

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

BETWEEN:

THE QUEEN on the application of

GOOD LAW PROJECT LIMITED

Claimant

and

SECRETARY OF STATE FOR HEALTH &
SOCIAL CARE

Defendant

WITNESS STATEMENT OF DEBORAH GOLD

I, DEBORAH GOLD, of National AIDS Trust, Aztec House, 397-405 Archway Road, London N6 4EY, will say as follows:

Introduction & Overview

1. I am Chief Executive of the National AIDS Trust.
2. I make this Statement in order to inform the Court of the concerns my organisation and the patients it represents have about the introduction of Serious Shortage Protocols (SSPs).

National AIDS Trust

3. The National AIDS Trust is a charity working on HIV policy. We work to achieve effective HIV prevention; early diagnosis of HIV; equitable access to treatment, care and support for people living with HIV; enhanced understanding of HIV and those living with it; and the eradication of HIV-related stigma and discrimination. We are recognised as leaders in HIV policy and are committed to partnership working in order to achieve this. We work in a collaborative and productive manner with a range of partner organisations. In collaboration with HIV clinicians, we have co-developed or contributed to best practice advice on, for example, the provision of HIV testing, Partner Notification, Post-Exposure Prophylaxis, psychological support for people with HIV, and standards on social care for people with HIV.
4. There are over 85,000¹ people living with HIV and being seen for care in England. These individuals come from a very wide range of backgrounds, geographies and ages. HIV is linked to an increased risk of co-morbidity, and therefore many people living with HIV are likely to have one or more additional long-term conditions.² This makes care additionally complex.
5. Despite its interest in this issue, National AIDS Trust is unable to bring this case because we are not in a position financially to fund the legal advice, nor to risk liability for the defendant's costs.

¹ Public Health England, annual HIV data tables 2017, <https://www.gov.uk/government/statistics/hiv-annual-data-tables>.

² <http://www.aidsmap.com/Co-morbidities-are-common-and-rising-among-people-with-HIV-in-the-US/page/3105593/>

The risks raised by SSPs

6. Please note that under usual circumstances, I would have provided detailed references for the following claims. However, in the available time, I have not been able to provide these. However, I understand that the British HIV Association (BHIVA) has also submitted a witness statement, and that this provides further clinical references and evidence for the points I make here.
7. We consider that the SSP would involve considerable risk for patients living with HIV. The first risk concerns the potential for reducing dosage or strength of medication. In the first instance, this is problematic because HIV medication is highly complex, and can involve careful calibration of dosage. Getting dosage wrong can risk health outcomes for patients.
8. Further, reducing dosage or strength could risk the patient developing drug resistance to the particular form of medication.
9. Replacing the prescribed medicine with a different medicine also leads to very significant health risks for the patient, again for a number of reasons.
10. The first such reason is that the patient may have a history of having tried different medication regimens in the past without success. They may also have developed drug resistance to certain medications. Prescriptions for these medications could risk the patient becoming extremely sick, with the medication proving unsuccessful in controlling the HIV.
11. As mentioned at paragraph 4 above, people living with HIV have a higher rate of co-morbidities than the general population. Consequently, they may have a number of other conditions for which they are also being treated. 72% of people with HIV have at least one other long-term condition and 38% are taking at least one other prescribed medication in addition to their HIV

medication.³ Effectiveness of HIV medication can be reduced by drug interactions, as can the effectiveness of drugs for other conditions. HIV medication effectiveness can also be affected by certain non-prescription medications.

12. For these reasons, the prescribing of HIV medication is a complex, specialist, and highly individualised process. National AIDS Trust believes that the only person safely able to alter an individual's HIV prescription is an HIV Consultant.
13. HIV is a highly stigmatised condition. Evidence shows that one of the key locations in which HIV stigma takes place is within health services.⁴ For that reason, many people living with HIV fear being treated differently in a range of healthcare settings, and many have been refused treatment because of their HIV status, and may therefore need support to share their HIV status with others.⁵ HIV can affect anyone, however certain groups in society are disproportionately affected by it. This includes gay men and people from the black African community.⁶
14. Given these concerns with stigma, many people living with HIV have developed relationships of trust with their HIV clinicians. Many may find it distressing to have to disclose and discuss their HIV status with a pharmacist that they may not know. Further, they may be confused, mistrustful and distressed by having to discuss, with a pharmacist in a chemists, a change of

³ 'Changing Perceptions: Talking about HIV and our needs' p.12 Positive Voices: the national survey of people living with HIV Nov 2018

⁴ <http://www.stigmaindexuk.org/posters/2016/healthcare-poster.pdf>;
https://www.nat.org.uk/sites/default/files/publications/web_PV_Changing%20Perceptions-Stigma-report.pdf

⁵ <http://www.stigmaindexuk.org/reports/2016/NationalReport.pdf>;
https://www.nat.org.uk/sites/default/files/publications/web_PV_Changing%20Perceptions-Stigma-report.pdf

⁶ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/769001/HIV_annual_report_2018_-_Appendix_101218.pdf

medication that they may have been taking for some time, for a serious condition (which if untreated will eventually lead to death). This will disproportionately impact gay men and black African people.

Lack of consultation

15. National AIDS Trust did not hear about the Serious Shortage Protocol until it was drawn to our attention by the solicitors Deighton Pierce Glynn, representing the claimant in this case, on 18 February 2019. This was surprising, because as an organisation that focuses purely on policy and carefully monitors the Department of Health and Social Care, the NHS and other relevant bodies to identify relevant consultations, we would have expected to come across this consultation had it been made public.
16. National AIDS Trust are a member of National Voices and it is understood that National Voices were approached in the informal consultation. However, National AIDS Trust were not approached by National Voices in relation to the informal consultation and we understand, from a subsequent member briefing on this topic, that this was due to the very short time they were provided with to respond.
17. That the informal consultation took place between only 5-12 December 2018, was extremely surprising. This is an exceptionally short period of time for such an important change in procedure and law, encompassing only a few working days, and meaning that even those invited to respond did not have time to seek input into their responses.
18. National AIDS Trust is well known to the DHSC and NHS England, and is formally registered as a stakeholder for Specialised Commissioning within NHS England. The Specialised Commissioning Directorate commissions care

for a number of rare and complex conditions, and as such, these conditions are likely to be most affected by this change. Despite being registered as a stakeholder, National AIDS Trust was not invited to respond to the consultation.

19. National Voices, in their response to the informal consultation, did make points we agree with, however not unexpectedly these points were not specific to HIV.
20. Paragraph 8 of the Response to the informal consultation circulated by the Government states that the protocols would not be suitable for treatments requiring 'biosimilar products where the medicines that are prescribed by brand for clinical reasons', this is vague, without specifically listing HIV as being unsuitable for the SSP, it is unclear whether the SSP would apply to HIV or not. This therefore falls far short of addressing the serious concerns of people living with HIV outlined above.
21. Hence had National AIDS Trust been consulted, we would have raised the serious concerns outlined above and would have hoped that these would have been taken into account by the Department when formulating the laws so that any risk could be minimised or avoided altogether. We would also have asked for a wider consultation in which patients affected would have been able to share their views. We would have requested that HIV was exempt from the Protocol.

Statement for the Claimant
Witness: Deborah Gold
Exhibits:
Date: 21 February 2019

Statement of Truth:

I believe that the facts stated in this Witness Statement are true.

Signed: 

(Full Name) Deborah Gold

Dated: 25 February 2019.