse of Drugs Regulations 2001 (SI 2001/3998). As health is a devolved matter, separate legislation was required in Northern Ireland: The Misuse of Drugs (No.2) Regulations (Northern Ireland) 2018 (2018/173). [↑](#footnote-ref-6)
7. Above, regulation 4. [↑](#footnote-ref-7)
8. *Explanatory Memorandum to the Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018* at 3.2. [↑](#footnote-ref-8)
9. The regulations make no reference to specific conditions. [↑](#footnote-ref-9)
10. In fact, twenty years earlier, a 1998 Select Committee had strongly recommended precisely the same reforms, having heard evidence of the relative safety and efficacy of cannabis as a treatment - in particular, but not exclusively, for patients suffering with pain and spasticity caused by multiple sclerosis (MS): *Cannabis* (House of Lords Science and Technology Select Committee (9th Report)) (1997-98). For an insight into a range of adult patient experiences with medicinal cannabis in the patients’ own words, see the podcasts and blogs on pleacommunity.org.uk) and Mary Biles, *Cannabis Voices* at <https://www.marybiles.com/podcast>,. [↑](#footnote-ref-10)
11. <https://www.crowdfunder.co.uk/united-patients-alliance>. [↑](#footnote-ref-11)
12. ‘Families protest over NHS medical cannabis rules.’ *BBC News*, 5th February 2020. Available at <https://www.bbc.co.uk/news/uk-england-51385994>. [↑](#footnote-ref-12)
13. Charlotte Caldwell took the Health Board in Northern Ireland to court to provide a prescription for her son Billy whose epilepsy is substantially mitigated by medicinal cannabis: <https://www.belfastlive.co.uk/news/health/billy-caldwell-medicinal-cannabis-battle-17749677>. At the time of writing, the family of Charlie Hughes are bringing action against NICE and their local NHS Trust for refusing to prescribe for their 2 year old son who suffers from West Syndrome – ‘Parents' NHS cannabis fight for toddler who suffers 100 epilepsy seizures a day’. *The Mirror,* 20th March 2020 at <https://www.mirror.co.uk/news/uk-news/parents-nhs-cannabis-fight-toddler-21851951>. [↑](#footnote-ref-13)
14. <https://www.kentonline.co.uk/canterbury/news/cannabis-plea-for-girl-in-intensive-care-227836/>. [↑](#footnote-ref-14)
15. ‘No new NHS patients prescribed cannabis oil since legalisation’ *The Guardian,* 1st July 2020; ‘Medicinal cannabis: why are doctors still not prescribing?’ *The Guardian,* 3rd November 2019. [↑](#footnote-ref-15)
16. MCCS FAQs - <https://www.ukmccs.org/medical-cannabis/faqs/> section 7 – as of June 2020 the estimated average costs for most conditions was around £500 per month, but families of children with epilepsy were facing costs of £1,000+ per month. [↑](#footnote-ref-16)
17. D. Nutt et al, ‘So Near and Yet So Far,’ (2020) 10 *BMJ Open* 1 at 1. [↑](#footnote-ref-17)
18. There were around 30 NHS prescriptions for unlicensed medicinal cannabis products in the first year: *The UK Review of Medical Cannabis: the needs of a nation – Part A* (Cross Party Parliamentary Group for Drug Policy Reform, 2020), pp5-6. Presumably, a number of these were repeat prescriptions. [↑](#footnote-ref-18)
19. ‘It is a source of deep frustration to me that…, because *a clinical decision* is needed for a prescription,… many parents who entirely understandably think that their child would benefit from medicinal cannabis now find that they cannot get a clinician to sign it off.’ HC Deb vol.658, col.37 8th April 2019 (emphasis added). [↑](#footnote-ref-19)
20. Experiences of the legalisation of medicinal cannabis, followed by a longer-term struggle for patient access, is a story shared elsewhere. See e.g.: D. Nutt, ‘Why medical cannabis is still out of patients’ reach’ (2019) 365 BMJ 1903 and N. Ries, 'Prescribe with Caution: The Response of Canada's Medical Regulatory Authorities to the Therapeutic Use of Cannabis' (2015-2016) 9 *McGill JL & Health* 215: recent research suggests that fewer than 10% of Canadian medical cannabis users obtain the drug solely from legal sources.’ At 241. [↑](#footnote-ref-20)
21. *Barriers to accessing cannabis-based products for medicinal use on NHS prescription* (NHS England, 2019) at 34. [↑](#footnote-ref-21)
22. Health and Social Care Committee, *Drug Policy: Medicinal Cannabis* (2019) at [21] (emphasis added). [↑](#footnote-ref-22)
23. ‘CBMPs’ for the purposes of the NICE Guideline are more broadly defined than CMPs in the 2018 regulations, as they include pure cannabidiol, licensed products (i.e. currently, Sativex, Epidiolex and nabilone) and synthetic cannabinoids. [↑](#footnote-ref-23)
24. NG144. [↑](#footnote-ref-24)
25. See further below and P. Case, ‘The NICE Guideline on Medicinal Cannabis: Keeping Pandora’s Box Shut Tight?’ (2020) 28(2) Med L Rev 401. [↑](#footnote-ref-25)
26. See sources noted above at notes 2, 9, 11, 12, 13, 14, 16, 17. [↑](#footnote-ref-26)
27. See section I below. [↑](#footnote-ref-27)
28. Cross Party Parliamentary Group for Drug Policy Reform, 2020, above at n.18, 48. [↑](#footnote-ref-28)
29. Although not always fulfilling its ‘gold standard’ reputation: see M. Kaplan, *The role of RCT evidence in drug reimbursement decision making processes* (2019), particularly chapter 1; C. Derkatch, ‘Method as argument: boundary work in evidence‐based medicine.’ (2008) 22(4) *Soc. Epistemol.* 371 at 376. [↑](#footnote-ref-29)
30. *Barriers*, n.20,at p9. [↑](#footnote-ref-30)
31. See the trepidation evident in E. Cannon, ‘Cannabis debate leaves GPs facing a prescribing conundrum’ *PULSE* (21st August, 2018). [↑](#footnote-ref-31)
32. W. Pederson and S. Sandberg, ‘The medicalisation of revolt: a sociological analysis of medical cannabis users’ (2013) 35(1) *Soc Health & Illness* 17 at 24. [↑](#footnote-ref-32)
33. I. Freckleton, ‘Internet Disruptions in the Doctor Patient Relationship’ (2020) 28(3) Med L Rev 502. [↑](#footnote-ref-33)
34. This group might be contrasted with ‘second wave’ who have heard of medicinal cannabis and suggest to their doctor that it might help them and those in the ‘third wave’ whose doctor initiates a conversation about medicinal cannabis in the belief that it will help their patients. [↑](#footnote-ref-34)
35. [2015] UKSC 11 at [76]. [↑](#footnote-ref-35)
36. See e.g. E. Sobo, ‘Parent use of cannabis for intractable paediatric epilepsy: everyday empiricism and the boundaries of scientific medicine’ (2017) 190 *Social Science & Medicine* 190. [↑](#footnote-ref-36)
37. T. Gieryn, *Cultural Boundaries of Science: Credibility on the Line* (University of Chicago Press, 1999) at 16. [↑](#footnote-ref-37)
38. L. Frith et al, ‘Ethical boundary-work in the infertility clinic’ (2011) 33(4) *Soc Health & Illness* 570, 571. [↑](#footnote-ref-38)
39. T. Gieryn. ‘Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists’ (1983) 48(6) *American Sociological Review* 781. [↑](#footnote-ref-39)
40. K. Lancaster et al ‘Making medicine; producing pleasure: a critical examination of medicinal cannabis policy and law in Victoria, Australia. (2017) 49 Int. J. Drug Pol. 117. [↑](#footnote-ref-40)
41. Y. Zolotov et al, ‘Medical cannabis: an oxymoron? Physicians' perceptions of medical cannabis.’ (2018) 57 *Int. J. Drug Pol*. 4. [↑](#footnote-ref-41)
42. D. Zarhin et al, ‘Rhetorical and regulatory boundary-work: The case of medical cannabis’ (2018) 217 *Soc Sci & Med* 1. [↑](#footnote-ref-42)
43. E. Sobo, ‘Parent use of cannabis’, above n.36. [↑](#footnote-ref-43)
44. Above, n.37. [↑](#footnote-ref-44)
45. Frith et al, n.38 at 571. [↑](#footnote-ref-45)
46. E.g. M. Quigley and S. Ayihongbe, ‘Everyday Cyborgs: On Integrated Persons and Integrated Goods’ Med L Rev (2019) 26(2) 276. [↑](#footnote-ref-46)
47. D. Zarhin et al, ‘Rhetorical and regulatory boundary-work’ above n.42. [↑](#footnote-ref-47)
48. E.g. S. Miner, ‘Demarcating the dirty work: Canadian Fertility professionals’ use of boundary-work in contentious egg donation’ (2019) 221 *Soc Sci and Med* 19, Frith et al (above, n.38) and K. Ehrich, et al, ’Social welfare, genetic welfare? Boundary-work in the IVF/PGD clinic’. (2006) 63 (5) *Soc. Sci. Med*. 1213 - all applying to actors’ operation of legislation in the field of fertility/reproductive services. [↑](#footnote-ref-48)
49. D. Zarhin et al, above, n.42. [↑](#footnote-ref-49)
50. For example, there is no list of eligible indications or conditions as there has been in the legislation used in other jurisdictions. Cf Zarhin et al’s account of Israel’s scheme (n.42), where there is a list of indications and eligibility requirements, and in Canada, the *Medical Marijuana Access Regulations 2001* as enacted, and as amended, set out a hierarchy of qualifying conditions which determined the eligibility criteria which were also stipulated in the regulations. [↑](#footnote-ref-50)
51. Ss.2-3 Medical Act 1983. [↑](#footnote-ref-51)
52. K. Lancaster et al ‘Making medicine; producing pleasure,’ above n.41. [↑](#footnote-ref-52)
53. A. Schlag et al, ‘Medical cannabis in the UK’, above n.2. [↑](#footnote-ref-53)
54. *Medical Cannabis: Recent Developments* (House of Lords, Library Briefings) (2020) p1. [↑](#footnote-ref-54)
55. Ibid at paras 5.1 to 9.1. [↑](#footnote-ref-55)
56. See *The therapeutic and medicinal benefits of cannabis-based products – a review of recent evidence* (June, 2018), at para 2.3. This was an evidence review based on ‘recently published good quality evidence reviews’ from the United States, Ireland, Australia and the World Health Organisation – see 4.5. [↑](#footnote-ref-56)
57. T. Rippin, ‘Israeli scientists begin trials into the effectiveness of cannabis in treating Covid-19’ *Euronews* 27th April 2020 available at https://www.euroweeklynews.com/2020/04/27/israeli-scientists-begin-trials-into-the-effectiveness-of-cannabis-in-treating-covid-19/. [↑](#footnote-ref-57)
58. See the Medical Cannabis Clinicians Society All-Party Parliamentary Group for Medical Cannabis under Prescription, *Recommendations and Guidance on Medicinal Cannabis on Prescription* (2020). [↑](#footnote-ref-58)
59. Recently moved to schedule 5. [↑](#footnote-ref-59)
60. Compassionate use and extended access programmes: *Barriers* (2019) above n.15, at p.6. [↑](#footnote-ref-60)
61. E.g. Bedrocan, Bedrolite, Bediol. [↑](#footnote-ref-61)
62. For details of and attempts to gauge the prevalence of self-medication using cannabis, see: the Centre for Medicinal Cannabis study published in 2020 leading to the hypothesis that there were around 1.4 million such users in the UK (available at <https://www.thecmcuk.org/1-4-million-uk-adults-self-medicating-with-illicit-cannabis>). See also M. Ware, H. Adams and G. Guy, ‘The medicinal use of cannabis in the UK: Results of a nationwide study. (2005) 59 *International Journal of Clinical Practice* 291; M. Sexton, C. Cuttler, J. Finnell, et al. ‘A cross-sectional survey of medical cannabis users: Patterns of use and perceived efficacy.’ (2016) 1(1) *Cannabis and Cannabinoid Research* 131; R. Coomber et al, ‘Using cannabis therapeutically in the UK: A qualitative analysis of how using an illicit drug therapeutically affects the life of users and their relationships with significant others, health care providers and the criminal justice system.’ (2003) 33(2) *Journal of Drug Issues* 325. [↑](#footnote-ref-62)
63. Misuse of Drugs Act 1971. [↑](#footnote-ref-63)
64. *Drugs and the Law* (the ‘Runciman report’) (2000) at para [38]. [↑](#footnote-ref-64)
65. see <https://www.cps.gov.uk/legal-guidance/drug-offences>. [↑](#footnote-ref-65)
66. E.g. ‘Arthritic plasterer who grew cannabis for pain relief is sentenced’ *Cornwall Live* May 2020 at <https://www.cornwalllive.com/news/cornwall-news/arthritic-plasterer-grew-cannabis-pain-4152714>. Judge Robert Linford remarked ‘I can see why you did it… There are medicinal cannabis products available from doctors and this is the right way to do it. Growing it yourself is the wrong way.” [↑](#footnote-ref-66)
67. R. Cooper, ‘In praise of the prescription: The symbolic and boundary object value of the traditional prescription in the electronic age’ (2011) 20(4) *Health Sociology Review* 462 at 468. [↑](#footnote-ref-67)
68. See M. Smith’s, ‘The relationship between pharmacy and medicine’ discussing manifest and latent functions of prescribing in R. Mapes (ed) *Prescribing Practice and Drug Usage* (CRC Press, 1980). [↑](#footnote-ref-68)
69. E. Pellegrino, ‘Prescribing and Drug Ingestion Symbols and Substances’ (1976) 10 *Drug Intelligence* 624, reprinted in (2006) *Pharmacology Annals* 1658 at 1660. [↑](#footnote-ref-69)
70. Avoiding the conclusion that ‘nothing can be done’: Pellegrino ibid at 1660. [↑](#footnote-ref-70)
71. M. Weiss and J. Sutton, ‘The changing nature of prescribing: pharmacists as prescribers and challenges to medical dominance’ (2009) 31(3) *Soc of Health & Illness* 406 at 406. [↑](#footnote-ref-71)
72. E. Pellegrino, n.70, 1660. [↑](#footnote-ref-72)
73. J. Metzl and M. Riba, ‘Understanding the Symbolic Value of Medications: A Brief Review’ (2003) 10(7) *Primary Psychiatry* 45. [↑](#footnote-ref-73)
74. Metzl and Riba above. [↑](#footnote-ref-74)
75. And similar transitions for the carer who may be involved in procurement and supply of otherwise illicit substances. [↑](#footnote-ref-75)
76. K. Lancaster et al ‘Making medicine’ above n.41 at 120 and A. Schlag, ‘An Evaluation of Regulatory Regimes of Medical Cannabis,’ n.2 at 4. [↑](#footnote-ref-76)
77. Cross Party Parliamentary Group for Drug Policy Reform, 2020 (above n.18) at 92. [↑](#footnote-ref-77)
78. K. Lancaster et al ‘Making medicine; producing pleasure’, above n.41 at 117. [↑](#footnote-ref-78)
79. Based on Zolotov’s interviews with medical practitioners in Israel: above n.41 at 8. [↑](#footnote-ref-79)
80. A. Schlag, ‘An Evaluation of Regulatory Regimes of Medical Cannabis’ n.2 [↑](#footnote-ref-80)
81. Above, n.10 at 8.7. [↑](#footnote-ref-81)
82. As above. See also recent concern expressed at the normalisation of medicinal cannabis being strategically pursued by those wanting to see reform of drug controls to enable recreational use: J. Gornall, ‘Big cannabis in the UK: is industry support for wider patient access motivated by promises of recreational market worth billions?’ (2020) BMJ 368. [↑](#footnote-ref-82)
83. Limited ‘non-medical prescribing’ can also be performed by pharmacists, prescribing nurses, dentists: Misuse of Drugs Act 1971. [↑](#footnote-ref-83)
84. See e.g. Ian Shaw’s application of ‘dirty work’ theory to doctors’ management of ‘difficult patients’: ‘Doctors, “dirty work” patients and revolving doors.’ (2004) 14(8) *Qualitative Health Research* 1032. [↑](#footnote-ref-84)
85. The issue of whether and how doctors should navigate determining whether a patient’s use of medicinal cannabis is ‘medicinal’ or ‘recreational’ is not addressed by the guidance discussed here, but is a complex issue which the author has reserved for future work. [↑](#footnote-ref-85)
86. *Responsibility for prescribing between Primary & Secondary/Tertiary Care* (NHS England, 2018) at 4.1.6 (<https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf>). [↑](#footnote-ref-86)
87. Ronnie Cowan, HC Deb vol. 660, 20th May 2019. [↑](#footnote-ref-87)
88. N. Britten, **‘**Prescribing and the defence of clinical autonomy’ (2001) 23(4) *Soc of Health & Illness* 478. [↑](#footnote-ref-88)
89. See above at n.20. [↑](#footnote-ref-89)
90. *Use of cannabis-based products in neurology - interim guidelines* (Association of British Neurologists, 2018). [↑](#footnote-ref-90)
91. Around 85% of prescribing of unlicensed products are in private settings: Cross Party Parliamentary Group for Drug Policy Reform report, 2020 (above n.16) at 5. Some of the remaining 15% are accessing via the NHS are not doing so by usual means but by e.g. producer sponsorship (Caldwell), compassionate or extended access programmes. [↑](#footnote-ref-91)
92. *Drug Policy* HC Health and Social Care Select Committee 2019 at 82. [↑](#footnote-ref-92)
93. See P. Case, ‘The NICE Guideline’, n.24 at 406. [↑](#footnote-ref-93)
94. *Cannabis Based Medicinal Products*, NG144 (published November 2019). [↑](#footnote-ref-94)
95. and there is reportedly little confidence in one of these which has been superseded by newer treatments for that condition Nabilone – see Cross Party Parliamentary Group for Drug Policy Reform, 2020, above n.18 at 48. [↑](#footnote-ref-95)
96. NG144, 1.3. [↑](#footnote-ref-96)
97. Lennox-Gastaut Syndrome and Dravet’s Syndrome only. This appraisal informed the anticipated Technology Appraisal Guideline published in December 2019: <https://www.nice.org.uk/guidance/indevelopment/gid-ta10410/documents>. [↑](#footnote-ref-97)
98. *Making Decisions Using NICE Guidelines* (accessible at <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines>). [↑](#footnote-ref-98)
99. E.g. See *Guidance for the use of medicinal cannabis in the treatment of chronic non-cancer pain in Australia* (Australian Government, Department of Health, Therapeutic Goods Administration,2017). [↑](#footnote-ref-99)
100. NG-144, 1.2.1 [↑](#footnote-ref-100)
101. NG144, 1.2.2. [↑](#footnote-ref-101)
102. C.f. the *Health Effects of Cannabis* report, which concluded that there was ‘substantial evidence’ that ‘cannabis is effective in controlling chronic pain in adults’ (National Academy of Science Engineering and Medicine, 2017) at 90. [↑](#footnote-ref-102)
103. ‘Rationale and Impact’ in NG-144. [↑](#footnote-ref-103)
104. *Cannabis* (House of Lords Science and Technology Select Committee (9th Report)) (1997-98), e.g. at 8.2. [↑](#footnote-ref-104)
105. D. Oliver, ‘Private practice by NHS doctors – still controversial?’ (2018) BMJ 362. [↑](#footnote-ref-105)
106. NG-144 at 1.5. [↑](#footnote-ref-106)
107. As above. [↑](#footnote-ref-107)
108. See sources at notes 12 to 18. [↑](#footnote-ref-108)
109. ‘Interim’ indicating its temporary nature and that the relevant source awaited publication of the finalised NICE guideline which was published in November 2019. [↑](#footnote-ref-109)
110. *Recommendations on cannabis-based products for medicinal use* (RCP, 2018). [↑](#footnote-ref-110)
111. *Guidance on the use of cannabis‐based products for medicinal use in children and young people with epilepsy* (BPNA, 2018). [↑](#footnote-ref-111)
112. *Cannabis-based medicines: a desktop guide* (RCGP, 2018)*.* [↑](#footnote-ref-112)
113. *Use of cannabis-based products in neurology – interim guidelines* (ABN, 2018). [↑](#footnote-ref-113)
114. *Interim policy position on cannabis-based medicinal products* (CQC, October 2019). [↑](#footnote-ref-114)
115. *Cannabis based medicinal products PS05/19* (RCP, 2019) [↑](#footnote-ref-115)
116. *BPS Position Statement on the Medicinal Use of Cannabinoids in Pain Management* (2018). [↑](#footnote-ref-116)
117. Accessible at <https://www.england.nhs.uk/medicines-2/support-for-prescribers/cannabis-based-products-for-medicinal-use/cannabis-based-products-for-medicinal-use-frequently-asked-questions/>. The Royal College of Nurses took the lead amongst professional health care bodies, actively supporting a change in the law when reforms were being discussed and setting up a specialist support group for patients: Cannabis Patient Advocacy and Support Service (CPASS) – [www.cannpass.org](http://www.cannpass.org). [↑](#footnote-ref-117)
118. Ss.2-3 Medical Act 1983. [↑](#footnote-ref-118)
119. J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship?* (Hart Publishing, 2007) at 6. [↑](#footnote-ref-119)
120. *Information for doctors on Cannabis-based products for medicinal use (CBPMs)* (GMC, 2018) which merely provides links to other sources of guidance. [↑](#footnote-ref-120)
121. ‘Supplementary Letter’ issued by the Department of Health and Social Care, NHS England, Welsh Government, etc. Tuesday 20th November 2018 - <http://www.hscbusiness.hscni.net/pdf/Cannabis%20Based%20Products%20for%20Medicinal%20Use%20Supplementary%20Letter%20FINAL.PDF> and also NHS England FAQs, ‘who can prescribe’. [↑](#footnote-ref-121)
122. (GMC, 2013), paras 67 to 70. [↑](#footnote-ref-122)
123. ibid at para 11. [↑](#footnote-ref-123)
124. See below in section III. [↑](#footnote-ref-124)
125. J. Miola, *Medical Ethics and Medical Law,* n.120 at 18. [↑](#footnote-ref-125)
126. Miola, above at 8. [↑](#footnote-ref-126)
127. J. Fuller, ‘Rhetoric and Argumentation: How Clinical Practice Guidelines Think’ (2013) *Journal of Evaluation in Clinical Practice* (2013) 433 at 433. [↑](#footnote-ref-127)
128. ABN (above n.115) in connection with ‘other epilepsies,’ at p.2. [↑](#footnote-ref-128)
129. BPNA (n.113) and NHS England FAQs (n.119). The ‘last resort’ approach is not unique to the UK’s regulatory framework – in Canada, the ‘last resort’ policy, initially at least, represented the official position of the Canadian Medical Association: N. Jackson and O. Leung, ‘Health Care Practitioners and the Cannabis Industry: Ethical Issues of Legalizing and Prescribing Cannabis’ (2019) *Sage Business Cases* at p.4. It also appeared in the medical declarations that doctors were asked to complete in Canada under the Medical Marijuana Access Regulations 2001 ((as amended), para 6(1)(e) ‘(e) …conventional treatments for the symptom have been tried or considered and have been found to be ineffective or medically inappropriate for the treatment of the applicant’ SOR/2005-177. A version of the last resort provision also applies in the ‘Special Access Scheme’ in Australia: *Special Access Scheme: Guidance for health practitioners and sponsors,* Version 1.1, September 2017, www.tga.gov.au/special-access-scheme-guidance-health-practitioners-and-sponsors. [↑](#footnote-ref-129)
130. See e.g. Vera Twomey at n.2 above. [↑](#footnote-ref-130)
131. Above n.113 at 5.2. [↑](#footnote-ref-131)
132. As above. [↑](#footnote-ref-132)
133. <https://www.england.nhs.uk/wp-content/uploads/2018/10/letter-guidance-on-cannabis-based-products-for-medicinal-use..pdf>. (emphasis added). [↑](#footnote-ref-133)
134. https://www.kingsfund.org.uk/projects/positions/nhs-waiting-times?gclid=EAIaIQobChMIjcnngfLi6QIVCLLtCh3uoASxEAAYASAAEgIwUfD\_BwE [↑](#footnote-ref-134)
135. Although NHS webpages list only the ‘common side effects’ (affecting more than 1 in 100 patients) of most medicines and not rarer but possibly more serious side effects. See however concerns expressed by GPs regarding the risk profiles of commonly prescribed non-steroidal anti-inflammatory drugs, a ‘high risk’ drug group with significant adverse events: J. McDonald et al, ‘GPs’ views and experiences of prescribing non-steroidal anti-inflammatory drugs: a qualitative study.’ (2017) BJGP. [↑](#footnote-ref-135)
136. Above, n.124. [↑](#footnote-ref-136)
137. Above n.124 at para 67. See G. Donovan et al who report that such prescribing in the UK is in fact ‘widespread’ accounting for £75 million NHS spend in 2016: ‘Unlicensed medicines use: a UK guideline analysis using AGREE II’ (2018) 26(6) *Int J of Pharm Prac* 515. [↑](#footnote-ref-137)
138. Above n.124 at para 69. [↑](#footnote-ref-138)
139. E.g. *R v Quayle* (see below)*, Allard v Canada* 2016 FC 236, 394 DLR (4th) at [135], *R v Mernagh* [2013] ONCA 67 at [26], *R v Beren & Swallow* [2009] BCSC 429 at [41], *R v Parker* (2000) 49 O.R. (3d) 481 at [25]. [↑](#footnote-ref-139)
140. [2003] EWCA Crim 2637. [↑](#footnote-ref-140)
141. E.g. the three ‘patient’ defendants in *R v Quayle* argued their cannabis use was informed by the relatively low risk profile compared to opioids and one was using cannabis to wean himself off opioid dependency. [↑](#footnote-ref-141)
142. In another context, Whipple J found that para 69 of the GMC’s guidance was not an exhaustive list of situations where unlicensed medicines could be prescribed and that the guidance did not ‘preclude the prescription of unlicensed medicines, simply because there is a licensed alternative available’: *Bayer and Novartis v NHS Darlington CCG* [2018] EWHC 2465 at 148 – it was not unlawful for CCGs to prefer a cheaper drug, not licensed for the particular use over two medications licensed for that purpose which were recommended by NICE. [↑](#footnote-ref-142)
143. All cited as obvious problems of ‘black market’ supply by the judgment: [2003] 231 (4th) DLR 104 at [22]. [↑](#footnote-ref-143)
144. *Recommendations and Guidance on Medical Cannabis under Prescription* (2nd Ed) (Medicinal Cannabis Clinicians Society) (2020). [↑](#footnote-ref-144)
145. MCCS, above, at 2.3. [↑](#footnote-ref-145)
146. With thanks to one of the reviewers for this observation. [↑](#footnote-ref-146)
147. Above at n.2. [↑](#footnote-ref-147)
148. NG-144. [↑](#footnote-ref-148)
149. Govt advice on prescribing unlicensed medicines and off licence prescribing: published 2009 – https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities. [↑](#footnote-ref-149)
150. [↑](#footnote-ref-150)
151. There were 51,250 hospital consultants as of September 2017, but GPs represents an additional 34,534 prescribers, and all of these would be in the NHS: *The NHS Workforce in Numbers* (Nuffield Trust, 30th May 2019), available at <https://www.nuffieldtrust.org.uk/resource/the-nhs-workforce-in-numbers>. [↑](#footnote-ref-151)
152. E.g. Jorja Emerson’s father who needed to travel from Northern Ireland each month to London to access a prescription: ‘Private firm to provide girl with medical cannabis after NHS ‘refuses to pay’ *Belfast Telegraph,* 3rd April 2019. [↑](#footnote-ref-152)
153. Regulation 167 of the *Human Medicines Regulations 2012* (2012/1916). [↑](#footnote-ref-153)
154. *Bolam* *v Friern Hospital Management Committee* [1957] 1 WLR 583; *Bolitho* *v City and Hackney Health Authority* [1998] AC 232; *Montgomery v Lanarkshire Health Board* [2015] UKSC 11. [↑](#footnote-ref-154)
155. Above, n.124 at para 70. [↑](#footnote-ref-155)
156. ‘The legal position is thus that any unlicensed use of a medicine makes the Trust liable for ‘product defect’: <https://www.palliativedrugs.com/download/Unlicensed%20Medicines%20V4.pdf> and ‘‘The Medicines Act allows appropriate prescribers to prescribe medicines without a licence providing they are happy to assume full liability for the prescription’: <https://www.eoecph.nhs.uk/Pharmaceutical_specials.pdf>. [↑](#footnote-ref-156)
157. Under the Consumer Protection Act 1987. [↑](#footnote-ref-157)
158. BPNA (n.113) at 4.1. [↑](#footnote-ref-158)
159. CQC (n.116), p3. [↑](#footnote-ref-159)
160. MCCS April article on insurance for prescribers available at <https://www.ukmccs.org/information/working-as-a-medical-cannabis-clinician-in-the-uk-finding-insurance/>. Given the uncertainty regarding the meaning of ‘personal responsibility’ identified above, it is probably prudent for prescribers to check their insurance/indemnity arrangements before prescribing unlicensed CBMPs. [↑](#footnote-ref-160)
161. *Glaxo Wellcome UK v Sandoz Ltd* [2019] EWHC 2545 at [40]. [↑](#footnote-ref-161)
162. P. L’Ecleuse, et al., ‘Off-label use and of medicinal products and product liability’ *Thomson Reuters Practical Law* (2013). [↑](#footnote-ref-162)
163. This seems to be suggested by O’Grady’s warning that doctors should be aware of the product liability implications of the wording ‘direct personal responsibility’: J. O’Grady et al (eds), *Medicines, Medical Devices and the Law* (2011, CUP) – at 55. [↑](#footnote-ref-163)
164. E.g. <https://www.bcpft.nhs.uk/documents/policies/u/1135-unlicensed-medicines/file> (Black Country Partnership NHS Foundation Trust) at 4.2. [↑](#footnote-ref-164)
165. See Donovan et al at n.139 above. [↑](#footnote-ref-165)
166. E.g. *Kennedy v Queens Medical Centre* (2001) (unreported), cited in I. Dodds-Smith and E. Townsend, ‘The supply of unlicensed medicines for individual patient use’ in J.Griffiths (eds) *Textbook of Pharmaceutical Medicine* (7th Ed) (BMJ Books, 2013) at 265. [↑](#footnote-ref-166)
167. The use of the RCT in some instances as a rhetorical tool, apparently to tilt the argument against complementary medicines in the defence of medical boundaries, is systematically and convincingly posited by, Colleen Derkatch in *Bounding Biomedicine* (Chicago University Press, 2016). [↑](#footnote-ref-167)
168. Derkatch (2008) above at 380. [↑](#footnote-ref-168)
169. M. Nagington and T. Sandset, ‘Putting NHS England on trial: uncertainty-as-power, evidence and the controversy of PrEP in England’ (2020) 46(3) *Medical Humanities* . [↑](#footnote-ref-169)
170. See suggestions that alternative medicines are required to meet a higher standard than conventional medicines, many of which have themselves not been the subject of positive RCT evidence: K. Borgerson, ‘Evidence-based alternative medicine? (2005) 48(4) *Perspectives in Biology and Medicine* 505. [↑](#footnote-ref-170)
171. Three placebo controlled RCTs of CBD as an adjunctive therapy for patients with Lennox-Gastaut syndrome and Dravets syndrome: E. Perrucca, ‘Hard Evidence at Last?’ (2017) 7(2) J Epilepsy Research 61. [↑](#footnote-ref-171)
172. Above n.135. [↑](#footnote-ref-172)
173. ABN (n. 115) at p1. [↑](#footnote-ref-173)
174. See e.g. F. Galan and I. Miller ‘Cannabinoids in treatment-resistant epilepsy: a review.’ (2020) 14 *Current Treatment Options in Neurology* 115 which provides an overview of relevant studies, and also now, since the interim guidance R. de Carvalho Reis et al, ‘Efficacy and adverse event profile of cannabidiol and medicinal cannabis for treatment-resistant epilepsy: Systematic review and meta-analysis’ (2020) 102 *Epilepsy & Behaviour* 106635. [↑](#footnote-ref-174)
175. RCP, above at n.112, 1.3. [↑](#footnote-ref-175)
176. Above at n.135. [↑](#footnote-ref-176)
177. RCGP (above n.114) at 1.5 (emphasis added) and also RCP (n.112), particularly at section 5 and CQC (n.116), KLOE E6. [↑](#footnote-ref-177)
178. Above n.124 at para 70 (emphasis added). [↑](#footnote-ref-178)
179. R. De Vries & T. Lemmens, ‘The social and cultural shaping of medical evidence: case studies from pharmaceutical research and obstetric science.’ (2006) 62 *Soc. Sci & Med* 2694. [↑](#footnote-ref-179)
180. H. Naci and J. Ioannidis, ‘How good is "evidence" from clinical studies of drug effects and why might such evidence fail in the prediction of the clinical utility of drugs?’ (2015) 55 *Annual Rev of Pharmacol Toxicology* 169. [↑](#footnote-ref-180)
181. S. Sismondo, ‘How pharmaceutical industry funding affects trial outcomes’ (2008) 66 *Soc Sci & Med* 1909, 1911. [↑](#footnote-ref-181)
182. E.g. M. Tonelli, ‘In Defense of Expert Opinion’ (1999) 74(11) *Academic Medicine* 1187 recognised the ‘epistemic gap’ between research generated knowledge and the treatment of individual patients. [↑](#footnote-ref-182)
183. A. Hatswell et al, ‘Regulatory approval of pharmaceuticals without a randomised controlled study.’ (2016) *BMJ Open* 6e011666. [↑](#footnote-ref-183)
184. Many anti-epileptic drugs prescribed to children are ‘off licence’: A. Rosati, et al, ‘Antiepileptic Drug Treatment in Children with Epilepsy’ (2015) 29 *CNS Drugs* 847. [↑](#footnote-ref-184)
185. K. Wartolowska et al, ‘Feasibility of surgical randomised controlled trials with a placebo arm: a systematic review’ (2016) *BMJ Open*, 6:e010194. doi:10.1136 and see P. McCullough, ‘Randomised trials in surgery: problems and possible solutions’ (2002) BMJ 324: ‘Treatments in general surgery are half as likely to be based on RCT evidence as treatments in internal medicine’ at 324. [↑](#footnote-ref-185)
186. C. Derkatch, ‘Method as argument: boundary work in evidence‐based medicine.’ (2008) 22(4) *Soc. Epistemol* 371 at 382. [↑](#footnote-ref-186)
187. H. Naci and J. Ioannidis, ‘How good is "evidence" from clinical studies of drug effects and why might such evidence fail in the prediction of the clinical utility of drugs?’ (2015) 55 *Annual Rev of Pharmacol Toxicology* 169. [↑](#footnote-ref-187)
188. O. Devinsky, J.H. Cross, L. Laux, *et al. ‘*Trial of cannabidiol for drug-resistant seizures in the Dravet Syndrome’ 376 (21) (2017) NEJM 2011. Indeed, the RCP guidance notes that medicine fell into error by prescribing opiates with little evidence of their effects long term: RCP guidance (n.112) at 4. [↑](#footnote-ref-188)
189. H. Naci and J. Ioannidis, ‘How good is "evidence" from clinical studies of drug effects and why might such evidence fail in the prediction of the clinical utility of drugs?’ (2015) 55 *Annual Rev of Pharmacol Toxicology* 169. [↑](#footnote-ref-189)
190. D. Nutt et al, ‘So Near Yet So Far.’ (2020), at n.16. [↑](#footnote-ref-190)
191. The emphasis in this paper is primarily on adult prescribing, with prescribing for children being reserved for another project. [↑](#footnote-ref-191)
192. Negligent prescribing may on occasion give rise to harms to third parties, e.g. whilst driving under the influence of the medication, but the duty of care to third parties is an involved issue deserving a paper of its own. [↑](#footnote-ref-192)
193. See citing of ‘personal liability’ as a reason for reluctance to prescribe in: I. Torjeson, ‘Cannabis based drugs: GPs should be able to prescribe to improve access, NICE says’ (2019) 366 BMJ l5107, M. Smith, ‘Medical Cannabis: we need a change in culture and far more government action.’ (2019) BMJ and K. Thorpe, ‘Working as a medical cannabis clinician in the UK: finding insurance’ 23rd April 2020 accessible at <https://www.ukmccs.org>. This concern is echoed more broadly for the prescription of unlicensed meds generally: A. Chisholm, ‘Exploring UK attitudes towards unlicensed medicines use: a questionnaire-based study of members of the general public and physicians’ (2012) 5 *International Journal of General Medicine* 27. [↑](#footnote-ref-193)
194. Searches of jurisdictions where medicinal cannabis prescribing has been in place for some time however, reveal little evidence that it is resulting in litigation against the doctor. See as an exception where negligence is in any event, fairly obvious, the case of Hollywood doctor, Dr Eidelman, who recommended cannabis for a 4yr old who he improperly diagnosed as having ADHD: https://www.latimes.com/local/california/la-me-ln-doctor-marijuana-20190128-story.html. [↑](#footnote-ref-194)
195. E.g. in *C v North Cumbria University Hospitals NHS Trust* [2014] EWHC 61 – considering whether administering second dose of Prostin was negligent in light of the available medical literature; *Fraser v Bolt* [2009] EWHC 2906 – harm caused by over-prescription of benzodiazepenes. [↑](#footnote-ref-195)
196. E.g. *Holton v GMC* [2006] EWHC 2960 – overdiagnosis of epilepsy in children and over-prescribing of aggressive medications resulting in fitness to practice proceedings. [↑](#footnote-ref-196)
197. *C v North Cumbria University Hospitals NHS Trust* [2014] EWHC 61 at [71]. [↑](#footnote-ref-197)
198. Above, n.155. [↑](#footnote-ref-198)
199. Lord Scarman in *Maynard v West Midland Area Health Authority* [1984] 1 WLR 634. [↑](#footnote-ref-199)
200. *De Freitas v O’Brien* [1995] PIQR 281. [↑](#footnote-ref-200)
201. M. Brazier and J. Miola, ‘Bye-bye *Bolam:* A Medical Litigation Revolution’ (2000) 8 Med L Rev 85 at 85. [↑](#footnote-ref-201)
202. Above, n.155. [↑](#footnote-ref-202)
203. R. Heywood, ‘”If the problem persists, come back to see me…” – An empirical study of clinical negligence cases against General Practitioners.’ (2018) *Med L Rev* 406 at 409. [↑](#footnote-ref-203)
204. [2014] EWHC 61 at [25]. [↑](#footnote-ref-204)
205. E.g. *PXW v Kingston Hospital NHS Trust* [2019] EWHC 840; *Shaw v South Tees Hospital NHS Trust* [2019] EWHC 2280; *Lane v Worcestershire Acute Hospital NHS Trust* [2017] EWHC 1900. C.f. *ARB v IVF Hammersmith & Anor* [2018] EWCA Civ 2803 at [59] ‘The identified practice of this clinic was neither reasonable nor responsible’ (appearing to attribute the ‘responsible’ requirement to the conduct of the defendant rather than of the expert). [↑](#footnote-ref-205)
206. Above at n.183. [↑](#footnote-ref-206)
207. All three terms being referred to in Lord Browne-Wilkinson’s judgment in *Bolitho.*  [↑](#footnote-ref-207)
208. Above at n.207. [↑](#footnote-ref-208)
209. *Wilsher v Essex AHA* [1988] 1 AC 1074. [↑](#footnote-ref-209)
210. Above at n.149. [↑](#footnote-ref-210)
211. *Eckersley v Binnie* [1988] 18 Con LR 1, at 79-80. [↑](#footnote-ref-211)
212. E.g. Sapphire Clinics, The Medical Cannabis Clinics, MyAccess Clinics – all registered with the Care Quality Commission. [↑](#footnote-ref-212)
213. CQC guidance (n.116). [↑](#footnote-ref-213)
214. Above at KLOE S4. [↑](#footnote-ref-214)
215. *Mills v Oxford University Hospitals NHS Trust* [2019] EWHC 936 at [118.] [↑](#footnote-ref-215)
216. *Roe v Ministry of Health* [1954] 2 All ER 131*.*  [↑](#footnote-ref-216)
217. See *Giles v Chambers* [2017] EWHC 1661 at [125] to [126] although in the context of cosmetic surgery. [↑](#footnote-ref-217)
218. *Medicinal Cannabis: an Introduction* (Webinar with Dr Kishan Mahabir, September 2019) hosted by SMMGP (‘Substance Misuse Management in General Practice’, a GP led charity) – available at <https://www.smmgp-fdap.org.uk/news/medical-cannabis-a-series-of-free-webinars>. [↑](#footnote-ref-218)
219. [2009] BCSC 429 at [39]. [↑](#footnote-ref-219)
220. Ibid at [40]. [↑](#footnote-ref-220)
221. See the court’s grateful acceptance of a Japanese neurologist’s (Dr Doh-Uhra) evidence for the purposes of fixing the standard of care in a case of experimental treatment (although corroborated by the evidence of three English expert witnesses): *An NHS Trust v Simms* [2002] EWHC 2734. [↑](#footnote-ref-221)
222. *Bolitho,* per Lord Browne-Wilkinson. [↑](#footnote-ref-222)
223. See J. Montgomery, ’The tragedy of Charlie Gard: A case for the regulation of innovation’ (2019) 11(1) *Law Innovation and Technology* 155 at 171, commenting on Dr Hirano’s proposed treatment for Charlie Gard, based on theory and not having visited Charlie or having viewed his medical records. [↑](#footnote-ref-223)
224. [2014] EWHC 61 at [25]. [↑](#footnote-ref-224)
225. See Donovan et al, n.139. Indeed both are mentioned in the GMC’s 2013 guidance. [↑](#footnote-ref-225)
226. Above n.124. [↑](#footnote-ref-226)
227. [2019] EWHC 1408. [↑](#footnote-ref-227)
228. Above at [135]. [↑](#footnote-ref-228)
229. Above at [107]. [↑](#footnote-ref-229)
230. See, for example, ‘Rajit Chandra: How reputation bamboozled the scientific community’ (2015) BMJ 351. [↑](#footnote-ref-230)
231. In *Cooper v Royal Berkshire NHS Trust* [2015] EWHC 644 – court expressed reservations about the logicality of an expert witness’s view on the likely cause of harm, being as it was, based on his clinical experience rather than academic papers. [↑](#footnote-ref-231)
232. *Stucken v East Kent Hospitals* [2016] EWHC – at 117, ‘Even in the current era of evidence-based medicine, I do not accept that there is no room for clinical judgment and received wisdom, particularly in a domain where the evidence base is thin. Absence of evidence is not the same as evidence of absence. [↑](#footnote-ref-232)
233. *Mulholland v Medway* NHS Foundation Trust [2015] EWHC 268at [96]. [↑](#footnote-ref-233)
234. [2014] EWHC 61 at [25]. [↑](#footnote-ref-234)
235. [2015] UKSC 11. [↑](#footnote-ref-235)
236. J. McHale, ‘[Falling between the gaps post the Declaration of Helsinki: innovative medical treatment in England – the case for comprehensive legal regulation](https://www.tandfonline.com/doi/full/10.1080/17579961.2019.1573399)’ (2019) 1 *Law Innovation and Technology* 93 at 100. [↑](#footnote-ref-236)
237. [2019] EWHC 938. A similar outcome can be observed in *Corke v Princess Alexandra NHS Trust* [2019] EWHC 487. [↑](#footnote-ref-237)
238. Ibid at [22]. [↑](#footnote-ref-238)
239. ‘Rationale and Impact – Chronic Pain’ in NG-144 (emphasis added). [↑](#footnote-ref-239)
240. Professor David Haslam <https://www.nice.org.uk/news/feature/david-haslam-getting-the-guidance-right>. [↑](#footnote-ref-240)
241. *NICE: Evidence Reviews for Prescribing cannabis based medicinal products* (published Nov 2019), at p.3. [↑](#footnote-ref-241)
242. Above n.2 at [75]. [↑](#footnote-ref-242)
243. Ibid. at [89]. This was reiterated in debates: ‘‘The guidance …is not a barrier to prescription’: Matt Hancock, HC Deb vol 658, *Access to Medicinal Cannabis,* 8th April 2019. [↑](#footnote-ref-243)
244. Above at n.123. [↑](#footnote-ref-244)
245. Above text accompanying n.138-148. [↑](#footnote-ref-245)
246. Para 70 (emphasis added). [↑](#footnote-ref-246)
247. See e.g. the use of guidance to this effect in the context of patient confidentiality in *ABC v St George’s Health Care NHS Trust* [2020] EWHC 455 at 192. [↑](#footnote-ref-247)
248. B. Guthrie et al, ‘The rising tide of polypharmacy and drug-drug interactions.’ (2015) 13(14) *BMC Medicine*. 74. [↑](#footnote-ref-248)
249. M. Duerden et al, *Polypharmacy and Medicines Optimisation* (Kings Fund, 2013). [↑](#footnote-ref-249)
250. ‘it is important for medical practitioners to be fully aware of the range of opinion and evidence on this matter in order to reach a balanced prescribing decision in the best interests of their patients.’ (MCCS 2020, guidance). [↑](#footnote-ref-250)
251. Of course this ‘freedom’ is largely confined to the private sector as NHS prescribing has so far been shackled by administrative hurdles. [↑](#footnote-ref-251)
252. At n.52 and with reference to s.35 Medical Act 1983. [↑](#footnote-ref-252)
253. [2015] UKSC 11. [↑](#footnote-ref-253)
254. J. Miola, *Medical Ethics and Medical Law,* above n.120 at 6. [↑](#footnote-ref-254)
255. [2018] UKSC 46 at [77]. [↑](#footnote-ref-255)
256. At [109]. [↑](#footnote-ref-256)
257. See the trepidation evident in E. Cannon, ‘Cannabis debate leaves GPs facing a prescribing conundrum’ *PULSE* (21st August, 2018). [↑](#footnote-ref-257)
258. Above, n.36 at [81]. [↑](#footnote-ref-258)
259. J. Herring et al, ‘[Elbow Room for Best Practice? *Montgomery,* patients' values, and balanced decision- making in person-centred clinical care](https://academic.oup.com/medlaw/article-abstract/25/4/582/3979483)’ (2017) 25(4) Med L Rev 582 at 584. [↑](#footnote-ref-259)
260. Ibid. at 584. [↑](#footnote-ref-260)
261. Ibid. at 589. [↑](#footnote-ref-261)
262. J. Montgomery, ’The tragedy of Charlie Gard’, n.225 at 163. [↑](#footnote-ref-262)
263. Above, n.35 at [82]. [↑](#footnote-ref-263)
264. S. Devaney and S. Holm, The Transmutation of Deference in Medicine: An Ethico Legal Perspective.’ (2018) 26(2) Med L Rev 202 at 214. [↑](#footnote-ref-264)
265. See [2015] UKSC 11, para [83] which states that the former role ‘is an exercise of professional skill and judgement: what risks of injury are involved in an operation, *for example,* is a matter falling within the expertise of members of the medical profession’ (emphasis added). [↑](#footnote-ref-265)
266. C. Simpson, ‘When hope makes us vulnerable’, (2004) 18(5) *Bioethics* 428. [↑](#footnote-ref-266)
267. R. Dresser, ‘‘The “Right to Try” Investigational Drugs: Science and Stories in the Access Debate’ (2015) 93 *Texas Law Review* 1631. [↑](#footnote-ref-267)
268. Montgomery, ‘the tragedy of Charlie Gard’, n.225 at 162. [↑](#footnote-ref-268)
269. M. Eijkerholt, ‘Medicine’s Collision with False Hopes’ (2020) 34(7) *Bioethics* 703, 706. [↑](#footnote-ref-269)
270. Eijkerholt at 706. [↑](#footnote-ref-270)
271. *Re J* [1992] 4 All ER 614; *Burke v GMC* [2005] EWCA Civ 1005. [↑](#footnote-ref-271)
272. See e.g. article 5(1) of Directive 2001/83/EC which states that a ‘specials’ prescription for a named patient must not be ‘solicited’. [↑](#footnote-ref-272)
273. J. Miola, ‘Postscript to the Medical Innovation Bill: clearing up loose ends’ *ILT* (2019) 11(1) 17, referring generally to the impact of increased uptake of innovative treatments on clinical trials at 24. [↑](#footnote-ref-273)
274. A useful summary of these for low-risk use can be found in Fischer et al, ‘Lower Risk Cannabis Use Guidelines for Canada (LRCUG): A Narrative Review of Evidence and Recommendations’ (2011) 102(5) Can J Public Health 324. [↑](#footnote-ref-274)
275. T. Keren-Paz, ‘No-fault (strict) liability for injuries from innovative treatments: fairness or also efficiency?’ (2019) 11(1) *Law Innovation and Technology* 55 at 62 [↑](#footnote-ref-275)
276. T. Cockburn & M. Fay, ‘Consent to Innovative Treatment’ (2019) 11 (1) *Law Innovation and Technology* 34 at 46. [↑](#footnote-ref-276)
277. *Decision Making and Consent* (GMC, 2020) para 9. [↑](#footnote-ref-277)
278. *Hall v Petros* [2004] WADC 87 at [348]. [↑](#footnote-ref-278)
279. GMC, above n.123 at para [73]. [↑](#footnote-ref-279)
280. Bearing in mind that a large proportion of the public may not know about the licensed/unlicensed distinction: A. Chisholm, ‘Exploring attitudes’ above n.194. [↑](#footnote-ref-280)
281. *Mills v Oxford University Hospitals NHS Trust* [2019] EWHC 936 at [204]. [↑](#footnote-ref-281)
282. Cross Party Parliamentary Group for Drug Policy Reform report, 2020 (above n.18) at 46. [↑](#footnote-ref-282)
283. *Rich v Hull and East Yorkshire* [2015] EWHC 3395 – judge says this about expert’s evidence and makes interesting comparison between generalities narratives and the specific patient’s circumstances at [41]. [↑](#footnote-ref-283)
284. Consider, for example, the case of patient advocate Lucy Stafford, who reports that the cost of her private prescriptions are saving the NHS money from reduced hospitalisation and reliance on other expensive medications: if the drugs appear to be cost effective in her case, on what basis is she not being prescribed these unlicensed products on the NHS: ‘Medical cannabis: Why are doctors still not prescribing it?’ *The Guardian,* 3rd November 2019.  [↑](#footnote-ref-284)
285. # Note the cases of families still pursuing NHS prescriptions: see ‘Netherlands to supply medical cannabis until July despite Brexit ban’ *The Guardian* 21st January 2021.

     [↑](#footnote-ref-285)
286. *Cannabis-based products for medicinal use (CBPMs) in humans* (Advisory Council on the Misuse of Drugs, 2020). [↑](#footnote-ref-286)
287. Above n.10 at 8.16. [↑](#footnote-ref-287)
288. See CQC above n.116, KLOE E1. [↑](#footnote-ref-288)
289. E.g. NHS England, *Letter: Guidance to Clinicians on Cannabis Based Products for Medicinal Use* (2018) referring to discussing with a peer clinician in the same specialism as good practice. [↑](#footnote-ref-289)