Neutral Citation Number: [2016] EWCA Civ 1100

Case No: C1/2016/3115

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT
THE HONOURABLE MR JUSTICE GREEN
[2016] EWHC 2005 (Admin)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 10/11/2016

Before:

THE RIGHT HONOURABLE LORD JUSTICE LONGMORE
THE RIGHT HONOURABLE LORD JUSTICE UNDERHILL
and
THE RIGHT HONOURABLE LADY JUSTICE KING DBE

- -

Between:

THE QUEEN ON THE APPLICATION OF NATIONAL AIDS TRUST	**First Respondent**
- and -	
1) THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD (NHS ENGLAND)	**Appellant**
2) THE LOCAL GOVERNMENT ASSOCIATION	**Second Respondent**
3) THE SECRETARY OF STATE FOR HEALTH	**Interested Party**

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- -

Jonathan Swift QC & Christopher Knight (instructed by **DAC Beachcroft LLP**) for the **Appellant**
Javan Herberg QC and Zoe Leventhal (instructed by **Deighton Pierce Glynn**) for the **First Respondent**
Jenni Richards QC & Nicola Greany (instructed by **Local Government Association**) for the **Second Respondent**
Joseph Barrett (instructed by **Government Legal Department**) for the **Interested Party**

Hearing dates: 15th September 2016

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Approved Judgment

Lord Justice Longmore:

Introduction

1. The issue on this appeal is whether NHS England, a commissioning body created by the Health and Social Care Act 2012 ("the 2012 Act"), as part of the Lansley reforms, has the power to commission medication for HIV/AIDS which goes by the somewhat mystifying acronym of PrEP; this stands for pre-exposure prophylaxis.

2. As is well known, Human Immunodeficiency Virus ("HIV") is a disease which attacks the immune system. It reduces the body's white blood cells so that it is less able and, in due course, unable to combat infection. It can be treated with Anti-Retroviral ("ARV") medication which suppresses the virus and is used successfully to treat people living with HIV. Such medication is expensive - £360,000 for treating a single person over his or her lifetime. An estimated 103,700 individuals in the United Kingdom are currently living with HIV. This expenditure might well reduce if a sufficient number of appropriate people are given PrEP medication; this is itself fairly expensive.

3. PrEP requires the identification of individuals who are HIV negative but are at comparatively high risk of contracting HIV and further requires that these individuals then take ARV medication. We were told that at least one study has reported that PrEP is 86% effective in that it stopped 17 out of every 20 HIV infections which could have happened if PrEP had not been administered. The way in which the medication works is, in broad terms, to inhibit dissemination of the virus from cell to cell and it thus limits the number of cells that became infected.

4. The question at the root of this appeal is out of whose budget the cost of PrEP medication is to be paid (the budget of NHS England or that of local authorities) if a decision is made that it should be made available to appropriate individuals.

5. The reforms initiated by the 2012 Act provide for medical services to be commissioned by Clinical Commissioning Groups ("CCGs"), local authorities and, importantly, the defendant and appellant, the National Health Service Commissioning Board normally known as "NHS England". In general terms, NHS England is responsible for the commissioning of a range of specialised services, including services in relation to HIV. Its specialised services budget for 2016/17 is £15.6 billion. ARV medication is normally prescribed and monitored by specialist HIV clinicians working in hospitals and is thus provided by NHS Trusts whose HIV clinical services are commissioned by NHS England through its specialised commissioning function.

6. NHS England submits that PrEP medication, being essentially preventative, belongs in the realm of public health which under the relevant legislation is the responsibility of local authorities. Accordingly it contends that it has no power to commission such medication. It has taken a little time to come to that view.

7. In September 2014 NHS England is Clinical Reference Group on HIV ("CRG") instituted a PrEP policy writing group tasked with developing a plan for the commissioning of PrEP. On 24th April 2015 it published a Specialised Services Circular to clarify its commissioning position on PrEP. That circular stated that NHS

England was the responsible commissioner for all anti-retroviral drugs including those used in HIV prevention in, for example, preventing mother to child transmission or in post-exposure prophylaxis ("PEP") following sexual or occupational exposure to HIV infection. The circular explained that PrEP was not currently commissioned by NHS England and that access to PrEP had been limited, so far to those in the study, which I have already mentioned.

8. Throughout 2014/2015 the CRG undertook a review and published a detailed evidence review and a draft policy proposition for NHS England to consider. The proposal was in favour of the routine commissioning of PrEP. The draft policy suggested that PrEP would be provided based upon eligibility criteria which would render an estimated 8000-12,000 gay men and a further 1,000 heterosexual individuals eligible for treatment. It postulated an estimated take-up rate of 50%.

9. In December 2015 the CRG's Draft Policy and the Evidence Review were published for consultation. The National Aids Trust, the first respondent to this appeal and the claimant below, responded accordingly. It was, at that point in time, the position of NHS England that it would conduct a full public consultation. However, on 21st March 2016 NHS England published a press release which said, for the first time, that local authorities were responsible for HIV prevention services and that, were NHS England to continue to commission such services, they could be subjected to legal challenge. That turned out to mean that proponents of other "candidate" treatments might assert that NHS England should be commissioning their preferred candidate treatment rather than PrEP.

10. NHS England accepts that the Secretary of State does have power to delegate authority to NHS England to commission PrEP but asserts that that would need to be accompanied by appropriate funding.

The Legislative Framework

11. Although NHS England was created by the 2012 Act, the statutory mechanism used by Parliament for creating NHS England and CCGs was to amend the existing National Health Service Act 2006 ("the Act") by adding provisions after section 1 of that Act.

12. Section 1 is the section which imposes on the Secretary of State the duty to promote a comprehensive health service and is in the following terms:-

> "**1. Secretary of State's duty to promote comprehensive health service**
>
> (1) The Secretary of State must continue the promotion in England of a comprehensive health service designed to secure improvement –
>
> (a) in the physical and mental health of the people of England, and
>
> (b) in the prevention, diagnosis and treatment of physical and mental illness.

(2) For that purpose, the Secretary of State must exercise the functions conferred by this Act so as to secure that services are provided in accordance with this Act.

(3) The Secretary of State retains ministerial responsibility to Parliament for the provision of the health service in England.

(4) The services provided as part of the health service in England must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed."

13. Sections 1H and 1I then set up both NHS England (under the name of the Board) and CCGs in this way:-

"**1H The National Health Service Commissioning Board and its general functions**

(1) There is to be a body corporate known as the National Health Service Commissioning Board ("the Board").

(2) The Board is subject to the duty under section 1(1) concurrently with the Secretary of State except in relation to that part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities.

(3) For the purpose of discharging that duty, the Board –

(a) has the function of arranging for the provision of services for the purposes of the health service in England in accordance with this Act, and

(b) must exercise the functions conferred on it by this Act in relation to clinical commissioning groups so as to secure that services are provided for those purposes in accordance with this Act.

(4) Schedule A1 makes further provision about the Board.

(5) In this Act –

(a) any reference to the public health functions of the Secretary of State is a reference to the functions of the Secretary of State under sections 2A and 2B and paragraphs 7C, 8 and 12 of Schedule 1, and

(b) any reference to the public health functions of local authorities is a reference to the functions of local authorities under sections 2B and 111 and paragraphs 1 to 7B and 13 of Schedule 1.

> **1I Clinical commissioning groups and their general functions**
>
> (1) There are to be bodies corporate known as clinical commissioning groups established in accordance with Chapter A2 of Part 2.
>
> (2) Each clinical commissioning group has the function of arranging for the provision of services for the purposes of the health service in England in accordance with this Act."

14. Section 2 of the 2006 Act then provides:-

> "The Secretary of State, the Board or a clinical commissioning group may do anything which is calculated to facilitate, or is conducive or incidental to, the discharge of any function conferred on that person by this Act."

15. Sections 2A and 2B referred to in section 1H(5) provide:-

> "**2A Secretary of State's duty as to protection of public health**
>
> (1) The Secretary of State must take such steps as the Secretary of State considers appropriate for the purpose of protecting the public in England from disease or other dangers to health.
>
> (2) The steps that may be taken under subsection (1) include –
>
> (a) the conduct of research or such other steps as the Secretary of State considers appropriate for advancing knowledge and understanding;
>
> (b) providing microbiological or other technical services (whether in laboratories or otherwise);
>
> (c) providing vaccination, immunisation or screening services;
>
> (d) providing other services or facilities for the prevention, diagnosis or treatment of illness;
>
> (e) providing training;
>
> (f) providing information and advice;
>
> (g) making available the services of any person or any facilities.
>
> (3) Subsection (4) applies in relation to any function under this section which relates to –

(a) the protection of the public from ionising or non-ionising radiation, and

(b) a matter in respect of which 'a relevant body has a function.

(4) In exercising the function, the Secretary of State must –

(a) consult the relevant body; and

(b) have regard to its policies.

(5) For the purposes of subsections (3) and (4), each of the following is a relevant body –

(a) the Health and Safety Executive;

(b) the Office for Nuclear Regulation

2B Functions of local authorities and Secretary of State as to improvement of public health

(1) Each local authority must take such steps as it considers appropriate for improving the health of the people in its area.

(2) The Secretary of State may take such steps as the Secretary of State considers appropriate for improving the health of the people of England.

(3) The steps that may be taken under subsection (1) or (2) include –

(a) providing information and advice;

(b) providing services or facilities designed to promote healthy living (whether by helping individuals to address behaviour that is detrimental to health or in any other way);

(c) providing services or facilities for the prevention, diagnosis or treatment of illness;

(d) providing financial incentives to encourage individuals to adopt healthier lifestyles;

(e) providing assistance (including financial assistance) to help individuals to minimise any risks to health arising from their accommodation or environment;

(f) providing or participating in the provision of training for persons working or seeking to work in the field of health improvement;

(g) making available the services of any person or any facilities.

(4) The steps that may be taken under subsection (1) also include providing grants or loans (on such terms as the local authority considers appropriate).

(5) In this section, "local authority" means –

(a) a county council in England;

(b) a district council in England, other than a council for a district in a county for which there is a county council;

(c) a London borough council;

(d) the Council of the Isles of Scilly;

(e) the Common Council of the City of London"

Paragraphs 7C, 8 and 12 of Schedule 1 referred to in section 1H (5) deal with blood supply, contraception and microbiological services. Paragraphs 1 – 7B and 13 of Schedule 1 refer to a number of services which would typically fall within the description "public health".

16. Section 7A provides:-

"**Exercise of Secretary of State's public health functions**

(1) The Secretary of State may arrange for a body mentioned in subsection (2) to exercise any of the public health functions of the Secretary of State.

(2) Those bodies are

(a) the Board …."

This is the section which gives the power referred to in paragraph 10 above.

17. Chapter A1 of Part 2 makes further provision in relation to NHS England including the requirement on the Secretary of State to publish an annual mandate specifying objectives which the Board should seek to achieve in each financial year. Section 13E provides:-

"**13E Duty as to improvement in quality of services**

(1) The Board must exercise its functions with a view to securing continuous improvement in the quality of services provided to individuals for or in connection with –

(a) the prevention, diagnosis or treatment of illness, or

(b) the protection or improvement of public health.

(2) In discharging its duty under subsection (1), the Board must, in particular, act with a view to securing continuous improvement in the outcomes that are achieved from the provision of the services.

(3) The outcomes relevant for the purposes of subsection (2) include, in particular, outcomes which show –

(a) the effectiveness of the services,

(b) the safety of the services, and

(c) the quality of the experience undergone by patients."

The Regulatory Framework

18. Section 3B of the Act gives the Secretary of State the power to require NHS England to exercise its powers to achieve specific objectives. So far as material, that power is formulated as follows:-

"**3B Secretary of State's power to require Board to commission services**

(1) Regulations may require the Board to arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service of –

(a) …

(b) …

(c) …

(d) such other services or facilities as may be prescribed.

(2) A service or facility may be prescribed under subsection (1)(d) only if the Secretary of State considers that it would be appropriate for the Board (rather than clinical commissioning groups) to arrange for its provision as part of the health service."

19. The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the 2012 Regulations") were made by the Secretary of State in exercise of this power. The material provisions came into effect on 1st April 2013. Part 3 of the 2012 Regulations is entitled "Services to be commissioned by the Board". There is no express definition of "Services". But there is a definitions section which sheds light on the three cognate terms "services", "health services" and "health care services".

20. Regulation 2 provides a definition of "health care services" in broad terms: ""health care services" means one or more services consisting of the provision of treatment for the purpose of the health service". The phrase "treatment" in the definition is important because this is also a defined term and its core resides in the concept of an

intervention to manage a person's disease, condition or injury. The definition is as follows:-

> ""treatment" except in Part 9 (waiting times), means an intervention that is intended to manage a person's disease, condition or injury and includes prevention, examination and diagnosis".

It is of relevance to the argument in this case that a health service includes (perhaps unsurprisingly) preventative medicine.

21. Part 3 of the 2012 Regulations, which enumerates the services to be supplied by NHS England, sets out a lengthy list of different services (ranging from dental services through infertility treatment and including services for prisoners and other detainees). Regulation 11 deals with a category described as "Specified services for rare and very rare conditions" and imposes on NHS England a duty to arrange to the extent that it considers necessary to meet all reasonable requirements "for the provision as part of the health service of the services specified in Schedule 4". Paragraph 17 of that Schedule then specifies:-

> "Adult specialist services for patients infected with HIV".

22. Read together, therefore, Regulation 11 of the 2012 Regulations and paragraph 17 of Schedule 4 to those Regulations require that NHS England "…must arrange, to such extent as it considers necessary to meet all reasonable requirements, for the provision as part of the health service of … Adult specialist services for patients infected with HIV".

23. Section 6C of the Act gives the Secretary of State comparable powers to require local authorities to exercise their public health functions. Pursuant to this power he made the Local Authorities (Public Health Functions etc.) Regulations ("the 2013 regulations") which also came into effect on 1st April 2013. Regulation 6 provides:-

> "(1) Subject to paragraphs (4) and (5), each local authority shall provide, or shall make arrangements to secure the provision of, open access sexual health services in its area—
>
> (a) by exercising the public health functions of the Secretary of State to make arrangements for contraceptive services under paragraph 8 of Schedule 1 to the Act (further provision about the Secretary of State and services); and
>
> (b) by exercising its functions under section 2B of the Act—
>
> (i) for preventing the spread of sexually transmitted infections;
>
> (ii) for treating, testing and caring for people with such infections; and

> (iii) for notifying sexual partners of people with such infections.
>
> (2) In paragraph (1), references to the provision of open access services shall be construed to mean services that are available for the benefit of all people present in the local authority's area.
>
> …
>
> (4) The duty of the local authority under paragraph (1)(a) does not include a requirement to offer to any person services relating to a procedure for sterilisation or vasectomy, other than the giving of preliminary advice on the availability of those procedures as an appropriate method of contraception for the person concerned.
>
> (5) The duty of the local authority under paragraph (1)(b) does not include a requirement to offer services for treating or caring for people infected with Human Immunodeficiency Virus."

The Judgment

24. Green J thought that, if the exception in section 1H(2) applied to deprive NHS England of all powers in relation to public health functions as set out in sub-section (5), the responsibility of NHS England would almost disappear and the exception would, in effect, apply to exclude matters which must have been, on any view, intended to be the responsibility of NHS England concurrently with the Secretary of State. He therefore looked for a way of limiting the scope of the exception and decided that the exception was designed to identify the entity with which NHS England had concurrent responsibility. In paragraph 78 he said:-

> "The default position under the legislation is that the Secretary of State is the concurrent partner to NHS England. But the functions of the Secretary of State may also be transferred to local authorities, in which case it is the local authorities who henceforward may be concurrent partners with NHS England. This can be tested by reading the words in Section 1H(2) in the following clarificatory way: "*The Board is subject to the duty under section 1(1) concurrently with the Secretary of State except* ***(so far as concurrency is concerned)*** *in relation to the part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities*". The added, emphasised words are merely clarificatory. The sentence can be logically read without them. But they do serve to show how the exception works."

He also held (para 81) that, in any event, the 2012 Regulations conferred power on NHS England to commission preventative HIV treatment.

25. Even if both those conclusions were wrong, he held (para 91-2) that commissioning preventative treatment was within the scope of section 2 of the Act as facilitating or

being conducive or incidental to the powers which NHS England undoubtedly did have to provide treatment for those infected with HIV. He also held that there was no discernible difference (physiological or otherwise) between PrEP and PEP which were both treatments for HIV. Since NHS England undoubtedly did have power to commission PEP, it must also have the power to commission PrEP, even though it was prescribed for persons as yet uninfected.

The Submissions

26. NHS England appeals those conclusions with the permission of the judge. On its behalf, Mr Jonathan Swift QC submitted:-

i) Section 1H(2) of the 2006 Act contained an exception to the general duty imposed by section 1(1) on NHS England in relation to the promotion of a comprehensive health service. That exception operated to exclude from that duty;

> "that part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities."

ii) provision of PrEP, if it was to be provided at all, would be provided in pursuance of public health functions of either the Secretary of State or local authorities;

iii) there was therefore no duty (and thus no power) for NHS England to commission PrEP;

iv) this was confirmed by the 2012 Regulations which required NHS England to supply "adult specialist services for patients infected with HIV"

v) PrEP was intended to be supplied to persons not (or, at any rate, not yet) infected and was not, therefore, a service which NHS England was authorised to supply pursuant to the 2012 Regulations;

vi) that situation could not be changed by reliance on section 2 of the Act which could not be read to enable NHS England to do something which they had no power to do; and

vii) provision of PEP was entirely different from provision of PrEP because PEP was only provided when the patient had been exposed to a particular event which was highly likely to result in transmission and establishment of the HIV virus while PrEP would be provided to those who had not yet had any significant exposure at all.

27. Mr Javan Herberg QC for the National Aids Trust and Ms Jenni Richards QC for the Local Government Association supported the judge's conclusions. They also relied on an argument made to the judge (but not referred to in his judgment) to the effect that the exclusion contained in section 1H referred to that part of the health service that "is" provided in pursuance of public health functions. If any particular desirable service was <u>not in fact</u> being provided by the Secretary of State or local authorities (as PrEP was not), then NHS England was authorised to provide it. NHS England had

therefore been within its powers to institute the policy writing group, to state in their April 2015 Circular that it was responsible for commissioning drugs used for HIV prevention, to issue their December 2015 draft policy in favour of commissioning PrEP and to seek public consultation upon it.

The scope of the section 1H exception

28. For my part I have some sympathy for the judge's conclusion that the concept of "that part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities" is so wide that it is liable to swallow up much of what one might expect NHS England to provide. That is particularly so when one reads in section 2A(2)(d) that steps to be taken by the Secretary of State for the purpose of protecting the public in England from disease or other dangers to health include (after research, microbiological services, vaccination and immunisation)

> "providing other services or facilities for the prevention, diagnosis or treatment of illness."

29. I cannot, however, see that the right way forward is to hold that the exception in section 1H is to be interpreted as referring only to the entity with which NHS England's duty is to be concurrent. If it was intended that NHS England had a duty in relation to public health functions, but that it was to be exercised concurrently with the Secretary of State or local authorities, that duty would as a matter of drafting be expressed in a language different from the language of "exception" used in section 1H. One cannot help wondering what the point of saying it in that form would be. It would be easier merely to say that NHS England had the responsibility for a comprehensive health service which is precisely what section 1H is not saying.

30. I would not, therefore, support the judge's conclusion on construction as set out in para 78 of his judgment.

31. That, of course, is not remotely the end of the matter because it is still necessary to ascertain the scope of the exception. The phrase "that part of the health service that is provided in pursuance of public health functions" is not defined as such, although it is stated in section 1H(5) that reference to the public health functions of the Secretary of State or local authorities is a reference to certain other parts of the statute. But those other parts likewise do not purport to give any comprehensive definition of "public health functions". I have already observed that, if reference to section 2A is to be regarded as definitional, its reference to both prevention and treatment of illness in general terms is, on the face of it, impossibly wide.

32. In these circumstances it is not only permissible but right in accordance with Hanlon v Law Society [1981] A.C. 124, 193-4 per Lord Lowry to have regard to the ambit of regulations intended to be made pursuant to the Act in relation to the commissioning of services and, in fact, made shortly after it was passed. Those regulations will be the best guide to the ambit of NHS England's responsibilities since it can hardly have been intended to authorise the commissioning by regulations of services which NHS England had no power to commission in the first place. There is also the negative point that in so far as there are regulations in relation to services to be commissioned by local authorities, those regulations may well be a guide to the powers of local

authorities. If such regulations authorised local authorities to commission PrEP one might conclude that such commissioning did indeed fall within the exception for public health functions contained in section 1H.

33. One matter that needs to be clarified before going to the detail of the regulations is that the mere fact that services in relation to health are preventative does not mean that such services are necessarily part of "public health functions". Mr Swift did not argue that they were and it is in any event clear from section 13E of the Act that NHS England's obligations with regard to the improvement in quality of services in relation to health extend to the prevention as well as the diagnosis and treatment of illness. Conversely, it cannot be said that the mere fact that health services constitute treatment means that such services are not part of public health function since both section 2A(2)(d) and section 2B(3)(c) of the Act contemplate that treatment may be part of the Secretary of State's duties in relation to the protection of public health and of both his and local authorities' functions in relation to the improvement of public health. The distinction between public health functions and non-public health functions must be sought in some distinction other than that between prevention and cure.

34. With that in mind one turns to the 2012 Regulations by which, as I have set out above, one of the specified services which NHS England is required to provide (as per section 3B(1)), in order "to meet all reasonable requirements for the provision as part of the health service", is

> "Adult specialist services for patients infected with HIV,"
> (Schedule 4, para 17).

The converse local authority regulation is regulation 6 already cited which, while requiring local authorities to make arrangements to secure the provision of open access sexual health services in its area for preventing the spread of sexually transmitted infections, specifically states that there is no requirement to offer services for treating or caring for people infected with HIV. There is thus a parallel requirement and non-requirement in relation to people/patients infected with HIV.

35. All parties relied on these Regulations. Mr Swift contended that offering PrEP could not be described as a service for patients infected with HIV for the simple reason that the treatment was only offered to those not yet infected and indeed to people who were at the time HIV negative. In this connection he had some difficulty in explaining why PEP fell within paragraph 17 of Schedule 4 if PrEP did not, since even PEP was prescribed to those persons who had been exposed to an event likely to give rise to an infection but in relation to whom there was no certainty of that infection. His contention was that exposure to such an event made all the difference.

36. Mr Herberg and Ms Richards contended that the duty on NHS England to arrange the services specified in Schedule 4 was part of the duty imposed by regulation 11 to meet all reasonable requirements for the specified services "as part of the health service" and that the phrase "health service" was one of the essential components of "health care services" which in turn is defined in the definition section as including treatment which is itself defined as

> "an intervention that is intended to manage a person's disease, condition or injury and includes prevention, examination and diagnosis."

37. Although this latter submission is somewhat elaborate that is only because of the inter-relation of the definitions of the relevant wordings and I would accept it. Once one recognises that the services specified in schedule 4 are "health care services", that "treatment" is one of those services and that treatment includes "prevention" that conclusion must carry through to the service in paragraph 17 "for persons infected with HIV".

38. A strict constructionist might point out that the definition of treatment begins with the phrase

> "an intervention that is intended to manage a person's disease, condition or injury"

and that the addition of

> "and includes prevention …."

only refers to prevention after any intervention to manage the relevant disease or condition. He might further point out that PrEP is to be administered to those without a disease or relevant condition. But this seems to me to be altogether too technical and legalistic on approach to a regulation which must be intended to be read and applied not by lawyers but by health service managers and doctors in their daily lives. The whole thrust of the Regulations is that local authorities are not to be responsible for HIV patients but rather that NHS England is to be responsible for them. If there is medication that can prevent susceptible persons from becoming infected and it is desirable that such medication be administered to reduce the overall bill for HIV services, NHS England has the power to commission such medication.

39. Suppose, however, that PrEP does not fall within the wording of paragraph 17 of Schedule 4, is that the end of the matter? I do not think it is because the relevant inquiry is whether the provision of PrEP is part of the health service which is provided in pursuance of the public health functions of the Secretary of State or local authorities. The Regulations do not seek to define the phrase "public health functions" but they are helpful in determining where the boundary between "public health functions" and "non-public health functions" lies. One sees that local authorities are not responsible for offering services to those infected with HIV but that NHS England is. Once it is appreciated that the fact that the treatment is preventative treatment does not automatically mean that it is to be assigned to the public health side of the boundary, it is much more sensible to regard all treatment associated with HIV as being a "non-public health function" since, otherwise, responsibility will become fragmented. In a general sense, therefore, reference to the Regulations is helpful in deciding which side of the somewhat artificial distinction mandated by section 1H(2) any particular preventative treatment lies. I would, therefore, conclude that PrEP does not fall within the section 1H(2) exception.

40. In these circumstances it is unnecessary to engage with the judge's conclusion that there is no difference of substance between PrEP and PEP. The fact that NHS

England accepts that it is under a duty to commission PEP cannot, of itself, determine whether it is under a duty to commission PrEP. Mr Swift submitted that there were additional features (such as the prescribing an extra drug) which made it different in any event. But in view of my conclusion that there is a power to commission PrEP this debate becomes irrelevant.

Section 2

41. It would, however, be unwise to refuse to recognise that Mr Swift's submissions do have some force and it is therefore necessary to consider the alternative submission which relies on section 2 of the Act which, it will be recalled, empowers NHS England:-

> "to do anything which is calculated to facilitate or is conductive or incidental to, the discharge of any function … conferred by this Act."

42. On any view NHS England has the function of commissioning treatment for those infected with HIV. It thus has the power to do precisely that. The question is, therefore, whether the discharge of that function is facilitated by commissioning treatment which prevents the onset of HIV and avoids the expenditure of treating those with full-blown HIV. To my mind the only answer to that question is "Yes".

43. If NHS England has the function of commissioning treatment for HIV, the discharge of that function will be greatly helped by reducing the numbers of persons infected with HIV. If, therefore, there is an available medical treatment for reducing those numbers, section 2 of the Act authorises the commissioning of that treatment because it makes it easier and less expensive for the primary function of providing services to those infected with HIV to be discharged.

44. One can alternatively ask whether commissioning such treatment is conducive to the discharge of the primary function of providing services to HIV infected patients. Again the answer must be yes, since the number of HIV infected patients will reduce and their treatment will overall be less expensive for the health service in general and NHS England in particular.

45. Mr Swift accepted in paragraph 65 of his skeleton argument that section 2 of the Act applied to authorise PEP but said that PrEP was different because it was applied to those not infected while those to whom PEP was supplied were assumed to be infected. For the purpose of section 2 this seems to me to be an irrelevant distinction.

"Is provided"?

46. What then of the argument that if treatment such as PrEP is not, in fact, provided by the Secretary of State or local authorities, then it does not fall within the section 1H(2) exception in any event. The contention has its attractions but is perhaps difficult to reconcile with what appears to be the intention of section 1H to carve, out of NHS England's responsibility, the public health functions of the Secretary of State and local authorities. I do not, therefore, think that the argument can be correct; sadly it seems to follow that bureaucratic squabbles about apportionment of responsibility will be the inevitable consequence of the Lansley reforms. The judge said (para 34) that

one of the purposes of the changes was to remove the Secretary of State from front line decision making and, no doubt, that is true. Whether it was further intended that the resulting bureaucratic squabbles should be resolved by spending taxpayers' money on expensive solicitors and barristers is, perhaps, doubtful. It would be far more sensible to have an internal mechanism for sorting out such disputes.

Conclusion

47. As it is, I would dismiss this appeal and uphold the order made by the judge.

Lord Justice Underhill:

48. I agree that this appeal should be dismissed, but I have not found the case entirely easy, and I should express my reasoning in my own words, though I can do so fairly shortly.

49. Although Longmore LJ has clearly identified the issues I will recapitulate the bare essentials as a necessary jumping-off point. The question is whether it is within the powers of the National Health Service Commissioning Board ("NHS England") under the National Health Service Act 2006 (as amended by the Health and Social Care Act 2012) to commission a treatment – or perhaps, more neutrally, an intervention – called PrEP (pre-exposure prophylaxis) for persons who are at high risk of exposure to infection with HIV (typically, by unprotected sexual intercourse with an infected person). PrEP consists primarily of the prescription of two kinds of anti-retroviral drug which are taken prior to the expected exposure, though they continue to be taken for a period thereafter. PrEP is substantially identical in its operation to PEP (post-exposure prophylaxis), which consists of the administration of the same drugs (plus a third) in the immediate aftermath of an exposure. In both cases the drugs do not prevent the virus entering the patient's system, and in that sense they do not prevent the initial infection; but they drastically inhibit its replication and thus (in most cases) prevent the disease becoming established. The power of NHS England to commission treatments generally derives (so far as relevant) from section 1H (2) of the 2006 Act, but that contains what appears to be a carve-out "in relation to that part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities". It is NHS England's case that the provision of PrEP, though not of PEP, falls within those words of exception – in short, that it is a public health responsibility – and that accordingly it is not within its power to commission it.

50. Green J's principal answer to that case was that the words of exception do not in fact limit the scope of NHS England's powers at all but are only concerned to make clear that in the public health field those powers are exercised concurrently with the Secretary of State and local authorities rather than concurrently with the Secretary of State alone. I agree with Longmore LJ in rejecting that construction. I think it is quite plain, both from the language of section 1H(2) itself and from the contextual materials to which we were referred, that Parliament did indeed intend to exclude NHS England from any responsibility in the field of public health, subject to the particular power given to the Secretary of State by section 7A of the Act, under which he may arrange for it to exercise any of his public health functions.

51. I also agree with Longmore LJ in rejecting the Respondents' fallback submission that the phrase "is provided" means that the application of the words of exception depends

on whether the part of the service in question is as a matter of fact being provided by the Secretary of State or local authorities at the relevant point in time. Quite apart from the obvious inconvenience of having to make a factual enquiry of that kind whenever the issue arose, I think that it is reasonably clear as a matter of ordinary language that the phrase is being used normatively rather than descriptively.

52. The question thus is whether the prescription of PrEP in the circumstances proposed falls under the "public health functions" identified in section 1H (5). That sub-section refers back to the provisions of sections 2A and 2B and the various specified paragraphs from Schedule 1. But those do not help much. The language of section 2A (1) – "protecting the public in England from disease or other dangers to health" – and section 2B (1) and (2) – "improving the health of the people of England" – is very general. The various examples of public health measures set out in sections 2A (2) and 2B (3), together with the specific functions specified in Schedule 1, are helpful indications of the broad scope of the functions in question, and reflect what no doubt an informed health practitioner would understand by the concept of "public health", but they do not afford a simple criterion for defining the boundary of "public health functions" in a borderline case. I have tried to see whether such a criterion could be inferred from the examples in sections 2A (2) and 2B (3), or the functions specified in Schedule 1, but the various possibilities have turned out to be chimerical. In particular, it does not seem possible to draw the dividing line between public health and "non-public health"[1] functions neatly along the line between the prevention of ill-health and its treatment. I understood Mr Swift, while relying on the distinction between prevention and treatment in the circumstances of this particular case, to accept that it was not a universal touchstone, partly at least because some provisions of the 2006 Act, and the Regulations made under it, specifically refer to the prevention of illness in the context of NHS England's duties: see, for example, section 13E (1) (a) (set out at para. 17 of Longmore LJ's judgment) or the definition of "treatment" in the 2012 Regulations (set out at para. 36).

53. In those circumstances the next port of call must be the Regulations made by the Secretary of State under sections 3B and 6B of the Act – that is, the 2012 and 2013 Regulations. The relevant provisions are, on the one hand, regulation 11 of the 2012 Regulations, read with paragraph 17 of Schedule 4, which requires NHS England to arrange for the provision of "adult specialist services for patients infected with HIV"; and, on the other, regulation 6 (1) (b) of the 2013 Regulations, which requires local authorities to provide services for preventing the spread of sexually transmitted infections and for treating, testing and caring for people with such infections but explicitly excludes services for treating or caring for people infected with HIV – for the precise language see paras. 20-23 of Longmore LJ's judgment.

54. Longmore LJ holds at paras. 37 and 38 of his judgment that the language of paragraph 17 of Schedule 4 can be read as covering the provision of PrEP. The strict constructionist in me at first resisted that conclusion. The difficulty is that the whole purpose of PrEP is that it should be given to persons who are <u>not</u>, at least at the moment that treatment starts, "infected with HIV" – it is indeed that element which distinguishes it from PEP – so that on a literal reading it would seem clearly to fall outside the terms of paragraph 17. That literal reading would not mean that no-one

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[1] There is no obvious antonym for "public health". "Private" clearly will not do. Other possibilities, such as "clinical", are potentially tendentious.

else had a specific power to commission or provide PrEP. On the contrary, it would fall squarely within the responsibilities of local authorities under regulation 6 (1) (b) (i) of the 2013 Regulations, since the provision of PrEP would be a service which prevented the spread of a sexually transmitted infection (namely HIV), and would be unaffected by regulation 6 (5) because it was not (adopting the same literal meaning) for "people infected with [HIV]". That distinction, drawing the line between the treatment of persons already infected and preventive interventions, would reflect a natural understanding of one of the differences between public health and non-public health functions, even if, as I have said, it is not an infallible touchstone. The case advanced by NHS England thus on the face of it not only corresponds to the literal language of the 2012 Regulations but would correspond to a coherent scheme.

55. In the end, however, I have concluded that that approach is wrong. In my view it is inherently very unlikely that the Secretary of State when making the 2012 Regulations intended that functions which were substantially identical should be split between different bodies. And that is particularly the case where the services in question are with the "rare and very rare" conditions which are the subject of regulation 11 and Schedule 4: the whole point of giving responsibility for such conditions to NHS England was evidently that it was more efficient and effective for the specialist expertise necessary to arrange for provision of services for such conditions to be concentrated and deployed at national level. The evidence in the present case shows that for all practical purposes the provision of prophylaxis for individual patients at high risk of imminent exposure to HIV infection (i.e. PrEP) forms a seamless continuum with its provision for those who have just been exposed to HIV infection (i.e. PEP), which it is common ground falls within the terms of paragraph 17. The evidence is very fully reviewed in the judgment of Green J at paras 17-22 and analysed at paras. 95-103: I need not reproduce those passages here. What it shows is that PrEP and PEP involve the prescription of the selfsame drugs, operating in the same way (that is, by inhibiting replication of the virus in the period immediately following infection) to the same kinds of very high-risk individual: the only difference is that in the one case the drug is already in the system at the time of (anticipated) infection with the virus and that in the other it is administered very shortly after (presumed) infection. The expertise necessary to commission the former is identical with that necessary to commission the latter. Yet, if NHS England's construction were correct, responsibility in this highly specialised area would be fragmented: PrEP would be the responsibility of local authorities, who would not (unless some specific arrangement were made) have access to the expertise of NHS England at all. I do not believe that such a result is likely to have been contemplated by the Secretary of State, and I believe that it is possible to construe the language of paragraph 17 so as to avoid it. It is true that at the point that PrEP is first prescribed the patient is not "infected with HIV". But the prescription is given on the basis that he is expected imminently to become so infected, and the drugs will have no relevant effect unless and until that occurs: as explained above, they operate by inhibiting the replication of the virus immediately following infection. If one focuses on the point in time when the treatment has its intended effect rather than the moment of prescription PrEP can in substance be said to be a treatment for "persons infected with HIV"; and if there remains a degree of literal inaccuracy it is not sufficient to compel the conclusion that a treatment with the characteristics of PrEP was not intended to fall within the statutory language. The same approach would of course apply to the equivalent language in regulation 6 (5) of the 2013 Regulations.

56. Having reached that point it is unnecessary to consider the Respondents' submission, recorded at para. 36 of Longmore LJ's judgment, that the term "services" in paragraph 17 includes, via the definitions of "health care services" and "treatment" elsewhere in the Regulations, a preventive intervention. On my approach PrEP would straightforwardly constitute treatment of an infected person.

57. Very strictly speaking, the fact that the 2012 Regulations purport to empower NHS England to commission PrEP is not a complete answer to the question. The Regulations are made under section 3B (1) (d) of the Act. As I read it, though I accept that it does not expressly say so, the power given under that head extends only to services which would fall within NHS England's functions as specified in section 1H (2), and thus does not extend to powers in the public health field: if the Secretary of State wishes NHS England to provide public health services he must use his powers under section 7A. It follows that if the provision of PrEP were in fact a public-health responsibility paragraph 17 of Schedule 4 would be *ultra vires* in so far as it purported to empower NHS England to commission it. But this problem does not arise in practice. In circumstances where the boundary line between public-health and non-public-health responsibilities is not clearly drawn in the primary legislation, it is legitimate, as Longmore LJ says at para. 32 of his judgment, to refer to where it is drawn in the related secondary legislation. If as I would hold, the 2012 Regulations empower NHS England to commission PrEP that justifies the conclusion that it does not constitute a public health responsibility and accordingly falls within the rule-making power.

58. In short, I believe that the provision of PrEP does not fall within the words of exception in section 1H (2) and, further, that NHS England is empowered to commission it by the 2012 Regulations. Having reached this conclusion, I need not express a view on whether the commissioning of PrEP would be within NHS England's powers on either of the alternative bases considered by Longmore LJ in paras. 39 and 41-45 of his judgment. I am not sure, however, that I would be prepared to give section 2 of the 2006 Act as expansive an effect as he does.

59. To avoid any possible misunderstanding, my conclusion does not mean that NHS England is obliged to commission PrEP treatment but only that it is empowered to do so. It remains for it to judge whether its provision constitutes a "reasonable requirement … as part of the health service" within the meaning of regulation 11.

Lady Justice King:

60. I agree that NHS England has the power to provide PrEP. It seems to me, as has been identified in the judgments of Longmore LJ and Underhill LJ, that not only can the source of that power be found by reference to more than one part of the legislation and rules, but each route is in itself capable of more than one interpretation. However one gets there, there is, in my judgment, such a power and the capacity for NHS England to provide PrEP; a conclusion which not only sits comfortably alongside public policy considerations, but in my judgment dovetails with the provision by NHS England of PEP.

61. I further endorse the views of Longmore LJ and Underhill LJ that the judge was in error in his construction of section 1H to the effect that the words of exception in the section are not intended to limit the powers of NHS England but to provide for local

authorities to be concurrent partners with NHS England in relation to public health functions. To interpret the section in such a way would undermine what I regard as the clear intention of Parliament that local authorities were to bear the responsibility for the provision of public health services subject to the Secretary of State's power under section 7A of the Act.

62. It is clear that NHS England has no power to provide PrEP if doing so would be pursuant to a "public health function". There is no definition of public health function and, as explained by both Longmore LJ and Underhill LJ, it is impossible to differentiate between the two by reference to a rubric of a sort which would allow easy and obvious differentiation; for example by saying: prevention = public health function and treatment/cure = not public health function.

63. If NHS England has the power to provide PrEP it can only be on the basis that the provision of PrEP is not a public health function.

64. Looking in the first instance at a route other than by virtue of section 2 or section 7A of the Act; Longmore LJ tracks a course through the Act and the 2012 Regulations establishing that one of the "specified services" which NHS England is required to provide per section 3B(1) in order to meet all "reasonable requirements for the provision as part of the health service" is "Adult specialist services for patients infected with HIV." [2012 Regulations, Schedule 4, paragraph 17]

65. In paragraph 36 of his judgment, Longmore LJ analyses the route by which it is demonstrated that the services to be provided under Schedule 4 para 17 include "preventative" intervention. I too am satisfied that the concept of "prevention" is embedded in the phrase "specialist services" found in paragraph 17.

66. In my judgment there is however one more hurdle to be crossed before it can safely be concluded that there is power to provide PrEP under the Regulations namely whether, in prescribing PrEP, NHS England is providing a service to a person "infected with HIV".

67. As Underhill LJ sets out at paragraph 54 of his judgment, on a strictly literal reading, PrEP would seem to fall outside paragraph 17, (but so too would PEP). As Underhill LJ put it, the provision of PrEP forms a "seamless continuum" with the provision of PEP. The provision of PrEP is based, in part, on the previous history of the potential patient together with an assumption that he will become infected as a consequence of the strong likelihood that he will have unprotected sex with an infected person. PEP is prescribed when that anticipated act has come to pass. At that stage, when PEP is prescribed, it is not known whether or not the person who has had the unprotected sex is in fact "infected" just that there is a strong likelihood that they have been.

68. For the reasons given by Underhill LJ, I would agree that paragraph 17 is capable of being properly construed as including the provision of a specialist service namely PrEP as a preventative treatment which is prescribed in anticipation of a person becoming infected but which does not 'bite' until the virus is present in the body and the person 'is infected.'

69. Such an interpretation complements the clear intention of the Regulations, namely that NHS England will provide the highly specialised services in relation to HIV, a

condition covered by those parts of the rules (regulation 11) referable to "rare and very rare conditions".

70. If I am wrong about that and such an interpretation would strain the wording of paragraph unacceptably far, then in my judgment both section 2 and section 7A of the Act each provide an alternative, although more cumbersome, way in which NHS England can be invested with the power to provide to those high risk categories of patient this drug which represents a considerable medical advance in the 'treatment' of HIV. Thereafter it is a matter for NHS England itself to decide whether the provision of PrEP constitutes a "reasonable requirement…. as part of the health service" within the meaning of regulation 11 of the 2012 Regulations.