IN THE HIGH COURT OF JUSTICE **CLAIM NO: AC-2024-LON-003354**
KING'S BENCH DIVISION
ADMINISTRATIVE COURT

B E T W E E N :-

THE KING (on the application of)
(1) ANAESTHETISTS UNITED LTD
(2) MARION CHESTERTON
(3) BRENDAN CHESTERTON

Claimants

-and-

THE GENERAL MEDICAL COUNCIL **Defendant**

-and-

(1) THE BRITISH MEDICAL ASSOCIATION
(2) THE ASSOCIATION OF ANAESTHESIA ASSOCIATES
(3) THE FACULTY OF PHYSICIAN ASSOCIATES
(4) THE ROYAL COLLEGE OF ANAESTHETISTS

Interested Parties

CLAIMANTS' SUBMISSIONS ON THE FINAL REPORT OF THE LENG REVIEW

Introduction

1. The Claimants' overarching submission is that the publication of the final report of the Leng Review ("**Report**") does not detract from this Court's role in deciding this claim and granting relief: indeed, it underscores the existing reasons for doing so and provides yet further support for the claim. In particular:

   (1) The Report is by a different person for a different function, and post-dates the GMC's decision-making (or non-decision making) in this case. As a matter of public law, it cannot affect the legality or not of the GMC's actions; at most, it might be a factor that goes to relief.

   (2) Furthermore, the Report does not answer the core question which the Court is asked to answer, namely whether the GMC has been and is acting unlawfully in its regulation of associates.

(3) That said the Report provides (if necessary, which it is not) further support for the Claimants' evidence as to the risks posed by associates (to which GMC regulation was required to respond) and the fundamental differences between associates and doctors, supporting the irrationality of the GMC's regulatory response (the foundational premise of which was extending to associates what it had always done for doctors). Indeed, the Report finds such safety concerns to arise in particular in the treatment of undifferentiated patients, where Leng recommends PAs/AAs should not be used (the very point made by the Claimants as an area in which the GMC could set standards, reflecting the safety risks presented by the Coronial evidence and the Prevention of Future Deaths ("**PFD**") Reports).

(4) The Report has endorsed the adoption and application of RCoA interim guidelines on supervision and scope of practice.

(5) However, the recommendations made in the Report do not address or meet the Claimants' case: even if fully implemented, there would remain unaddressed risks to which the GMC needs to respond and which it is the body best-placed to address.

(6) In any event, those recommendations are not binding and it is not known if they will all be implemented, and if so when or by whom, and indeed there is reason to believe that this may take some considerable time in relation to many of them, and so the *status quo* remains unlawful and is likely to be so for some time.

(7) The publication of the Report does not render the claim non-justiciable, or otherwise increase the deference due to the GMC. Quite the reverse: it makes the GMC's total failure even to consider departure from the doctor's model, even when faced with much of the same evidence and the PFDs, all the more inexplicable.

2. Each of these seven points is expanded upon below.

1) <u>The Report does not alter the legality of the GMC's decision-making</u>

3. The claim addresses the rationality of the GMC's regulatory response to the particular risks posed by associates, as understood from time to time as more evidence came to the fore on such risks (particularly evidence any rational regulator would consider like the comprehensive and consistent survey evidence and the PFDs and other coronial materials). It challenges the policy of in effect doing no more than applying the Good Medical Practice ("**GMP**") developed for doctors to associates, and subjecting associates (once registered) to

the same fitness to practise ("**FTP**") process and doing no more on the basis either that the GMC had no power to do more (such lying outside its remit) or that no "compelling evidence" had emerged to require it to do more. And, as the incremental disclosure has shown, it raises basic questions about what decisions were in fact taken and when and by whom, and for what reasons. The actual decisions – particularly review decisions as later compelling evidence of risk emerged – are impossible to discern.

4. None of this is addressed by or affected by the Leng Review. Moreover, given the GMC's regulatory obligations are ongoing it is impossible to see how a non-binding review conducted by an expert instructed by a different body (DHSC/Secretary of State) could affect the legality of decisions taken by the GMC. At most, were concrete steps taken to implement the Leng recommendations, whether by the GMC or some other body, that might affect the need for or scope of relief granted.

2) <u>Lack of answer to core question for Court</u>

5. In particular, whilst obvious, it is worth emphasising that the Leng Review was not asked to, and the Report does not, answer the question asked of the Court, namely whether the GMC's regulation of associates has been and is lawful and, in particular, whether it has rationally responded to the risks posed by associates in the regulatory scheme which it has created, both in terms of the substantive scheme it has created and the process by which it arrived at that scheme.

6. Indeed, the Report does not consider what the GMC has done in any meaningful detail. It addresses the advent of regulation by the GMC at a high level only, and notes that its survey responses *"[r]evealed a range of views on the potential impact of GMC regulation"* (p.70). The only specific change to which it refers is the assessment and standardisation of PA and AA courses by the GMC (p.70; p.84). It does not, therefore, pass direct comment on the question of whether the extant regulation created by the GMC rationally addresses the risks associates pose; however, it is implicit in its finding that there are ongoing unacceptable risks and the fact that it recommends change that it does not consider that the *status quo*, which includes GMC regulation, adequately addresses those risks. Further, the Report refers to material differences in the education and training of associates versus doctors (p.68) and recommends the uncoupling of the GMP for doctors and PA/AAs in recognition of the material differences between the roles (see Recommendation 15; and pp.95 and 100) which is tantamount to the rejection of the default use of the *"doctor's model"* for the regulation of associates, which has

been the dominant rationale in the GMC's approach to regulating associates. The Report is, therefore, entirely consistent with the Claimants' case.

3) Support for Claimants' case on risk and inappropriateness of doctors' model

7. The Report reviews the evidence on the risks posed by associates and strongly supports the case on risk put forward by the Claimants (see especially Annex 2 to the Claimants' Skeleton Argument). The points made echo and overlap with the points that have been made by the Claimants, underscoring the validity of those concerns. Importantly, the Report does not suggest that evidence of risk has emerged for the first time in the course of the review itself. Rather, it corroborates the evidence on risk that has long existed and to which the Claimants have drawn the Court's attention and which the GMC should have, but largely did not, consider and review when deciding how to regulate associates.

8. The Report highlights that the empirical evidence base on the safety of associates was weak (p.37). Nonetheless, the Report identifies that the limited published research in this area provided "*no compelling evidence that PAs were safe to work as doctor substitutes in primary care*", which finding was corroborated by a rapid review of the literature which found that there was "*weak and mostly international evidence assessing the safety of PAs in primary care*" (p.38). As for safety in secondary care, the published evidence "*did not allow for any firm conclusions to be drawn*" (p.43). The evidence on the safety of AAs revealed a higher than expected proportion of never events (p.48).

9. The review therefore placed weight on "*wider perspectives*" when assessing safety, including a dedicated review survey with over 8,000 responses (pp. 50ff). These responses echo the evidence summarised in Annex 2 to the Claimants Skeleton Argument and the survey evidence that is already before the Court (in relation to which the parties supplied a joint note after the hearing). In particular:

   (1) In relation to problems relating to limits on practice:

      (a) Concerns were raised by patients about "*clarity of PA practice, with little shared understanding of what conditions a PA could and could not diagnose and treat*" with patients feeling "*less confident in seeing a PA for a new or complex condition*" (p.52).

      (b) The Report notes that staff raised concerns about "*confusion about a PA's knowledge, skills or experience, which might lead to unnecessary risk to patients*", which concerns were "*borne out in the wider evidence, with several sources highlighting an*

asymmetry between a PA's perception of their own practice and the view of the supervising doctor" (p.55). Tellingly, the Report finds that "*PAs were more confident in their abilities than any other healthcare professional"* (p.55).

(c) In terms of the views of doctors, in relation to PAs working in primary care, 94% of resident doctors who responded to the review's survey reported feeling uncomfortable with at least one activity currently undertaken by PAs, and only 5% felt that the PA role was clearly defined within their organisation (with PAs radically disagreeing with these positions) (p.56). The Report notes the polarisation of views and states that "*[i]t is probably reasonable to expect that actual appropriateness of PA activities lies somewhere between the two extremes"* (p.57). The results were similar to those in surveys by other bodies (pp.56 and 59) and with respect to secondary care (see pp.60-61) and AAs (see p.64).

(d) The report refers to the problem of PAs being inappropriately substituted for doctors, stating that "*Effective local change management seems to have been lacking in the rollout of PAs"* such that "*[w]hen capacity was limited in local services, the easy option in some cases was simply to fill gaps in medical rotas with PAs*", which was "*done without taking into account the more limited training of the PAs and how the roles would interact, other than with the caveat that they would be supervised by doctors*", which state of affairs may have "*potentially exposed patients to unnecessary risk"* (p.78).

(e) In relation to PAs seeing undifferentiated patients, the Report notes that "*[s]afety concerns raised in relation to PAs were almost always about making a diagnosis and deciding the initial treatment, particularly in primary care or the emergency department, where patients first present with new symptoms. It is here that the risk of missing an unusual disease or condition is highest, and where the more extensive training of doctors across a breadth of specialties is important. Making the wrong initial diagnosis and putting patients on an inappropriate pathway can be catastrophic. This was frequently flagged as the principal risk of PAs seeing undifferentiated patients."* (p.89)

(2) In relation to problems relating to supervision/delegation (which, as the Claimants have repeatedly and consistently pointed out, is an issue that affects the regulation of doctors as much as associates):

(a) The Report notes a "*recurring theme*" being "*the issue of accountability*", with "*a wide range of supervision models in use*" (p.70);

(b) The review's survey responses report only 7% of resident doctors, 32% of GPs and 33% of consultants as being confident in the supervision in place (c.f. 90% of associates) (p.70);

(c) The Report deems effective supervision to be "*a core part of success*", yet finds it "*surprising*" that doctors have not been properly trained on this issue, or given adequate time to support the new roles, which it describes as "*an important omission*" (p.78).

(3) In relation to problems relating to informed consent, a systematic review of patients' understanding of PAs found that they "*often assumed PAs to be doctors*" and that one of the main issues for patients related to "*clarity about who they were seeing, with many commenting on the confusion between the PA and a doctor*" (p.51), with "*negative findings about the role of the PA in primary care*" being "*particularly related to confusion over the role, with many patients assuming they had seen a doctor*" (p.52), and patients in secondary care similarly "*unable to identify that they had seen a PA or to distinguish how PAs differed from doctors*" (p.53).

10. The Report also supports the point made by the Claimants (see in particular Annex 4 to the Claimants' Skeleton Argument) that doctors and associates are fundamentally different:

(1) It notes the radical differences in their pre and post-qualification training (pp.67-9).

(2) It explains in particular that PA training leaves them significantly less skilled at "*the most critical and complex area of medicine*", namely clinical reasoning and diagnostics, and that a PA's education is "*more limited*" in this regard, with newly qualified PAs performing "*significantly weaker in the diagnostic domains*" relative to newly qualified medics, especially in "*complex care settings, with evidence suggesting that PAs were under-equipped to manage undifferentiated multimorbidity*" (p.68).

(3) Significantly, the Report recommends that the requirements for regulation and reaccreditation in GMP should be "*presented separately*" for associates and doctors, "*to reinforce and clarify the differences in roles from those of doctors*" (p.95).

(4) Fundamentally, therefore, the Report lends strong support to the Claimants' case that it was irrational for the GMC simply to extend to associates the same regulatory approach it has always taken to doctors. That is still a finding that this Court should make.

4) Recommendations endorse use of RCoA guidelines

11. The Report has endorsed the adoption and application of RCoA interim guidelines on supervision and scope of practice in unqualified terms (see Recommendation 9; and pp.91-92, as well as the allied Recommendation 12) – guidelines which are highly prescriptive – which is precisely the sort of action the Claimants have long urged upon the GMC (see e.g. Grounds, §116(3)(b)-(d) and §116(5)(c) **[CB/A/1/36-38]** and Claimants' Skeleton, §§51-52), as without GMC endorsement such guidelines are liable (as before, with the RCoA 2016 guidelines) to be ignored or not applied properly by NHS Trusts. Yet the GMC's use of such guidelines, even in the very recently adopted April 2025 Ethical Hub Guidance **[SB1/G/24/464]** is at best equivocal and limited (see **[SB1/G/24/466]** "*If you are unsure or concerned about what an AA is doing, then you can ask them… This may be modelled on the supervisory approach set out by the Royal College of Anaesthetists in 3.10 of the [Interim Guidelines]*".

5) Recommendations do not meet Claimants' case

12. Beyond this the recommendations made by the Report do not meet the concerns raised by the Claimants. Even if they were binding and implemented in full (as to which, see below), there would remain substantial deficits in terms of patient safety, which mean that the GMC cannot now say that the issues raised by this claim have fallen away (e.g. to support an argument the Court should decline relief on a "no substantial difference" basis). The fact that the Leng Review has found it necessary to make these recommendations does not undermine the case that the GMC has acted irrationally to date: far from it. If anything, it underscores the fact that a rational regulator, possessed of the powers conferred upon the GMC, and faced with the abundance of evidence already described, would have taken these steps already: at the very least it would have given proper consideration to the need to impose these and possibly other requirements – whether alone or with others – in order to address the distinct risks posed by associates, consideration which the GMC has never undertaken. The recognition in this Report that there should be such requirements bolsters the case for the Court intervening and placing obligations on the GMC to take action.

13. As for safe limits on practice:

(1) Beyond Recommendation 9 for AAs, the Report does not propose a scope of practice, but rather suggests that:

(a) For PAs, there be "*defined national initial job descriptions for PAs in primary and secondary care*" (p.84) then, "*the opportunity for ongoing training and development in the context of a formal certification and credentialling programme*" with formal credentialling to meet standards to be agreed with medical Royal Colleges and specialists (Recommendation 2, p.87) and the opportunity to become an 'advanced physician assistant', but no anticipation of career progression beyond the advanced level (Recommendation 3, pp.87-88). The Report also recommends that PAs should not see undifferentiated patients "*unless triaged into adult patients with minor ailments and within clearly defined clinical protocols*" (Recommendation 4, p.88-89) and that PAs should acquire two years' experience before working in primary care (Recommendation 5, p.89). These are all limits that the GMC could impose on associate practice using its powers under the Order.

(b) For AAs, there be "*defined national initial job descriptions…for AAs when they first qualify*" (p.84), that they should "*continue working within the boundaries set in the interim scope of practice published by the RCoA*" (Recommendation 9, p.91), also with "*the opportunity for ongoing training and development in the context of a formal certification and credentialling programme*" with formal credentialing meeting appropriate standards as determined by the RCoA (Recommendation 10, p.92) and the opportunity to become an 'advanced physician assistant in anaesthesia' but no anticipation of career progression beyond the advanced level (Recommendation 11, pp.92-93).

It is clear, therefore, that the Review concluded that there should be some substantive limits on what associates may do – and an implicit ultimate ceiling (see also the reference to "*limiting the functions*" carried out by associate roles in Recommendation 17, p.96).

(2) However, these recommendations do not meet the Claimants' concerns. In particular:

(1) The Report is silent on the question of enforcement. Even if individual job descriptions may fall for enforcement at the individual level, and standards for formal credentialling may fall to the Royal Colleges, there is a clear role for the regulator in enforcing the limits on career progression, for example, by ensuring

that individuals do not work outside the areas for which they have been certified and credentialled and beyond the implicit ceiling. The GMC has clear statutory powers to give effect to and enforce these recommendations, for example by determining the standards applicable to associates' experience and performance (Article 3(1)(c) of the Order), approving education and training qualifications for the purposes of enabling those standards to be attained (Article 4 of the Order) and then carrying out periodic assessments to ensure those standards are still met by a registrant (Article 7 of the Order). The Report recommends that the GMC *"make any necessary changes to the curriculum and training provided to PAs and AAs to reflect the role set out in this report" "with the support of the relevant royal colleges"* and overseeing *"standards for postgraduate training programmes set by the Faculties of PA and AA"* (p.100) but it says nothing about how compliance with the standards reflected in these programmes will be enforced on a continuing basis and the implicit ceiling applied.

(2) In relation to the limitation on PAs regarding undifferentiated patients, the report does not make clear *who* should triage patients as presenting with only *"minor ailments"*. There is also a key inconsistency between the recommendation and the template job description in Annex 5, which includes acting *"as first point of contact for suspected minor or common conditions in adults"* (p.122). As the case of Emily Chesterton demonstrates, failing to spot whether or not a condition is indeed minor is a key risk of using PAs in diagnostic settings. The suggestion that they should continue to see undifferentiated patients within defined clinical protocols obviously raises the question of what those protocols will be. The task of creating a rule to give effect to this limitation has not been specifically assigned (see pp.98-100). Again, there is a clear role for the GMC in giving effect to such a limitation, for example via amendments to GMP and other binding guidance e.g. in relation to what constitutes working within the limits of an associate's competence (GMP, §1) and following guidance on professional standards (GMP, §4 **[SB1/G/18/363]**). The Report recommends that the GMC *"revise the text in Good Medical Practice to provide distinct categories for PAs and AAs"* (p.100) but says nothing more granular about what those distinct categories of guidance need to reflect.

That there will be a need for such enforcement is clear from the recent rejection of the Report's recommendations by United Medical Associate Professionals, who question the authority of NHS England to mandate contractual changes between employers and

employees or to remove the authority of associates to "*exercise clinical judgement*" in favour of "*national clinical protocols*" which do not currently exist.[1] Absent intervention from the Court, there is no obligation upon the GMC to take steps to enforce such limits, or to give proper consideration as to whether and how to do so.

(3) The fact that the Leng Review has found these requirements to be necessary does not undermine the case that the GMC has acted irrationally to date: far from it. If anything, it underscores the fact that a rational regulator possessed of the powers conferred upon the GMC and faced with the abundance of evidence already described would have taken some if not all of these steps already e.g. work with the RCoA to endorse its interim scope of practice and the working of AAs within it absent further certification or credentialling. At the very least the GMC (if acting rationally) would have, upon receipt of critical evidence amounting (on any rational view) to mandatory relevant considerations (like the PFDs or the Survey evidence, or the combined effect of the two), *considered* departing from its "doctors model" approach, and reached a reasoned view on the same, engaging with other bodies as required; but the GMC did not such thing.

14. As for supervision,

(1) The Report's Recommendation 6 (p.89-90) in relation to the supervision of PAs is pitched at a high level and amounts, essentially, to the recommendation that there be a clear team structure with a single "*named doctor*" taking overall responsibility for each PA as their formal line manager or "*named supervisor*".

(2) Elsewhere, the Report refers to GMC guidance on what the named supervisor must do (p.99). The guidance is not specified, but it appears to be a reference to the April Supervision Practice Advice **[SB1/G/24/464]**, which the Court will recall was produced shortly before the claim was heard and the development of which has never been properly explained. As explained in written (Claimants' Skeleton, §60) and oral submissions, this document has major limitations: (i) it does *not* have the status of formal guidance; rather, it states on its face that it does not set new standards, (ii) it is unclear whether it sets normative rules or simply describes the expected factual statue of affairs (e.g. "*Their named supervisor…will have a clear understanding of their competence, skills and experience…*"), (iii) it is non-committal in that it does not formally adopt other

[1] See Preliminary Advice for members on employment arrangements following the Leng Review and related NHS guidance | UMAPs.org.uk responding to https://www.nhsemployers.org/system/files/2025-07/NHS%20England-Letter-Response-for-recommendations-Leng-Review.PDF

guidance on supervision, e.g. the Scopes of Practice of the Royal Colleges (including the RCoA which sets strict supervision requirements: see §11 above), (iv) it does not address appraisal, and (v) it is not addressed to associates at all, only to the doctors who supervise them.

(3) Therefore, just as the production of the April Supervision Practice Advice was not a complete answer to the claim, neither are the Report's recommendations, at least not until they manifest in concrete binding guidance, especially given the evidence of softer guidance being historically ignored e.g. Royal College guidance. In any event, ultimately the recommendations on supervision do not take matters much further: it is notable that that there is still no suggestion, for example, of a requirement to keep suitable documentary records of decisions to delegate (see e.g. Grounds, §70(5) and §120 **[CB/A/1/24-25 and 39]**). The Report recommends that the GMC *"ensure that management training is built into the curricula for future generations of doctors at both undergraduate and postgraduate level"* (p.100) but goes no further than that.

15. As for patient consent:

(1) Whilst the changes of title suggested by the Report (Recommendations 1 and 9, pp.86 and 91) are welcome, as are the suggestions of standardised measures such as national clothing, badges, lanyards and staff information (Recommendation 7, p.90), the Report does not address the question of how associates should introduce themselves and, crucially, does not recommend that they be required to tell patients that they are not a doctor. It contrasts, therefore, to the safety measures that were put in place for example by the Surrey and Sussex NHS Trust following the Regulation 28 Report into the death of Pamela Marking, who introduced a simple clear rule that associates must say to patients "I am not a Doctor" **[FSB/O/280/5354]**. The Report also does not explain why such an introduction is not required given the Claimants' evidence which the Report echoes.

(2) The Report identifies that it falls to the GMC to "*change the name of PAs and AAs to physician assistant and physician assistant in anaesthesia (PAA) rather than associate*" (p.99). This recognises the significance of the name on the register by which associates are known in creating or dispelling confusion, and the role of the GMC in providing clarity.

The Report therefore recognises the dangers posed by mistaken identity, and the role of the GMC in clearing up confusion, but does not grasp the nettle on this issue. This remains an issue that this Court should decide.

6) Status of the recommendations

16. The Leng Review was a non-statutory review and there is of course no guarantee that its recommendations will all ultimately be acted upon, not least given the resistance encountered already as referred to above (and, indeed, recommendations from even full statutory inquiries are frequently not brought into effect). If all the recommendations are taken forward, it is unknown what form the ultimate changes will take and in what timeframe they will take effect. It is possible that they will take a very long time indeed and will ultimately only be incompletely implemented. The only recommendation that the Report suggests be implemented *"immediately"* is the title change, and otherwise it suggests a worryingly time-consuming process of DHSC nominating a medical leader and setting up a working group to set out a *"vision"* for the project (p.98). With the benefit of the experience of how long it took to progress from the decision that the GMC should regulate associates to that regulation coming into effect, it is of concern that many of the risks identified by the Report and in this claim could continue unabated for a very long time indeed while this process plays out, with no guarantee at the end of it that the result will fully address all of the risks.

17. By contrast this Court must decide this case now, and decide whether the GMC has undertaken proper rational decision making and, if so, whether it has reached a rational result. It is the GMC (and no other body) that is the duly appointed national regulator of associates with a remit to ensure their safety and public confidence in them; that being so there remains a clear utility and purpose in the Court deciding the claim and granting appropriate relief. Indeed, it may be the only way to ensure that the risks endemic within the *status quo* are addressed in a timely way. Even if the relief ultimately granted is that the GMC's approach to date has unlawfully failed to address the risks in a rational way and so it must reconsider this question, that instruction would be a crucial lynchpin within the process that is hopefully to unfold in response to the Report. Importantly, it would provide an *obligation* to reconsider where currently there is none, and that reconsideration would occur with the benefit of the Court's explanation as to where the previous process went wrong.

7) Justiciability of claim

18. Finally, nothing about the publication of the Report changes the position from that which existed when the claim was heard, which is that the advent of this sort of review cannot render non-justiciable a claim that the Court is otherwise able to decide.

19. The GMC's previous suggestion that this claim is somehow "*off-limits*" because it trespasses upon the realm of policy has always been without merit and remains so. In essence, the GMC has argued that it ought to be afforded total deference because deciding what scheme of regulation to create was a multifaceted question with competing arguments on both sides. But it is trite to say that deference has to be earned and that the Court can still intervene, even in the realm of polycentric decision-making, where the decision-maker has acted irrationally, both by failing to reach a rational result but also by adopting an irrational process: here, by adopting a *per se* approach that it was not the GMC's role to make these changes, by deciding that it would simply recreate for associates what it had done for doctors despite the major differences in the risks they pose, by adopting an irrational (even if informal) test that it would take "*compelling evidence*" of risk to shift from that position and then by failing to review the actual evidence of risk and thus apply that test at all. The Court was addressed orally on why process irrationality has always been part of the Claimants' case, and why the Court in any event has the power to grant suitable relief in that regard.

20. The publication of the Report does not change this. The position might be different if the Report had positively recommended that the GMC *not* do the things the Claimants say it must, but that is far from being the case. Indeed, as set out above, the Report is not only highly consistent with the action the Claimants seek, but actually suggests that changes be made which fit within those requests (even if they do not fully meet them), with the GMC being the body best-placed to make them. The Report therefore solidifies the need for this Court to grant the claim and give relief.

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24 July 2025