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Case No: CO/2979/2016

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 02/08/2016

Before :

MR JUSTICE GREEN

- -

Between :

National Aids Trust	**Claimant**
- and -	
National Health Service Commissioning Board (NHS England)	**Defendant**
- and -	
The Secretary of State for Health	**Interested Party**
- and -	
The Local Government Association	**Interested Party**

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Karon Monaghan QC and **Zoe Leventhal** (instructed by **Deighton Pierce Glynn**) for the **Claimant**
Jonathan Swift QC (instructed by **DAC Beachcroft LLP**) for the **Defendant**
Nicola Greaney (instructed by **Local Government Association) for the Interested party**

Hearing date: 13th July 2016

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Approved Judgment

Mr Justice Green :

A. Introduction, summary and conclusion

1. This Claim is brought by a charity which specialises in achieving the best policy for treatment and prevention of HIV and AIDS, the National Aids Trust ("NAT"). The challenge is to a decision of the Defendant, NHS England, to refuse to consider in its commissioning process an anti-retroviral drug to be used on a preventative basis for those at high risk of contracting AIDS. The treatment is known as "PrEP". The charity argues that both medically and economically the case for NHS England to commission the drugs for this prophylactic treatment is overwhelming and indeed there has been no suggestion from NHS England that this is not the case. A quick comparison of the cost of treating HIV related infections across a person's lifetime, compared to the relative cost of providing drugs on a prophylactic basis, shows that the savings from PrEP may be considerable. In these budgetary constrained times, when there is an ever increased focus on preventative medicine as a means of curbing future costs, the policy logic appears unassailable and, once again, it is said that there is no serious demur to this proposition from NHS England.

2. NHS England argues that the reason why it has decided not to commission PrEP on a preventative basis is very simple: It has no legal power to do so under the governing legislation, the National Health Service Act 2006 ("NHSA 2006"). It is argued that under the relevant legislation it does not possess a power to perform "*public health functions*" that are carried out by the Secretary of State or local authorities pursuant to their respective statutory powers and duties. Further, pursuant to regulations promulgated by the Secretary of State there is now a division of labour between NHS England and local authorities with the latter assuming responsibility for preventative medicine in relation to sexually transmitted diseases. Accordingly since the proposed commissioning of PrEP is squarely for preventative medicine in the field of sexually transmitted diseases this is now the sole task of the local authorities (or the Secretary of State) but not NHS England.

3. The local authorities disagree. They are represented in this litigation by the Local Government Association ("LGA"). They have argued that not only do they consider that NHS England is wrong in law but that (a) the consequences (if NHS England is correct) are illogical and inefficient because NHS England will then have responsibility for dealing with the greatest portion of the HIV/AIDs policy which includes treatments identical or extremely closely related to PrEP but will leave it to the local authorities to deal with the tail end and (b) the local authorities have no money and no budget for such preventative health in this field in any event.

4. At its core this judicial review is about the allocation of budgetary responsibility in the health field. No one doubts that preventative medicine makes powerful sense. But one governmental body says it has no power to provide the service and the local authorities say that they have no money. The Claimant is caught between the two and the potential victims of this disagreement are those who will contract HIV/AIDs but who would not were the preventative policy to be fully implemented.

5. Notwithstanding any and all of the above the issue for the Court is a narrow one – is NHS England correct in its analysis of its powers and duties? If it is then the wider

policy and budgetary issues which arise are for the Secretary of State and Parliament to sort out.

6. In my judgment the answer to this conundrum is that NHS England has erred in deciding that it has no power or duty to commission the preventative drugs in issue. In my judgment it has a broad preventative role (including in relation to HIV) and commensurate powers and duties. But I have also considered the position if I am wrong in this. On this alternative hypothesis I am of the view that NHS England has still erred in concluding that it has no power to commission the PrEP drugs in question. Either: (i) it has mischaracterised the PrEP treatment as preventative when in law it is capable of amounting to treatment for a person with infection or (ii), NHS England has in any event the power under the legislation to commission preventative treatments (and therefore falls within its powers however that power is defined); because it facilitates and/or is conducive and/or incidental to the discharge of its broader statutory functions.

7. Before addressing the issues in detail I should express my gratitude to all counsel for the conspicuous clarity with which they analysed the complex issues arising in their written submissions and in the manner in which they delivered their oral arguments.

B. The parties

8. **The National Aids Trust:** NAT is a registered charity and a company limited by guarantee. The objects of the charity, as set out in its Memorandum and Articles of Association, are to promote public health through effective HIV prevention and early diagnosis of HIV infection. It includes the purpose of promoting the rights, dignity, health and well-being of people affected by HIV or at risk of infection in the UK and to advance the education of the public in general, including policy makers, opinion formers and decision makers, in order to increase awareness and understanding of HIV and AIDS and to eradicate HIV-related stigma, discrimination and equality.

9. NAT aims to deliver these charitable objects through a series of strategic goals. First, by seeking effective HIV prevention in order to halt the spread of HIV. Second, through secure early diagnosis of HIV to ethical, accessible and appropriate testing. Third, to secure equitable access to treatment, care and support for people living with HIV. Fourth, to enhance understanding of the facts relating to HIV and the issues surrounding living with HIV. Fifth, to eradicate HIV-related stigma and discrimination. NAT is a small charity with only 15 members of staff. Its activities are overseen by the Board of Trustees who are the directors and members of the company. The Board of Trustees includes, amongst its number, prominent HIV clinicians and academics.

10. **The Secretary of State for Health**: Proceedings in this claim were served on the Secretary of State for Health. The Secretary of State for Health has written to the Court indicating that he does not intend to file an Acknowledgement of Service nor make submissions in the proceedings. He has explained that he intends to remain "*neutral*" in the dispute. However the position of the Secretary of State is important in understanding the issues arising, not least because the Secretary of State provides to NHS England an "annual mandate" ("the Mandate") setting out the objectives which NHS England is required to pursue. The Mandate has a statutory function and is described in the following way in the 2016/17 document: "*NHS England is*

responsible for arranging the provision of health services in England. The mandate to NHS England sets the Government's objectives and any requirements for NHS England, as well as its budget. In doing so, the mandate sets direction for the NHS, and helps ensure the NHS is accountable to Parliament and the public. Every year, the Secretary of State must publish a mandate to ensure that NHS England's objectives remain up to date". The Mandate is promulgated in accordance with section 13A(1) of the NHSA 2006, as amended by the Health and Social Care Act 2012.

11. The Mandate for 2016/17 requires NHS England to continue to sustain a comprehensive National Health Service in England of high quality and free of charge to everyone at the point of use. The Mandate sets out specific objectives for NHS England to pursue. Objective 4 emphasises the importance of preventative medicine:

> "**OBJECTIVE 4: To lead a step change in the NHS in preventing ill health and supporting people to live healthier lives**.
>
> 2.8. The escalating demands of ill health driven by our lifestyles also threaten the long-term sustainability of the NHS. Across the health and care system, we want the NHS to do more to tackle smoking, alcohol and physical inactivity. We fully support the focus in the Five Year Forward View on preventing avoidable ill health and premature mortality. We ask NHS England to lead a step-change in the NHS on helping people to live healthier lives by tackling obesity and preventable illness. In particular, this includes contributing to the Government's goal to reduce child obesity and doing more to reach the five million people at high risk of diabetes and improve the management and care of people with diabetes. As part of the Prime Minister's 2020 Dementia Challenge, we expect NHS England to make measurable improvement in the quality of care and support for people with dementia and to increase public awareness."

12. The total budget for 2016/17 for NHS England is circa £107bn. It has responsibility for allocating and investing funds to improve health and well-being, secure high quality care, derive value for money for the public's investment and to create a sustainable future for the NHS.

13. **NHS England**: The Defendant, the National Health Service Commissioning Board, is commonly referred to as "NHS England". It was established pursuant to the NHSA 2006. It is responsible for directly commissioning a range of specialised services as prescribed by regulation. Other NHS services are commissioned by Clinical Commissioning Groups ("CCG"). There are presently 146 prescribed services which range from renal dialysis and secure in-patient mental health services, through to treatment for rare cancers and life-threatening genetic disorders. The budget for the commissioning of specialised services for 2016/17 is £15.6bn.

14. NHS England has itself routinely in the past assumed responsibility for preventative medicine generally and preventative medicine in relation to HIV. As a matter of

policy the NHS England has placed great store by preventative medicine generally and in working cooperatively with other health providers and, I am entitled to infer, NHS England view this as an implementation of its statutory duties under the NHSA 2006. The "Five Year Forward View" issued by NHS England in October 2014 contains the following in paragraphs [1] – [4] of the Executive Summary:

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> "**1. The NHS has dramatically improved over the past fifteen years**. Cancer and cardiac outcomes are better; waits are shorter; patient satisfaction much higher. Progress has continued even during global recession and austerity thanks to protected funding and the commitment of NHS staff. But quality of care can be variable, preventable illness is widespread, health inequalities deep-rooted. Our patients' needs are changing, new treatment options are emerging, and we face particular challenges in areas such as mental health, cancer and support for frail older patients. Service pressures are building.
>
> 2. Fortunately **there is now quite broad consensus on what a better future should be**. This 'Forward View' sets out a clear direction for the NHS – showing why change is needed and what it will look like. Some of what is needed can be brought about by the NHS itself. Other actions require new partnerships with local communities, local authorities and employers. Some critical decisions – for example on investment, on various public health measures, and on local service changes – will need explicit support from the next government.
>
> 3. The first argument we make in this Forward View is that the future health of millions of children, the sustainability of the NHS, and the economic prosperity of Britain all now depend on a **radical upgrade in prevention and public health**. Twelve years ago Derek Wanless' health review warned that unless the country took prevention seriously we would be faced with a sharply rising burden of avoidable illness. That warning has not been heeded -and the NHS is on the hook for the consequences.
>
> 4. The NHS will therefore now back hard-hitting national action on obesity, smoking, alcohol and other major health risks. We will help develop and support new workplace incentives to promote employee health and cut sickness-related unemployment. And we will advocate for stronger public health-related powers for local government and elected mayors".
>
> (Emphasis in the original)

15. This text emphasises not only the importance of preventative medicine but also the importance of removing inequalities in provision and in the importance of working

cooperatively with others, such as local authorities. This latter point was more explicitly articulated on page [11] of the Report:

> "*Targeted prevention.* While local authorities now have responsibility for many broad based public health programmes, the NHS has a distinct role in secondary prevention. Proactive primary care is central to this, as is the more systematic use of evidence-based intervention strategies. We also need to make different investment decisions -for example, it makes little sense that the NHS is now spending more on bariatric surgery for obesity than on a national roll-out of intensive lifestyle intervention programmes that were first shown to cut obesity and prevent diabetes over a decade ago. Our ambition is to change this over the next five years so that we become the first country to implement at scale a national evidence-based diabetes prevention programme modelled on proven UK and international models, and linked where appropriate to the new Health Check. NHS England and Public Health England will establish a preventative services programme that will then expand evidence-based action to other conditions".

16. **Local Government Association**: Proceedings were also served on the LGA. The LGA has served Grounds indicating its support for the Claimant and has participated fully in this case. The LGA is an association of local authorities comprising 435 local authority members. It is the national voice of local government, a cross-party organisation working with and on behalf of local authorities to support, promote and improve local government. The interests of the LGA's members are directly affected by the subject matter of the claim. It is apparent from its detailed written submissions that the LGA supports the detailed submissions in law made by the Claimant. It is, at the outset, worth recording two submissions made by the LGA to the following effect:

> "… it is important for the Court to understand that local authorities do not have the funding that would enable them routinely to commission PrEP; nor would local authorities receive any of the financial benefits of commissioning PrEP: those savings (namely, the costs of providing lifetime care for those with HIV) would accrue to the benefit of NHS England".

The second point (about accrued benefit) is one that reflects the complexities of health care budgeting. If local authorities must bear the brunt of funding preventative treatment in this area the benefit (measured in terms of savings in post-infection treatment) accrues to NHS England who will reap the rewards in terms of reduced future expenditure on diagnosis and treatment; such is the budgetary economics of prevention being better than cure. This is one of the reasons why the LGA considers that the position adopted by NHS England is illogical and inefficient in a world of budgetary constraints.

C. The different types of treatment for HIV: Anti-retroviral medication

17. Human Immunodeficiency Virus ("HIV") is a disease attacking the immune system. It reduces the body's white blood cells so that it is less able, and in the fullness of time

unable, to combat infection. Anti-retroviral ("ARV") medication suppresses the impact of HIV and for many years has been used to treat people who are living with HIV. It has been used to treat those individuals whose CD4 count (i.e. white blood cells which give a reliable indication of the health of the immune system) falls below a certain level. Normally, medication is prescribed and monitored by specialist HIV clinicians working in hospitals and it is thus provided by NHS Trusts whose HIV clinic services are commissioned by NHS England through its specialised commissioning function. The development of science in this area has resulted in ARVs becoming more and more effective to the point that assuming availability of ARVs, and adherence to medication regimes, individuals living with HIV stay alive for decades, do not develop AIDS and enjoy a normal life expectancy.

18. According to published data the costs for treating a single person with HIV over his/her lifetime is around £360,000. Further, there are an estimated 103,700 individuals in the United Kingdom living with HIV. Evidence given on behalf of the Claimant, and not challenged by the Defendant, estimates that a record number (2,800) of gay men in the United Kingdom acquired HIV in 2014, i.e. approximately 8 gay men contract HIV on a daily basis. Each such individual represents a projected cost of £360,000 to the NHS which amounts to an additional cost of £2.88m accruing to the NHS daily. The position of the Claimant is that PrEP could reduce that cost dramatically.

19. So far as prevention is concerned, the most obvious and cheapest form involves raising awareness and promotion of the use of condoms. Progress has been made in this regard but after more than 30 years it is clear that such efforts will only achieve a limited amount and there remains a cohort of largely resistant individuals who are at significant risk of transmitting the virus or contracting it themselves. This may be because they are in a long-term relationship with an individual who has HIV whose infection is not adequately suppressed through treatment, or because of lifestyle or substance misuse issues. Furthermore, many men, even using best efforts, are unable to use condoms with 100% consistency. In relation to this resistant group, medical prevention is essential to reduce the risk of the virus spreading and thus limit the personal, public health and financial costs of contracting HIV. In consequence, ARVs are now widely deployed as preventative measures. In England these are provided, essentially, in three ways. First, to help reduce the risk of transmission from mother to child *in utero* (MTC). Second, to help reduce the risk of transmission from infected persons who are not clinically indicated as requiring ARVs for their own benefit, to third persons (known as Treatment as Prevention - "TasP"). Third, as post-exposure prophylaxis ("PEP") for those individuals who have been clinically assessed as having had a high risk of HIV exposure event in the preceding 72 hours and who are therefore at risk of having contracted the infection but who are not proven actually to be infected. All three preventative methodologies are funded by NHS England because, so argues the Claimant, it is far cheaper to fund this preventative medication than pay for the cost of ARV medication for the remainder of the infected person's life. Of these three methods, TasP and PEP are provided through specialised commissioning whereas MTC is procured through an agreement with the Secretary of State pursuant to section 7A NHSA 2006.

20. PrEP is a further method of using ARV medication to reduce or limit the risk of transmission of HIV. It involves identifying individuals who are HIV negative but

who, as with PEP, are at high risk of contracting HIV. It requires those individuals to take ARV medication to avoid contracting HIV. The medication can be taken either daily or upon demand and clinical studies have demonstrated the efficacy of either method. The efficacy of PrEP taken daily was assessed in the United Kingdom by a trial called "Pre-exposure option for reducing HIV in the UK: Immediate or Deferred" ("PrOUD"). The results of this study were released in 2015 and showed that one HIV infection was prevented for every thirteen gay men who took PrEP. A French study (Ipergay) has also considered the efficacy of PrEP when taken on demand, i.e. not daily but only before and after sexual intercourse. Both studies found that PrEP was 86% effective, i.e. it stopped 17 out of every 20 HIV infections that could have happened in the absence of PrEP. Studies with heterosexual men and women showed that PrEP works well with individuals who are able to adhere to the medication regime. One African study demonstrated that it was 75% effective (i.e. it prevented 15 out of every 20 HIV infections that would otherwise have occurred). A study in Botswana revealed similar positive results. Both were randomised controlled trials. PrEP was licensed in the US in 2012 and the US Center for Disease Control ("CDC") has published clinical guidance for PrEP based upon the risk of infection. In the US, in excess of 30,000 individuals, predominantly gay men, are now taking PrEP.

21. It is apparent from the above that both PEP and PrEP are forms of prophylaxis. Expert evidence given to the Court (and not challenged by the Defendant), by Professor Sheena McCormack, of the Medical Research Council Clinical Trials Unit at University College London, explained the relationship between PrEP and PEP. She explained that both operated in the same way. The active metabolites of Tenofovir and Emtricitabine work inside the human cell to inhibit replication of HIV. Neither prevents HIV getting into the human cell and therefore do not prevent transmission of virus from one person to another. The time taken from exposure to cell entry is approximately 30 minutes based upon laboratory experiments. However, in order to progress to an established infection HIV has to disseminate from cell to cell. The effect of the antiretroviral drugs inhibits replication and thereby limits the number of cells that become infected. The consensus within the scientific community is that without such drugs dissemination to established infection is likely to happen within the first ten days. The drugs limit the number of infected cells and the natural immune responses are better able, in the circumstances, to identify and eradicate infected cells. Professor McCormack says that the only difference between PrEP and PEP is that in the case of PrEP the drugs are given before exposure (pre-exposure prophylaxis) and in the case of PEP they are given within 72 hours (post-exposure prophylaxis). The medical consensus is that the later the drugs are started the more time HIV has to spread from cell to cell and to escape the immune system. Professor McCormack states:

> "8. In both cases, PEP and PrEP, the drugs stop HIV replicating and allow the body's immune system to clear the infected cells. In neither case do the drugs stop transmission. What they both do is prevent dissemination into an established infection.
>
> 9. Another way of looking at it is that HIV infection requires three phases: transmission, dissemination, and establishment. Both PEP and PrEP work on the dissemination phase, and the physiological benefits of the drugs are, in both cases, only

> present if transmission has already occurred. The only difference is that PrEP is taken before, as well as after, potential transmission occurs, whereas PEP is taken only after potential transmission has occurred".

22. Evidence given by Mr John Stewart for NHS England accepts the broad thrust of the scientific analysis of Professor McCormack. Mr Stewart is the Director of Strategy and Policy for Specialised Commissioning at NHS England. At paragraph [31] of his witness statement he accepts that the actions of the active ingredient (Truvada) "… *at the molecular level is the same whether the drug is provided as part of the PEP service or whether it is provided as part of the PrEP service*". (It is right to record that Mr Stewart goes on to identify certain differences between PEP and PrEP which he says justify the two being treated as different services. I address this issue in Section H(iii) below).

23. So far as the relationship between PrEP and TasP is concerned a document published by NHS England entitled "Clinical Commissioning Policy: Treatment as Prevention (TasP) in HIV Infected Adults" (July 2015) explains that NHS England intended to commission earlier initiation of treatment in HIV infected adults as a strategy for HIV prevention. In this document TasP is described in the following way:

> "In the UK, British HIV Association guidelines for HIV treatment recommend starting treatment depending on how a person's immunity is doing, which is measured with the CD4 count. The standard is to start when the CD4 count has declined to 350 cells/mm^3 or less. The guidelines are also recommended as a point of good practice that clinicians discuss and offer TasP with all newly diagnosed patients whatever their CD4 count. A consistent and national policy position is required to equitable access in England to TasP.
>
> To avoid preventable morbidity and mortality, people with diagnosed HIV require treatment with antiretroviral therapy (ART) when their immune system, as monitored by CD4 lymphocyte counts, shows signs of weakening. Anyone with symptomatic HIV infection should be treated urgently. Treatment as prevention (TasP) is a prevention intervention aimed at bringing forward the time when treatment is given to people with diagnosed HIV infection in order to prevent onward transmission of HIV to sexual partners and ultimately to reduce HIV within the population.
>
> A "test and treat" policy for HIV infection is used in many resource rich countries including the USA and France…Such a policy means that irrespective of CD4 count, treatment is indicated to reduce the risk of onward transmission of HIV to uninfected partners. World Health Organisation (WHO) guidelines recommend that ART is initiated regardless of clinical stage or CD4 cell count when HIV-positive individuals are in a sero-discordant partnership "to reduce transmission risk"…".

24. It is thus apparent that TasP is a policy identified for persons who would not otherwise be given medication because their CD4 count is below 350 cells/mm^3. The declared rationale is one of prevention rather than cure. The objective is to curb the onset of HIV and thereby reduce or eradicate the risk of transmission. The object, therefore, is not only to prevent the infection taking hold in the individual but, most importantly, to prevent transmission to third parties.

25. The legal significance of (in particular) the similarities and differences between PEP and PrEP is a relevant issue in this case and I deal with it fully at Section H below.

D. The way the dispute has come about: Steps taken by NHS England to commission PrEP

26. NHS England, in September 2014, instituted a PrEP policy writing group ("the CRG") tasked with developing a plan for the commissioning of PrEP. On 24th April 2015 NHS England published a Specialised Services Circular to clarify its commissioning position on PrEP. That circular stated that NHS England was the responsible commissioner for all antiretroviral drugs including those used in HIV prevention either in preventing mother to child transmission or as post-exposure prophylaxis following sexual or occupational exposure to HIV infection. The circular recorded that in February 2015 the results of the PrOUD study (see paragraph [20] above) indicated that PrEP was highly productive reducing the risk of infection by 86% in this group. The circular explained that PrEP was not currently commissioned by the Defendant and that access to PrEP had been limited, in the past, to those in the PrOUD study.

27. 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 8 – 12,000 gay men and a further 1,000 heterosexual individuals eligible for treatment. It postulated an estimated take-up rate of 50%.

28. In December 2015 the CRG Draft Policy and the Evidence Review were published for consultation. The Claimant 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 that the 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:

> "As set out in the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013, local authorities are the responsible commissioner for HIV prevention services.
>
> Including PrEP for consideration in competition with specialised commissioning treatments as part of the annual CPAG prioritisation process could present risk of legal challenge from proponents of other 'candidate' treatments and interventions that could be displaced by PrEP if NHS England were to commission it.

> While NHS England is not responsible for commissioning HIV prevention services, we are committed to working with local authorities, Public Health England, the Department of Health and other stakeholders as further consideration is given to making PrEP available for HIV prevention".

NHS England proposed, instead, to introduce a pilot from which it was estimated 500 individuals could benefit at a cost of approximately £2m. It appeared to contend that it had the power to fund this pursuant to sections 13K and 13L of the 2006 Act which concern research and innovation. However, its view now was that it did not, otherwise, have the power in law to commission PrEP. The Specialised Services Commissioning Committee of NHS England met on 31st May 2016 to consider its position. The remit of the committee was to consider the legal basis for commissioning PrEP in the light of the external legal advice that NHS England had received to the effect that it did not have the power to commission PrEP. It was acknowledged that the Secretary of State could, were this legal advice to be accepted, delegate the power to commission PrEP to NHS England under the relevant legislation but it was noted that this would need to be accompanied by appropriate funding.

E. The legislative framework

29. I turn now to consider the relevant legal framework which governs the powers and duties of NHS England. In order to understand the way in which relevant responsibility for the prevention and treatment of HIV has been allocated it is necessary to consider three different sets of legislative provisions: (a) Part 1 of the NHSA 2006; (b) the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("the 2012 Regulations"); and (c), the Local Authorities (Public Health Functions etc.) Regulations 2013 ("the 2013 Regulations"). The 2012 Regulations and the 2013 Regulations were both made pursuant to the NHSA 2006. The provisions of the NHSA 2006 in issue were introduced into the Act by the Health and Social Care Act 2012, with effect from 1 April 2013.

(i) The establishment of NHS England

30. NHS England was established under Section 1H(1) of the NHSA 2006. Its formal title is the "National Health Service Commissioning Board". The provision reads:

> "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")".

(ii) The duties on NHS England under the NHSA 2006

31. **The primary (concurrent) duty**: The primary duty of NHS England is set out in section 1H(2). Under that section the duty on NHS England is not expressly described but, rather, it is defined by cross-reference to the duty that the Secretary of State is subject to. The duties of NHS England operate "*concurrently with the Secretary of State*". The content of the duty is said to be that in section 1(1) NHSA 2006. Section 1H(2) - (4) provides:

> "(2) The Board is subject to the duty under section 1(1) concurrently with the Secretary of State except 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.
>
> (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".

32. The duty in section 1(1) on the Secretary of State, which therefore also applies to NHS England, is to:

> "… 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".

33. The duty is to: "*… continue the promotion in England of a comprehensive health service…*". The duty thus emphasises that the duty applies to the whole of "*England*" and is "*comprehensive*" (the requirement to provide a "*comprehensive*" service was introduced by amendment under the Health and Social Care Act 2012). The subject matter of the duty is defined broadly to catch, in substance, all forms of medicine and explicitly incudes preventative medicine. The task of NHS England is 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*".

34. The amendments to the NHSA 2006 introduced by the Health and Social Care Act 2012 brought about a structural shift in the powers of the Secretary of State. Many of the powers of the Secretary of State were transferred to third parties and in particular NHS England. A purpose underlying the changes was to remove the Secretary of State from front line decision making and to allocate to the Minister a more residual

role. Thus, when NHS England was set up, the Secretary of State could influence its decision making only *via* the Mandate and not by direct instruction. Under section 13Z2 the Secretary of State can intervene more directly only in the case of failure by NHS England.

35. **Secondary duties**: The NHSA 2006 also imposes a series of secondary duties which affect the manner in which the primary duty is to be exercised. Sections 13Cff all concern the way in which NHS England must "e*xercise its functions*" or make commissioning decisions. I can summarise these duties as follows. NHS England must exercise it functions:

a) effectively, efficiently and economically (section 13D);

b) with a view to securing continuous improvement in the quality of services provided to individuals for or in connection with (i) the prevention diagnosis or treatment of illness or (ii) the protection or improvement of public health (section 13E);

c) having regard to the duty to reduce inequalities between patients with respect to their ability to access health services and reduce inequalities with respect to outcomes achieved for them by the provision of health services (section 13H);

d) with a view to enabling patients to make choices with respect to aspects of health service provided to them (Section 13I);

e) to promote innovation in the provision of health services (section 13K);

f) to promote research (Section 13L);

g) to promote education and training (Section 13M); and,

h) to promote the provision of services in an "*integrated way*" where this could improve the quality of services provided and reduce inequalities between persons with regard to their ability to access relevant services and reduce inequalities with regard to outcomes (Section 13N(1)). The duty goes beyond provision of services and incudes the provision of "*health related services or social care services*" (Section 13N(2)). The duty to promote integration also involves NHS England in encouraging CCGs to enter into arrangements with local authorities (Section 13N(3)).

(iii) The exception in Section 1(H)(2): What does it apply to?

36. I turn now to the second part of section 1H(2) which, by its terms, creates an exception. The meaning of this exception is one of the pivotal issues in this case. It is convenient to set out the provision again:

> "(2) The Board is subject to the duty under section 1(1) concurrently with the Secretary of State *except 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*".
>
> (Emphasis added)

A central issue in this case is to work out *what* the exception applies to. There are two main candidates. First, (as argued by NHS England) the exception is as to the scope of the "*duty"* under section 1(1). The second (as argued by the Claimant and the LGA) is that the exception is only as to the identity of the person whom the primary duty of NHS England is to be performed "*concurrently*" with (but not therefore the scope of the duty itself), and as to this the concurrent partner is either the Secretary of State or local authorities.

37. According to Section 1H(2) the exception is delineated by reference to the "*public health functions"* of the Secretary of State or local authorities. Section 1H(5) explains that this phrase is to be determined by reference to the "*functions*" of the Secretary of State or the local authorities under other specified sections of the NHSA 2006:

> "(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".

38. There is no need for the purpose of this judgment to set out all of the details of these various statutory provisions. The important point is that these other statutory provisions make it plain that they cover just about all of the possible activities, tasks and functions that the Secretary of State or a local authority could conceivably perform in relation to the provision of a health service. For instance the *public health functions* of the Secretary of State are stated in Section 2A(1) to be "… *for the purpose of protection the public in England from disease or other dangers to health*". They include the functions of: conducting research or such other steps as the Secretary of State considers appropriate for advancing knowledge and understanding; providing microbiological or other technical services (whether in laboratories or otherwise); providing vaccination, immunisation or screening services; providing other services or facilities for the prevention, diagnosis or treatment of illness; providing training; providing information and advice; making available the services of any person or any facilities. Similarly the "*public health functions*" of local authorities under Section 2B are cast in equally broad and all-encompassing terms.

39. This however gives rise to a problem since the "*public health functions*" of the Secretary of State and the local authorities are cast in such broad and sweeping terms that *if* they serve to reduce the scope of the duty on NHS England they, more or less, reduce it to nought. Indeed, Mr Jonathan Swift QC for NHS England could not

identify any residual service that would be left ***if*** the duty of NHS England was defined and limited in this way. I return to this, and the argument advanced by NHS England to overcome this difficulty, at paragraph [65ff] below.

40. For present purposes it is sufficient to explain that NHS England relies heavily upon these exceptions to whittle down the scope of its duties and its concomitant powers to commission. And it argues that, in the light of this analysis, PrEP falls outside of the powers that it has to commission medicines because it serves a public health function. Further, (it is argued) the power to commission preventative medicines in this field now rests with the local authorities who have been entrusted with a duty to provide preventative sexual health services pursuant to the 2013 Regulations adopted in 2013 (referred to below). The breadth and scope of the phrase "*public health functions*" is thus key to this case.

41. I have set out my conclusions as to the proper construction of this exception at paragraphs [70] – [82] below.

(iv) The specific commissioning duties of NHS England: The 2012 Regulations

42. The manner in which the NHSA 2006 allocates responsibility for commissioning as between NHS England and CCGs is of relevance to this issue. Section 3(1) NHSA 2006 imposes a duty on CCGs to arrange for the provision (to the extent considered necessary to meet all the reasonable requirements of the persons for whom it has responsibility) of the following services: (a) hospital accommodation; (b) other accommodation for the purpose of any service provided under this Act; (c) medical, dental, ophthalmic, nursing and ambulance services; (d) such other services or facilities for the care of pregnant women, women who are breastfeeding and young children as the group considers are appropriate as part of the health service; (e) such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as the group considers are appropriate as part of the health service; and (f), such other services or facilities as are required for the diagnosis and treatment of illness.

43. However the duty under section 3(1) does not apply *"in relation to a service or facility if the Board has a duty to arrange for its provision"*.

44. The importance of this is that the Secretary of State has, exercising powers under *(inter alia*) NHSA 2006, imposed a duty on NHS England to arrange for the provision of certain medical services. Section 3B of the 2006 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".

45. 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. They came into effect on 1 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*".

46. Regulation 1 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*".

47. 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) but is not limited to preventative medicine.

48. Part 3 of the 2012 Regulations is entitled "*Services to be commissioned by the Board*". It then 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 in this particular Regulation a duty is imposed on NHS England 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 Schedule 4 concerns HIV. It refers to "*Adult specialist services for patients infected with HIV*".

49. Read together, 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*". And this would, because of the combined effect of the definitions of "*health care services"* and "*treatment*", include preventative services.

50. NHS England argues however that paragraph 17 is drafted in the present tense ("*infected*") and connotes therefore only a person who is actually infected with HIV and therefore precludes preventative treatment provided to persons who are not actually infected. There are (at least) four obstacles which prevent this interpretation being correct. First, it ignores the fact that the definitions section deems the service to include treatments for prevention. "*Treatment*" is defined in Regulation 1 as an intervention "*to manage a person's disease*". Read with an overly grammatical eye this could indicate a person with an *actual* disease only. But the extension of the expression "*treatmen*t" to embrace preventative treatment means that it also includes "*interventions to prevent a person becoming infected with HIV*". Second, this conclusion is consistent with the NHSA 2006 read as a whole. This is in my view the only construction which also makes sense against the broad target duties of NHS England under sections 1(1) and 6 NHSA 2016 pursuant to which NHS England has a preventative duty which is coterminous with that of the Secretary of State (see paragraphs [33] – [35] above). Given that the 2012 Regulations were adopted under powers conferred in the NHSA 2006, to construe the 2012 Regulations so as to exclude preventative treatments would run counter to the duties of NHS England under the enabling legislation. Third, given that prevention is such an important part of health care provision and forms an integral part of the Mandate and the expressions "*prevention*" and "*preventing*" are used as recognised terms in the legislation, then **if** the legislature had intended to exclude prevention in the case of HIV it is inconceivable that the Secretary of State in the 2012 Regulations would not simply have said so and used the relevant expressions "prevent/prevention" to create an express carve-out. But he did not do so. It would for instance have been the easiest of drafting exercises to have added a caveat to paragraph 17 so that it referred to "*Adult specialist services for patients infected with HIV, excluding preventative treatments*", or "*Adult specialist services for patients infected with HIV which does not extend to treatment for the prevention of HIV*". These simple drafting options were not taken. The absence of such express words reinforces my conclusion that the legislature did not intend to exclude prevention. Fourth, a comparison of the drafting techniques in the 2013 Regulations relative to those in the 2012 Regulations also supports the conclusion that the legislature intended to include preventative medicine for HIV in the 2012 Regulations (see paragraph [56](c) below).

51. In short the 2012 Regulations confer upon NHS England the jurisdiction to commission treatments for HIV on a preventative basis.

(v) The powers and duties of the local authorities: The 2013 Regulations

52. It is important also to consider (a) the nature of the primary duty imposed upon local authorities and (b) the power of the Secretary of State to govern the exercise of that duty by the local authorities. This is relevant because it is a part of NHS England's argument that it is now the local authorities who have the sole duty to provide preventative medicine in the field of sexually transmitted diseases which includes HIV (see NHS England Press Release cited at paragraph [28] above).

53. The primary duty of the local authorities is set out in Section 2B NHSA 2006. There are three main points to observe. First, the provision identifies the broad "target" duty which is to "*improve the health of the people in its area*" (section 2B(1)). Second, it makes clear that the functions of the local authorities are concurrent with those of the Secretary of State (Section 2B(2). Third, it lists the steps that the authorities and the

Secretary of State are empowered to take and makes clear that these include preventative treatments. The provision states:

> "(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)".

54. Section 6C empowers the Secretary of State to direct, through the promulgation of regulations, how the local authorities are to exercise their duty and powers. It makes clear, importantly, that the Secretary of State may not only direct how the local authorities will exercise their own powers and duties but it also enables the Secretary of State to require the local authorities to perform (on a non-exclusive basis – see Section 6C(4) cited below) the duties and powers of the Secretary of State. It provides as follows:

> "(1) Regulations may require a local authority to exercise any of the public health functions of the Secretary of State (so far as

> relating to the health of the public in the authority's area) by taking such steps as may be prescribed.
>
> (2) Regulations may require a local authority to exercise its public health functions by taking such steps as may be prescribed.
>
> (3) Where regulations under subsection (1) require a local authority to exercise any of the public health functions of the Secretary of State, the regulations may also authorise or require the local authority to exercise any prescribed functions of the Secretary of State that are exercisable in connection with those functions (including the powers conferred by section 12).
>
> (4) The making of regulations under subsection (1) does not prevent the Secretary of State from taking any step that a local authority is required to take under the regulations.
>
> (5) Any rights acquired, or liabilities (including liabilities in tort) incurred, in respect of the exercise by a local authority of any of its functions under regulations under subsection (1) are enforceable by or against the local authority (and no other person).
>
> (6) …".

55. In the exercise of these regulation making powers, the Secretary of State promulgated the Local Authorities (Public Health Functions and Entry to Premises by Local Healthwatch Representatives) Regulations 2013 ("the 2013 Regulations"). These also came into effect on 1 April 2013. Regulation 6 states as follows:

> "(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".
>
> [Emphasis added]

So far as is relevant to this case, HIV is a sexually transmitted infection.

56. There are four points to observe about the duty on the local authorities under the 2013 Regulations:

a) First, the 2013 Regulations were adopted under different statutory powers to the 2012 Regulations. They are thus parallel measures but the promulgation of one does not have any effect (such as curtailing the scope) on the other. Had this been their intended effect then the legislature would have expressly provided for this result.

b) Second, they impose a duty on local authorities to provide, *inter alia*, services for preventing the spread of sexually transmitted infections. However the duty is a qualified one. Under Section 2B local authorities have a target duty imposed upon them to improve the health of people in their area but in fulfillment of that duty the authorities have a discretion (cf "*may*" in section 2B(3)) to take one or more of the steps identified there, which includes the actual provision of any service. It was accepted in argument by Mr Jonathan Swift QC that, at least in principle, a local authority could in the proper exercise of its discretion and judgment decide, quite rationally, not to provide a particular service such as the provision of PrEP because (for instance) it took the view that given its limited budget the provision of education and free condoms sufficed. This means that the allocation of responsibility to local authorities for preventative treatments in the broad field of sexually transmitted infections does not, necessarily, mean that local authorities would commission PrEP or that there would therefore be a consistent nation wide policy on HIV prevention.

c) Third, the provision excludes in any event from the duty imposed on local authorities the offering of services "*for treating or caring for people infected with*" HIV. The purpose of this carve–out is to focus

the duty on prevention services, i.e. the stage before treatment or care of those "*infected with*" HIV. There is no definitions section in the 2013 Regulation and nothing in that Regulation therefore extends the concept of treatment to preventative medicine, as there is in the 2012 Regulations (see paragraphs [45] – [49] above). The legislature has expressly sought to differentiate between treatment and care and other (i.e. preventative) treatments. This is relevant, in my view, to the point made at paragraph [50] above that when the legislature seeks to differentiate between preventative and other services it does so expressly and not by implication. This supports my conclusion that the absence of an express carve-out for prevention in the 2012 Regulation is intentional and indicates that preventative medicine in the case of HIV is within the powers of NHS England.

d) Fourth, the 2013 Regulations do not, anywhere, say that they limit or in any way affect the scope of the duty on NHS England under the 2012 Regulations. In particular in so far as they cross refer to the duties of any other person they do so only in relation to the duty of the Secretary of State under Regulation 6(1)(a) and (5) in order to make clear that the allocation of responsibility to local authorities does not prevent parallel action by the Secretary of State (see above). The 2013 Regulations do not purport to limit or cut down the duties on NHS England imposed upon it under the NHSA 2006.

F. The competing policy arguments: The limits of purposive construction

57. Both parties have resorted to competing public policy arguments in order to advance their respective purposive constructions of the legislation. Before turning to the analysis of the statutory provisions in the light of the arguments of the parties it is necessary to say something about the limits of the interpretative exercise. It is important to remember when engaging in any exercise of purposive construction or interpretation that the Court is *not* engaging in an exercise at large of identifying the various possible policy issues with a view to weighing them and then selecting what the Court considers to be the most felicitous. On the contrary the exercise lies in the narrower exercise of identifying the intention of the legislature and then giving effect to it. In *R (Andrews) v Secretary of State for Environment Food and Rural affairs* [2015] EWCA Civ 669 ("Andrews") per Lord Dyson MR at paragraph 33 addressed the principle in the following way, in the context of an Act of 1801:

> "33. Even in relation to modern statutes, which are drafted by skilled specialist draftsmen and are assumed to be drafted with precision and consistency, the courts adopt a purposive (in preference to a literal) interpretation so as to give effect to what is taken to have been intended by Parliament. We use the phrase "purposive interpretation" as shorthand for an interpretation which reflects the intention of Parliament. The court presumes that Parliament does not intend to legislate so as to produce a result which (i) is inconsistent with the statutory purpose or (ii) makes no sense or is anomalous or illogical. A purposive interpretation is all the more appropriate in a statute

> which is couched in language which is less consistent and more imprecise than that generally found in modern statutes".

58. In *R v Harvey* [2014] UKSC 73 the Supreme Court stated in relation to legislation concerning the proceeds of crime:

> "In para 8 of Waya, POCA was described as "framed ... in broad terms with a certain amount of ... 'overkill'". Lord Walker and Lord Hughes went on to say that "[a]lthough the statute has often been described as 'draconian' that cannot be a warrant for abandoning the traditional rule that a penal statute should be construed with some strictness", adding that, "subject to this and to [the Human Rights Act 1998], the task of the Crown Court judge is to give effect to Parliament's intention as expressed in the language of the statute. The statutory language must be given a fair and purposive construction in order to give effect to its legislative policy"".

59. In *UBS AG et ors v Commissioners for Her Majesty's Revenue and Customs* [2016] UKSC 13 the Supreme Court was concerned with the interpretation of a fiscal statute. Lord Reed (with whom Lord Neuberger, Lord Carnwath and Lodge Hodge agreed) reiterated that whatever the context (*in casu* tax) the ultimate question was always one of statutory construction:

> "63. "Unfortunately", the Committee commented in *Barclays Mercantile* at para 34, "the novelty for tax lawyers of this exposure to ordinary principles of statutory construction produced a tendency to regard *Ramsay* as establishing a new jurisprudence governed by special rules of its own". In the *Barclays Mercantile* case the Committee sought to achieve "some clarity about basic principles" (para 27). It summarised the position at para 32:
>
> > "The essence of the new approach was to give the statutory provision a purposive construction in order to determine the nature of the transaction to which it was intended to apply and then to decide whether the actual transaction (which might involve considering the overall effect of a number of elements intended to operate together) answered to the statutory description. ... As Lord Nicholls of Birkenhead said in *MacNiven v Westmoreland Investments Ltd* [2003] 1 AC 311, 320, para 8: 'The paramount question always is one of interpretation of the particular statutory provision and its application to the facts of the case'".

As the Committee commented, this is a simple question, however difficult it may be to answer on the facts of a particular case.

60. In the present case the starting point for the identification of purpose must lie *within* the statutory terminology. If it is clear from such an analysis what the legislative

intent is then the fact that there might have been other policy considerations at play which could have led to a different outcome is beside the point. If the construction is however ambiguous then as Lord Dyson MR observed in *Andrews* (ibid) the Court will assume that the legislature did not intend to "*legislate so as to produce a result which (i) is inconsistent with the statutory purpose or (ii) makes no sense or is anomalous or illogical*".

61. In my judgment when the NHSA 2006 is considered both as a whole but also by reference to its specific provisions it has the following broad characteristics and purposes; First, it imposes broad duties and powers on NHS England to secure the provision of health services to the entirety of the population and nation wide; second, the duty includes all aspects of preventative medicine; third it exercises its powers and duties concurrently with other providers of services which includes the Secretary of State, CCGs and local authorities; fourth these services are to be provided comprehensively and in an integrated manner; fifth, the service is to be provided efficiently and so as to avoid inequalities of provision or outcome.

62. I should refer briefly to an argument that lurked only marginally below the surface of the oral and written submissions of all parties. All parties fully appreciate that the case has wide budgetary ramifications. NAT is concerned that if local authorities have the sole duty and power to provide for preventative HIV treatment they will not be able to afford to commission PrEP and, moreover, given the breadth of their powers (see paragraph [56(b)] above) they might lawfully be able not to provide PrEP. The LGA makes the same point. I have set out at paragraph [16] above the submission of the LGA in this regard. NHS England is also concerned at the budgeting implications of the issue and recognises that all such issues involve the making of "hard" decisions. It argued that since the local authorities had (on its argument) the duty to make preventative treatment (such as PrEP) available it was the duty of the Secretary of State to ensure adequate funding. Budgetary constraints are or may be transient and relative. They do not in my view provide guidance as to the proper construction of the legislation. The task of the Court is to interpret the enactments according to the intent of Parliament. If this gives rise to unexpected financial ramifications then this is for the Government to resolve and this might include Parliament amending the legislation. But *prima facie* this is not a factor which can guide the proper interpretation of the Act and it is not something I have taken into account. In relation to this particular topic I emphasise one point which should, in any event be obvious. The determination of the scope in law of the duty and powers of NHS England is not an indication of how those powers will be exercised to secure fulfilment of the duty. The NHSA 2006 confers upon NHS England what might fairly be described as a broad discretion as to how it exercises its powers to achieve its target duties and in this connection the manner in which it exercises its judgment to achieve the most effective use of scarce financial resources is legitimately a matter calling for the exercise of judgment. The availability of resources is thus relevant at this stage; but not at the *a priori* stage of interpretation of the scope in law of that power and duty, which is what this case is about.

G. Analysis and conclusion on the scope of the powers and duties of NHS England

63. In my judgment NHS England does have power to commission PrEP. This is for the following reasons.

(i) The need for purposive construction

64. The starting point is a recognition that Section 1H(2) and in particular what the exception therein applies to is ambiguous and open to a series of potential different meanings. The upshot of this is that it requires to be read purposively in order to identify Parliament's intent. And as to this the principal source of inspiration is the legislation itself, rather than from broader and extraneous policy reasons. I should add that no one has sought in this connection to rely upon pre-legislative material (see as to the admissibility of such material S*olar Century et ors v Secretary of State of Energy and Climate Change* [2014] EWHC 3677 (Admin) at paragraphs [40] – [52]; approved on appeal [2015] EWCA Civ 117).

(ii) NHS England's arguments about the scope of Section 1H(2)

65. Mr Swift QC, for NHS England, advanced two different principal submissions about the scope and effect of Section 1H(2). First, he argued that when that provision was read, purposively, as a whole it made clear that the power of NHS England did not include commissioning in respect of treatments provided to the population or subsets of the population as a whole. Second, and more specifically, he argued that under the 2012 Regulations the express powers and duties of NHS England did not extend, in the field of sexually transmitted diseases, to preventative medicine. I deal with each argument separately.

66. First, it was argued that the scope of the duty under section 1H(2) and under section 1(1) was circumscribed by the exception in section 1H(2) which used the phrase "*public health functions*" to curtail the duty on NHS England (see paragraphs [36] – [40] above). Mr Swift QC argued that the phrase should be construed purposively to refer to all aspects of health provisions which were directed in a broad sense to the public, as opposed to services directed at individuals. In the course of oral argument Mr Swift's submissions evolved and he articulated the scope of the exception in the following way: NHS England does not have to commission for the purpose of protecting the public from disease or other dangers to health or for improving health where the treatment focused upon the public as a whole or subsets or groups of the population as a whole (as opposed to identified individuals). The paradigm example of treatments falling therefore within the exception and outside of NHS England's powers were preventative treatments since they were provided to the population as a whole or subsets thereof. This, he argued, was what flowed from the limiting words "*public health functions*" in the exception in Section 1H(2) and this therefore defined the scope of the carve-out from the duties otherwise imposed on NHS England.

67. In oral argument and in response to a question from the Court it was made clear NHS England was <u>not</u> arguing that its duty was <u>only</u> curtailed if and when the Secretary of State exercised a power to allocate a particular function to (say) a local authority (as it had under the 2013 Regulations). On the contrary the curtailment of the duty on NHS England flowed directly out of the language of section 1(H(2) <u>standing alone</u>. It necessarily follows from this argument that *if* NHS England is correct then it has no duty to provide public health services, in substance, *at all*. Although Mr Swift, was chary of accepting that this was a proxy for preventative medicine the excision of "public health functions" from the duty of NHS England would, it seems clear, cover preventative services since such treatments are by their nature provided to the population generally or to sub-sets thereof.

68. Indeed, when it was contended, this test was applied to PrEP it was apparent that it was a treatment offered to sub-sets of the population who did not have a diagnosis of HIV (i.e. they were not actually infected) and as such PrEP did not fall within the powers of NHS England to commission. PrEP was preventative medicine which was part of the "*public health functions*" of the local authorities and the Secretary of State, but not NHS England.

69. Mr Swift QC however was forced to accept that this analysis was not the logical end result of simply applying the instructions in Section 1H(5) which – as set out in paragraphs [37] – [39] above – would lead to the exception wholly eliminating the duty. NHS England did not suggest that this could be a sensible end-result for any process of construction to lead to. Indeed to construe section 1H(2) in this way would be absurd. It was for this reason that NHS England's final position was framed not by reference to the actual words of section 1H(2) but by reference to a broad, purposive, meaning of the phrase "*public health functions"*.

(iii) Critique of NHS England's analysis of section 1H(2)

70. I do not accept this analysis.

71. There is no logical way of construing Section 1H(2) which leads to Mr Swift's outcome. The NHS England approach entails ignoring the express language of section 1H(5) which makes clear that the expression "*public health functions"* is to be given the statutory meaning set out in the other provisions of the legislation identified in that sub-section. It is only if one ignores this instruction and proceed to give to the phrase its own meaning which is unrelated to the statutory definition that the NHS England interpretation can make any sense. Moreover, the consequences of the NHS England arguments are to strip from it all powers to commission preventative treatment, which is itself a conclusion inconsistent with the NHSA 2006 read as a whole and inconsistent with the Mandate given to NHS England by the Secretary of State. It is, for reasons too obvious to spell out, a very far reaching conclusion indeed if it is correct. In short, if one applies the exception in Section 1H(2) as limiting the duty in Section 1(1) then one is driven by the instructions in Section 1H(2) and (5) to describe an exception of such breadth that it has the effect of wiping out the duty. This is a consequence which is absurd and illogical and applying normal principles of purposive construction (see paragraphs [57] – [60] above), not one that Parliament can have intended.

72. But even if, to overcome this problem, one instead ignores the statutory test and gives the phrase "*public health function"* a free standing meaning then I still do not accept that it leads to the conclusion that NHS England has no power to commission preventative treatments. The expression "*public health function*" is not synonymous with or a proxy for preventative medicine. It is far wider and includes all treatment provided to individual members of the *public* whether with established infections, or otherwise on a preventative basis. So, even on this alternative basis I cannot see that it was Parliament's intent to construe "*public health functions*" as a factor limiting the duty and neatly excluding preventative medicines, but including curative treatments. In short if I were to construe "*public health functions*" according to the NHS England contention the court would arrive at a result which was inconsistent with the legislation as a whole, inconsistent with NHS England's own understanding of its role (see paragraphs [14] – [15]), and inconsistent with the express view of the Secretary

of State in the Mandate which is a statutory document which has to be laid before Parliament and which imposes a duty on NHS England in that it must "… *seek to achieve the objectives stated in the mandate*" (cf Section 13A(1) – (7) NHSA 2006) (see paragraph [11] above).

73. Further, if NHS England was correct and section 1H(2) had the limited meaning attributed to it then when the Secretary of State came to exercise his power to adopt the 2012 Regulations he could not, lawfully, have defined treatment as including preventative medicine: See paragraph [47] above. The 2012 Regulations are subordinate legislation and cannot confer upon NHS England powers that it cannot otherwise possess under the provisions of the enabling Act. If under the NHSA 2006 NHS England cannot commission preventative treatments it cannot acquire that power under secondary legislation. The short point is that the assumption underlying the 2012 Regulations is that NHS England does have the power to commission for preventative medicine.

74. There are other reasons as well which are against NHS England's construction. The formulation advanced by NHS England is an unattractive way from a drafting perspective in which to construe the Act.

75. First, it is simply not a test spelled out in the Act. Parliament could, and in my view would, have addressed such a fundamental and highly controversial issue head on if it had intended to draw this distinction and limit to NHS England's commissioning powers. I do not find it credible that for such an important issue as responsibility for preventative medicine Parliament would have created a carve-out which came about through a very far from obvious drafting side-wind. Had Parliament intended to limit NHS England's powers in this way I would have expected to have seen a proper explanation and justification for this in admissible pre-legislative material. No one has suggested however that there is anything in the admissible material which supports NHS England's argument.

76. Second, as a test the NHS England formulation is highly imprecise. Where does one draw the line between services to an individual and services to the population at large? The debate and argument that occurred in this case as to the difference between PrEP and PEP is a case in point. Mr Swift QC for NHS England argued that the jurisdiction of a public body such as NHS England was a matter of law. A court could and must determine whether, in a given case, it had exceeded its powers and acted *ultra vires*. But to do this draws the Courts into analysing extremely fine technical and scientific distinctions between different sorts of treatments since, as this case vividly shows, the dividing line between prevention and cure is by no means a clear bright line.

77. Third, the duty on NHS England in the 2012 Regulations has not been revoked by or otherwise addressed in the 2013 Regulations. I accept the submission of Ms Greaney for the LGA that the 2012 Regulations are free standing and impose a duty on NHS England in relation to HIV which includes preventative medicine (see the analysis at paragraphs [45] – [49] above). That conclusion, based on the interpretation of the specific regulations, is moreover, consistent with the analysis of the primary and secondary duties imposed on NHS England in the NHSA 2006 itself which expressly embrace the provision of preventative medicine.

(iv) Section 1H(2) is about exceptions to the identity of the concurrent partner

78. In my judgment there is a different and perfectly logical way of interpreting section 1H(2). As set out at paragraph [36] above the two main alternatives are that the exception governs the scope of the duty; or alternatively, that it governs concurrency. In my judgment the exception applies to concurrency. This does not do linguistic damage to Section 1H(2) and makes good sense. 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.

79. The insertion of these words would make clear that where a part of the public health function is provided by the Secretary of State or (alternatively additionally because when the Secretary of State allocates functions to local authorities, this is not on an exclusive basis and the Secretary of State retains jurisdiction – see paragraphs [53] and [64] above) the local authorities, then NHS England's partner includes that particular entity.

(v) Reinforcing factors from elsewhere within the Act

80. This conclusion is reinforced by purposive considerations drawn from elsewhere within the Act:

    a) As set out above the Secretary of State can, through regulation, impose a duty to provide health services on local authorities. This power on the part of the Secretary of State to choose who the provider is helps explain both the principle of concurrency and the fact that as an exception to concurrency with the Secretary of State there may be concurrency also with the local authorities.

    b) An important principle evinced in the Act is that of integrated service (see paragraph [35(h)] above). This supports the conclusion expressly referred to in Section 1H, that the exercise of powers and duties is concurrent, since concurrency would be an important component of any integrated health provision service. In this connection, and standing back from the fray, it is easy to see why Parliament would have favoured the concurrent, integrated approach. If (for the sake of argument) the local authorities were budgetarily constrained and there was limited financial capacity for the local authorities to provide a comprehensive service (see paragraph [56(b)] above) then concurrency and integration means that a more joined-up service provided as between NHS England and the local authorities might be possible and

this might, in turn, improve the overall scope of provision. In my view it is part of the purpose of this legislation to create a structure whereby the various providers can act conjunctively (concurrently) to secure optimal provision. On the argument advanced by NHS England, however, if responsibility falls exclusively to the local authorities and NHS England is thereby absolved from all responsibility then the provision of an integrated service is prejudiced.

c) Further the Act seeks to avoid unequal provision of services (see paragraph [35(c)] above). If the provision of preventative HIV services is allocated solely to the local authorities then there is a real risk that the provision will be geographically unequal (especially where it is legitimate for each authority to exercise discretion as to the nature and extent of provision – see paragraph [56(b)] above). The concurrent, integrated, provision of services which includes NHS England playing a role serves Parliament's aim of reducing inequality.

d) Under section 13C NHSA 2006 NHS England has a duty to act "*with a view to securing that health services are provided in a way which promotes the NHS Constitution*" which includes, at principle 1, that the service is "*designed to improve, prevent, diagnose and treat both physical and mental health conditions*" and involves a "*duty to promote equality through the services it provides*". The Mandate (see paragraph [11] above) is to the same effect.

(vi) The 2012 Regulations.

81. I turn now to NHS England's second way of arguing the point based upon its narrow construction of paragraph [17] of Schedule 4 to the 2012 Regulations. I have set out at paragraphs [42] – [51] above my analysis of the construction of the 2012 Regulations and my conclusions. These conclusions explain why the second way in which NHS England advances its arguments is rejected. In short the 2012 Regulations confer upon NHS England jurisdiction to commission preventative treatments in the field of HIV.

(vii) Conclusion

82. It follows from the above that NHS England misdirected itself in law when it concluded that it had no power to commission PrEP. This suffices for the decision to be set aside.

H. **Section 2 NHSA 2006 – the general powers provision**

(i) The issues

83. I turn now to the alternative arguments of NAT and the LGA, namely that even if NHS England is correct in its narrow construction of Section 1H(2) and/or the 2012 Regulations the commissioning of PrEP is still within its jurisdiction. This is because: (i) PrEP is not, when properly analysed, a preventative treatment but is a treatment, along with PEP, for those who may be assumed to be infected with HIV; or (ii) even

if PrEP is properly to be analysed as a preventative treatment NHS England may still commission it by the exercise of its general powers under Section 2 NHSA 2006.

84. Section 2 NHSA 2006 empowers NHS England to do "*anything*" which is calculated to facilitate or is conducive to or incidental to the discharge of any of its functions. The issue of general powers only arises if I am incorrect in my conclusion that the NHS England has power to commission preventative medicine. If I am correct then the issue is academic because there is no need to resort to an extension of its express powers for NHS England to justify the commissioning of PrEP. In consequence the analysis below proceeds upon the alternative basis that NHS England is correct in its principal argument that prima facie it has no jurisdiction to commission PrEP because it is a preventative treatment.

85. On this hypothesis NAT argues that since NHS England commissions PEP (and indeed is quite firm in its view that it has the power to commission PEP) then there is no logical distinction to be drawn between PEP and PrEP and if the former can be commissioned then so can the latter and that, accordingly, even on NHS England's own legal argument it is in error in its decision about PrEP.

86. For its part NHS England argues two alternative points. First, PEP is treatment for an assumed infection but PrEP would be provided on the assumption that the person concerned was infected with HIV and this is a critical distinction under the NHSA 2006. Secondly, even if PEP is not a treatment for actual infection then it falls within Section 2 and NHS England may commission it but PrEP does not and falls outside the scope of Section 2. There is a potential sting in the tail to NHS England's finely tuned arguments. If I were to conclude that PEP was *not* materially distinguishable from PrEP but that both were preventative then, on NHS's own argument, it would, *prima facie*, have no power to commission PEP, never mind PrEP.

87. In order to unravel this issue in the text below I (a) consider the scope of Section 2 NHSA 2006; (b) consider the differences and similarities between PrEP and PEP; and then (c) set out my conclusions on the two arguments set out in paragraph [83] above.

(ii) The scope of Section 2 NHSA 2006: The general powers provision

88. Whatever the proper scope of NHS's *prima facie* power it can be extended pursuant to Section 2. The power applies to all of the relevant actors involved, i.e. the Secretary of State, NHS England and CCG's. As applied to NHS England it can bring within the scope of its powers certain activities which, otherwise, would be beyond its jurisdiction. Section 2 provides:

> "General power
>
> 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".

89. Mr Swift QC argued that properly construed this was a narrow extension premised upon necessity. He cited in support the judgment of the House of Lords in *Hazell v Hammersmith and Fulham London Borough Council* [1992] 2 AC 1 in which the

House had to consider where there was an incidental power to enter various types of financial transaction (so called "swaps") when there was no express power in the relevant legislation. The issue thus turned upon the extent to which legislation otherwise silent as to incidental powers nonetheless conferred an incidental power. As to this Lord Templeman said (ibid page 31E) that the case law showed that a power could arise but only when it was incidental to or consequential upon the use of a statutory power (citing *Attorney General v Mersey Railway* [1907] AC 415) but that *"… a power is not incidental merely because it is convenient or desirable or profitable*". As such, it was contended, NHS England could not invoke Section 2 to broaden its jurisdiction simply because it might be convenient, desirable or profitable to commission PrEP. Mr Swift also cited *Ward v Metropolitan Police Commissioner* [2006] AC 1 AC 23 at paragraph [23] where Baroness Hale stated that as a general principle there can be implied into a statutory power "…*such incidental powers as are necessary for its operation*".

90. Ms Monaghan QC for the Claimant pointed out however that these authorities addressed the situation arising in the *absence* of a statutory incidental or general powers provision but that, where – as here – one existed, the issue was one of simple statutory construction and there was no proper basis for curtailing the scope of the statutory provision by reference to cases which were not on point. Indeed, she countered, if Mr Swift's analysis was in fact the basis upon which the decision was taken to exclude PrEP then NHS England had obviously proceeded upon a false basis in law since, once again, NHS England had misdirected itself as to its powers.

91. In my judgment Ms Monaghan QC is correct. The scope of the incidental or collateral powers attributable to NHS England are to be determined by reference to the language of Section 2 and not to some narrower test which arises when Parliament has not spoken and has not conferred an express general power. The difference between the two situations is important. In the latter case (no express power) the court is concerned to construe an enactment which (because of its silence on collateral powers) may be assumed to be intended to be strictly construed and that explains why the Courts have long taken the positon that all that is implied is that which is necessary to enable Parliament's intent to be fulfilled. The Courts cannot introduce wider powers just because it might, on one policy view, be thought to be desirable or convenient. That would amount to impermissible judicial activism. However when there *is* an express general powers provision then Parliament has explicitly intended there to be some leeway conferred upon the decision maker, possibly because it is recognised that there are fuzzy or unclear marginal cases over which the decision maker needs flexibility.

92. In the present case there are various indications from within Section 2 that the incidental power is quite generous. In particular it may be exercised when it is "*calculated to facilitate"* the discharge of any function conferred upon NHS England and/or when it is "*conducive*" to the discharge of that function and/or when it is "*incidental*" to such discharge. By using three expressions to enlarge the scope of the power all of which require NHS England to use its judgement Parliament is deliberately seeking to avoid the argument that the provision of a particular treatment that might otherwise be on the margins of NHS England's powers is outside of its jurisdiction.

(iii) PEP v PrEP: Analysis

93. I turn now to consider the position of PrEP and PEP in light of the above analysis.

94. As part of the evidence of Mr Stewart on behalf of NHS England, a compare and contrast chart described as a "PEP and PrEP brief" was prepared, and it was relied upon by all parties to the litigation. It is thus safe to treat this as an accurate description of differences and similarities.

95. The parties have sharply different views on this document. NHS England sought to rely upon it to suggest that PEP and PrEP were fundamentally different; and NAT sought to rely upon it to show that insofar as there were differences they were differences without relevant distinctions. I set out below the chart in full:

PEP and PrEP brief

The Human Immunodeficiency Virus (HIV) can only be passed on through infected blood, semen, vaginal fluids or breast milk. HIV is mainly transmitted through vaginal or anal intercourse without a condom or by sharing a needle or syringe with someone who is living with HIV and not on treatment. Occupational exposure mainly due to needle-stick injury could also be a form of transmission.

	PEP/PEPSE	**PrEP**
Description of intervention	Post-exposure prophylaxis using anti-retroviral (ARV) drugs for the prevention of HIV includes PEP - post-exposure prophylaxis, when the exposure is the result of occupational risk (i.e. needle-stick injury) and PEPSE - post-exposure prophylaxis following sexual exposure when the exposure is as a result of high risk sexual activity.	Pre-exposure prophylaxis for the prevention of HIV, or PrEP, is an HIV prevention method involving the use of daily ARV treatment before exposure to HIV in people who do not have HIV infection and who are at high risk of HIV infection through sexual exposure to reduce their risk of becoming infected.
Rationale	PEP/PEPSE uses the opportunity to abort HIV infection by inhibiting viral replication through early administration of ARVs to reach circulating inhibitory levels immediately after exposure to the virus (and no later than 72 hours of exposure).	PrEP is based on achieving inhibitory levels of circulating ARVs prior to HIV entering the body to inhibit HIV replication as the virus enters the body, keeping HIV from establishing a permanent infection.
Type of intervention	Early intervention after rigorous risk assessment of exposure. The clinical risk assessment determines the risk of HIV	ARVs in PrEP are given before and after an individual's possible exposure to HIV. ARVs can be taken every day, this requires strict adherence as evidence

	entering the body by the type of exposure and the risk of the source being infectious. PEP aims at aborting HIV infection by inhibiting viral replication immediately after exposure. ARVs are prescribed daily for 28 days initiated as early as possible after exposure and no later than 72 hours.	shows that the level of protection is strongly related to level of adherence to daily medication. Although recent studies among MSM show that 'event-driven PrEP' taking ARVs just before and after sex (2 tablets between 2 and 24 hours before sex and then 1 tablet a day for 2 days after sex) is also effective – currently not recommended for not-MSM.
Patients groups	All individuals deemed to have been exposed to HIV after rigorous clinical risk assessment and within 72 hours of exposure.	Adults at *very high* risk of sexual exposure to HIV. Serodiscordant couples where the HIV infected partner is not on treatment or has detectable viral loads; MSM and transgender women at very high risk of exposure through sexual intercourse (see patient pathway).
Estimated prevalence	NHS E does not routinely collect data on the use of ARVs specifically used for PEP/PEPSE. In 2015/2016, 9,141 starter packs were dispensed in London and only 5,247 (64%) continuation packs. Based on GUMCADv3 data, about 5,000 MSM each year have PEPSE.	Based on GUMCADv3 data, about 17,000 MSM each year have a bacterial STI, about 5,000 have a rectal STI, and about 5,000 have PEPSE (groups are not mutually exclusive). These are all considered very high risk groups for HIV infection. PHE estimates based on the San Francisco cohort estimate 3,000 to 8,500 MSM would access PrEP each year.
Drugs used	tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) (Truvada OD) and Raltegravir BID for 28 days	tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) (Truvada OD)
Patient pathway	The PEP pathway often involves occupational health or A&E evaluation; individuals deemed to have significant risk of exposure after risk assessment should be referred to a GUM clinic. PEPSE is access by self-referral to GUM, sexual health services or SARCs; or via A&E departments if out of hours. All persons requiring PEP/PEPSE are risk assessed	Deciding if someone needs PrEP is based on an assessment by a suitably qualified healthcare professional in a level 3 GU service. PrEP should be used in adults at very high risk of HIV infection: 1. MSM and transgender women who are currently HIV negative and who are clinically assessed to be at high risk of HIV: a) Have a documented confirmed HIV negative test during an earlier episode of care in the preceding year (i.e. 42-365 days

	by an experienced sexual health adviser or sexual health consultant to assess the likely exposure and risk of infection. A baseline HIV test is performed before any PEP/PEPSE discussion. Post-exposure prophylaxis should be initiated as early as possible, preferable within 24 hours and no later than 72 hours of exposure so services are required to provide 24-hour access including out of hours expert advice. Pregnancy should not alter the decision to start PEP/PEPSE, women must be offered a pregnancy test and counselled that ARV agents used for PEP/PEPSE are unlicensed in pregnancy and the possible risks/benefits must be discussed.	ago); and b) Condomless intercourse in the previous 3 months documented in the clinical notes; and c) Affirm their likelihood of repeated condomless intercourse in the next 3 months documented in the clinical notes. OR 2. The HIV negative partner (confirmed by a current documented negative HIV test) of a diagnosed person with HIV who is not known to be virally suppressed and with whom condomless intercourse is anticipated. OR 3. HIV negative heterosexual men and women clinically assessed and considered to be at high risk of HIV acquisition PrEP should be used as part of a comprehensive set of prevention services. Prescriptions will be for no more than 3 months and people using PrEP will be asked to attend for regular sexual health check-ups (every 3 months) and monitoring of renal function (urine and occasional blood tests).
Follow up	No further follow-up is required after completion of full 28 days treatment. Individuals seeking PEPSE should be encouraged to attend for future regular sexual health check-ups; it is indicated to perform an STI screen at baseline, as well as at 2 weeks post-exposure.(BASHH 2015) An HIV test at baseline as well as a follow-up HIV test 8-12 weeks after exposure, ideally using a 4th generation laboratory venous blood HIV test is indicated.(BASHH 2015) No further follow-up is	Follow up required every 2-3 months to: Evaluate and support PrEP medication adherence, more often follow up is recommended if inconsistent adherence is identified. Perform HIV antibody testing (or fourth generation antibody/antigen test) and documenting negative results. Assessing risk behaviours and providing risk reduction counselling and condoms. Pregnancy testing, pregnancy is not a contraindication for PrEP but the ARVs used are not licensed in pregnancy. Monitoring serum creatinine levels

	required.	and creatinine clearance every six months.
Key messages	PEPSE is not to be used instead of safe sex strategies. Practicing safe sex including condoms remains the only method for reducing the risk of all STIs.	PrEP is not intended to be used in isolation, but rather in combination with other HIV prevention methods. Practicing safe sex including condoms remains the only method for reducing the risk of all STIs.

96. The key points arising from this chart are as follows:

97. **Prophylaxis:** Both treatments are described as prophylaxis, i.e. in neither case is there proven infection on the part of the person receiving the treatment. ARVs in both pre and post exposure prophylaxis operate by inhibiting replication of the HIV virus and thus preventing dissemination of the initial infection (*if* it occurs) from becoming an established infection (see paragraphs [21] and [23] above). As such neither PrEP nor PEP prevent the infection but both treat "infection" if and when it occurs. In order to be physiologically effective, transmission needs to have taken place (i.e. infection) but ARVs are most effective the earlier they are active after transmission.

98. **Risk**: In the case of both PEP and PrEP the individual concerned engages in high risk sexual activity and is, accordingly, at high risk of infection. They are both "*event driven treatments*". In relation to PEP the individual *has* engaged in "*high risk sexual activity*" (see Description of Intervention box) and "*significant risk of exposure*" (See Patient Pathway box). In relation to PrEP the treatment is for those who are at "*very high risk of becoming infected through sexual exposure*" (see Type of Intervention box) and for "*adults at very high risk of infection*" (see Description of Intervention box). In argument Mr Swift QC contended that PEP was a form of "emergency" treatment but on the basis of risk assessment the same would apply to PrEP since there is no clear distinction in risk profile between PEP and PrEP and both are predicted to engage actual high risk sexual activity. In the case of PEP patients they have engaged in such activity in the past and are likely to in the future; in the case of PrEP patients they are very high risk because they engage in such activity and are likely to do so again in the future.

99. **Overlap between PEP and PrEP groups**: Logic dictates that those receiving PEP and PrEP are in the same or at least a very similar sub-set of the population. The Estimated Prevalence box above (for PrEP) makes the point that the PEP and PrEP *"groups are not mutually exclusive"*. These are all considered very high risk groups for HIV infection because of their past/present/future sexual activities.

100. **Timing**: PrEP is given before and after the high risk event whereas PEP is a post-exposure prophylaxis following the high risk event. There is thus a difference in timing of administration. Again logic dictates that a person receiving PEP could very easily have been a person receiving PrEP. The difference in timing does not describe any feature of the at-risk group which materially distinguishes one from the other but is a reflection of the point in time at which the at-risk person comes into contact with

the health care system. This is, in my view, a distinction lacking any material significance.

101. **Type of intervention**: PEP is taken for 28 days minimum (see boxes for "Type of Intervention" and "Follow Up") whereas PrEP is intended to be taken indefinitely because that person is in a group of persons who are at risk of engaging in risky activities. However the same can logically be said for many who could be treated with PEP, many of whom will fall into the same category of person who could benefit from PrEP.

102. **Drugs used**: The drugs used are essentially the same and this is reflected in the comparison chart. The evidence of Professor McCormack to the effect that the micro-biological effects are more or less identical is not materially challenged in this respect (see paragraphs [22] – [23] above). Mr Swift QC, for NHS England, drew my attention to the fact that some PEP drugs apparently include an additional active ingredient but (a) he accepted that on NHS England's analysis the key issue for the purposes of the Act was *not* chemistry and (b) there is no evidence before the Court to suggest that there is any significant therapeutic difference between the PEP and PrEP drugs.

103. **Stand-alone treatment**: Neither are stand-alone treatments but are to be used in conjunction with other safe sex strategies (see Key Messages box).

(iv) Conclusions

104. In view of the above my conclusions on the arguments arising are as follows.

105. *NHS England's primary argument – those treated with PEP are infected but those treated PrEP are not*: As a matter of pure science this is not a sustainable proposition. Both PEP and PrEP are administered to persons who have not been diagnosed with HIV and as such in neither case can it sensibly be said that they are necessarily "infected" in a manner which can be scientifically proven. In the case of PrEP and PEP the patients are at high risk of infection but this is different to a state of actual infection. To overcome this difficulty Mr Swift QC had a more nuanced secondary argument, which, on reflection, in my view, has much to commend it. He argued that the test of infection was not to be determined from a narrow scientific perspective because it was Parliament's intent that the determination of whether a person was "infected" was a clinical decision which could involve a high degree of specialised judgment and assessment and was in order to decide whether to provide a particular treatment. In the case of those receiving PEP they were "assumed" to be infected because they were at such high risk and the probability that they would become infected but for the PEP treatment was substantial. When a clinician diagnosed a person as "infected" this was done to justify the provision of a treatment to "cure" the infection. Of course that diagnosis could turn out to be wrong and the patient may in actual fact not be "infected" as initially concluded. But that would not mean that the treatment was wrongly administered or that the clinician had not used all requisite skill and care or that when the patient presented he was not correctly diagnosed as "infected". On these bases it was therefore a proper clinical assumption to make that the patients treated with PEP were infected. I can see the force in this argument. In my view Parliament was not demanding scientific purity in drawing distinctions between prevention and cure (infected/not-infected). It was recognising

instead that the science is frequently equivocal and that the conclusion that a person is "infected" is routinely one of skilled clinical value judgement and that in some very high risk situations an assumption might properly be made in order to justify a particular treatment.

106. Mr Swift QC contended that in relation to PEP clinicians therefore properly assumed patients were infected and this distinguished PEP from PrEP which was different and that was a valid distinction to draw. He accepted that the issue for the court was not one of margin of appreciation but was an issue of law for the Court to decide, because it went to the statutory power and jurisdiction of NHS England and whether a challenged act was *ultra vires*. But he said that in determining the issue the Court could take into account the expert conclusion of clinicians as to whether an infection existed. He thus argued that (in the present case) because clinicians assumed that those who presented after a high risk event could be *assumed* to have contracted the infection then this was sufficient, in law, to engage the jurisdiction of NHS England to provide the requisite curative (PEP) treatment. But he argued that because a patient who presented as part of a group who generally engaged in high risk events there could be no equivalent assumption that they were infected and (it followed) PrEP was for prevention not cure.

107. Pulling these strands together so far as PEP is concerned I accept: (i) that the test of infection (as part of the test for distinguishing prevention from cure) is a test based upon pragmatic clinical judgment and not one of absolute scientific purity; (b) that in the case of those presenting following a high risk event exposing them to HIV clinicians are entitled to assume that they are infected (irrespective of the absolute scientific facts); and (c) that the provision of PEP therefore falls within the jurisdiction of the NHS England to provide. This brings me to the next stage in the analysis which is to consider the position of PrEP.

108. *NHS England's argument – PEP and PrEP are distinguishable in terms of risk and timing*: I turn now to the critical question – if PEP is cure then, by parity of logic, should PrEP be treated as cure? And if it does not, does it fall within NHS England's powers under Section 2? The answer to this lies in a comparative analysis of PEP as against PrEP. On the basis of the analysis above I can see no *material* difference between PEP and PrEP that would justify a different treatment of PrEP relative to PEP. Both: (i) involve prophylaxis; (ii) both involve the person engaging (in the future and/or the past) in very similar if not identical events carrying a very high risk of infection: (iii) the patient groups overlap; (d) the micro-biology in both cases is more or less identical; (e) both involve the provision of individualised treatment and an assessment of personal risk; (f) and in both the treating of a person with the relevant drugs is intrinsically likely to prevent future infection (see for the evidence of this in relation to PrEP paragraph [22] above). In my view PrEP is, by parity of reasoning to PEP, a treatment provided to those who should be assumed to be infected.

109. But even if this is wrong then NHS England still has the power to provide PrEP by virtue of Section 2 NHSA 2006. PrEP is so closely related in all respects to PEP that if there is good sense in providing PEP then that same reasoning applies to PrEP and the distinctions which do exist between PrEP and PEP are distinctions without relevant differences. NHS England has not put forward any argument which supports a case that providing PrEP is not conducive to the performance of its function or

convenient in that respect or not incidental to the discharge of its general functions. Indeed, until NHS England took external legal advice about its powers it was well on the way to coming to this very conclusion (see paragraphs [26] – [28] above). The only evidence before the Court suggests that providing PrEP would meet all of these tests. The costs benefit analysis is clearly in favour (see paragraphs [18] above). PrEP is an efficient and integrated means of treating HIV in affected communities. It is consistent with the Mandate (see paragraph [11] above). It is consistent with NHS England's own published statements of policy (see paragraph [14] above). It facilitates an integrated, efficient and consistent provision of HIV treatment.

Overall conclusions

110. I therefore conclude as follows. First, the power of NHS England includes commissioning for preventative purposes and this includes for HIV related drugs. Second, in the alternative even if NHS England does not have a power to commission on a preventative basis the commissioning of PrEP is to be treated in the same way as the commissioning of PEP, i.e. both are provided on the basis that the patient is assumed to be infected. Third, in the further alternative the commissioning of PrEP is within the power of NHS England under Section 2 NHSA 2006, even if properly analysed it is a preventative treatment.

111. For these reasons the application for judicial review succeeds.

112. I will hear submissions as to next steps including whether and if so in what terms appropriate declarations should be made.