Statement for the Claimant
Witness: Chloe Orkin
Exhibits:
Date: 25/02/19

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 PROFESSOR CHLOE ORKIN

I, Professor Chloe Orkin, of the British HIV Association, The Spirella Building, Bridge Road, Letchworth, Hertfordshire SG6 4ET, will say as follows:

Introduction & Overview

1. I am Chair of the British HIV Association, which I represent in this statement. I am also a Consultant Physician in HIV Medicine at Barts Health NHS Trust and Clinical Professor in HIV Medicine at Queen Mary University of London.

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).

British HIV Association

3. The British HIV Association (BHIVA) is the leading UK association representing professionals in HIV care. Since 1995, we have been committed to providing excellent care for people living with and affected by HIV. BHIVA is a national advisory body on all aspects of HIV care and we provide a national platform for HIV care issues. Our representatives contribute to international, national and local committees dealing with HIV care. In addition, we promote undergraduate, postgraduate and continuing medical education within HIV care. As of early 2019, BHIVA is a nearly 1,000-member strong charitable Association working to ensure that people living with or affected by HIV in the UK have access to the highest possible standard of care to meet their many, and frequently complex, needs. For over twenty years we have worked tirelessly to ensure that this important sector of the healthcare sphere is represented well at every level. BHIVA produces national guidelines on all aspects of HIV, ranging from testing and diagnosis, appropriate monitoring and antiretroviral therapy in a wide range of different clinical situations, to giving guidance on best practice in the management of HIV-related comorbidities, in order to achieve this. BHIVA sets the standards of care for people living with HIV in the UK and delivers a national audit programme to monitor quality of care. The Association provides educational programmes and resources to both specialists and non-specialists, and disseminates knowledge and best practice through a wide range of meetings, national conferences and via our website and our journal, HIV Medicine. BHIVA funds an array of research projects and, BHIVA-funded research is eligible for adoption into the National Institute of Health Research portfolio.

4. Despite its interest in this issue, the British HIV Association is unable to bring this case because of the financial risks, the need to gain approval of the executive board and members of the organisation.

The risks raised by SSPs

5. We believe that there are significant risks associated with SSPs that could lead to serious harm and even death. Prescribing HIV treatment can be very complex and depends on a number of different factors including the type of HIV virus itself, the patients' co-morbidities, co-medications, lifestyle and previous treatment history[1]. HIV treatment has to be tailored to each individual patient and we recommend that each patient is involved in decisions about their treatment[2]. We are concerned about the potential risks associated with SSPs including changing the dosage of medications, switching to alternative medications or formulations including generics, without the HIV team's knowledge or input. We describe these risks below:

6. Without prior knowledge of a patient's medical history, chemists may dispense drugs that the patient had previously experienced side-effects or allergy from before. An important example of this is the commonly used HIV drug abacavir, which causes hypersensitivity reactions such as rashes, fever and malaise in 5-8% of people. If a hypersensitivity reaction develops the drug is stopped. Restarting abacavir in these individuals is contraindicated as it can cause life-threatening reactions such as Stevens Johnson Syndrome and toxic epidermal necrolysis[3].

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[1] BHIVA Guidelines for the treatment of HIV-1- positive adults with antiretroviral therapy, 2015 (2016 interim update).
https://www.bhiva.org/file/RVYKzFwyxpgiI/treatment-guidelines-2016-interim-update.pdf

[2] BHIVA Standards of care for people living with HIV, 2018.
https://www.bhiva.org/file/KrfaFqLZRlBhg/BHIVA-Standards-of-Care-2018.pdf

[3] Shapiro M, Ward KM, and Stern JJ. A near-fatal hypersensitivity reaction to abacavir: case report and review of the literature. AIDS Read 2001;11:222-226

7. Due to advances in treatment, people living with HIV are getting older and developing multiple co-morbidities. 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[4]. Drug to drug interactions are common and need to be looked at by a specialised HIV pharmacist along with the HIV physician. Drug interactions can be very harmful and may even cause death. For example if a patient is taking protease inhibitors (a very commonly used class of medication to treat HIV) and are prescribed an inhaler containing steroids for asthma, then they may develop Cushings syndrome (where there are excess cortisol levels in the body). This is because the protease inhibitor increases the levels of the steroid from the inhaler in the blood. Furthermore, medications that can be commonly bought from a chemist without prescription such as calcium supplements or stomach acid suppressants can interfere with the absorption of HIV medication resulting in sub-therapeutic levels. These kind of drug to drug interactions are routinely picked up by a specialist HIV pharmacist and physician, but may be overlooked by non-specialists.

8. If the person living with HIV is given a new drug, or one that they do not recognise, they may not take it until their usual medication is available, or until they can be seen by their HIV physician. It is essential that patients take their HIV treatment every day as treatment interruptions can be harmful. Daily treatment ensures high enough drug levels in the body to suppress viral replication. We know that if the drug is missed for even a day that the virus can start to replicate again and damage the immune system. Being immunocompromised puts the patient at risk of opportunistic infections and malignancies which can cause long term disability and even death.

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[4] Positive Voices: the national survey of people living with HIV Nov 2018

9. Missing treatment can also lead to the virus developing resistance against drugs. This means that when the patient restarts treatment, it may no longer work. When the virus develops resistance it is often to the whole class of drugs, not just the one the patient was taking. This can significantly limit the patient’s future therapy, resulting in the need to take a more complicated regimen with increased pills. If drug resistance occurs in more than one class of HIV drug, then there is a risk that the virus may eventually become untreatable.

10. When HIV medication is started, side-effects such as nausea, vomiting, diarrhoea, rashes and sleep disturbance are common. This can also happen when people have their medications changed to generic versions as the non-pharmaceutically active parts of the medication can be different to those in the branded versions. Switching medications as proposed by the SSPs make these side-effects more likely, and may be detrimental to patients.

11. HIV diagnoses have recently started to fall in England and this has been mainly attributed to the fact that if a person is on effective treatment with suppressed virus, that they are uninfectious[5]. If a person misses treatment and the virus starts to replicate again, they are at higher risk of passing the virus onto others. SSPs therefore have a public health impact as they may lead to fewer people having a suppressed viral load with a greater risk of HIV transmission to others.

12. The population of people living with HIV in England is very diverse with a large number of people from Black, Asian and minority ethnic backgrounds and gay men. HIV disproportionally affects some of the most marginalised groups in

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[5] Rodger AJ et al for the PARTNER Study Group. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. JAMA, 2016:316(2):1-11.
http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2016.5148

society including migrants (who may have English as a second language), transgender people, drug users and sex workers[6]. Untreated HIV can have multiple serious long-term complications resulting in disability. This proposal would therefore have a disproportionate impact on these already marginalised groups.

13. HIV remains a highly stigmatised condition with people living with HIV often experiencing stigma and discrimination from health care professionals in other sectors[7]. As a result HIV professionals work hard to build long term, trusting and therapeutic relationships with their patients. Seeing a pharmacist they are not familiar with or who they feel is not specially trained in HIV medications, could deter them from taking the medications and negatively impact on their relationship with the HIV team potentially leading to disengagement from care.

14. Caring for people living with HIV can be complex and we individualise treatment to each patient. Currently HIV treatment is only prescribed by HIV teams as it is deemed too complex for even primary care practitioners, let alone non-specialist pharmacists. In our opinion, the only person qualified to choose and prescribe antiretroviral therapy is the patient's HIV physician in conjunction with the HIV multidisciplinary team, which includes a HIV specialist pharmacist.

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[6] Progress towards ending the HIV epidemic in the United Kingdom 2018 report. Public Health England.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/769001/HIV_annual_report_2018_-_Appendix_101218.pdf

[7] The People Living with HIV Stigma Survey UK. London, 2015.
http://www.stigmaindexuk.org/reports/2016/NationalReport.pdf

Lack of consultation

15. The British HIV Association did not hear about the Serious Shortage Protocol until 18 February 2019 when we were contacted by the National AIDS Trust. We were also not aware that an informal consultation took place between 5-12 December 2018. As the leading organisation for professionals working in HIV in the UK, we would have expected to have been consulted.

16. We have now seen the response to the informal consultation. Paragraph 8 of the response states that the protocols would not be suitable for treatments for epilepsy or treatments requiring ‘biosimilar products where the medicines that are prescribed by brand for clinical reasons’. Biologics (eg. insulin) are medications that are created through biological processes in living cells. Biosimilar products are very similar versions of biologics. Such biologics or biosimilars are not used in HIV therapy. This assurance would therefore not cover medicines used in HIV therapy. In addition Paragraph 8 completely fails to address the real concerns in relation to co-morbidities, explained above in the section that deals with the risks raised by SSPs.

17. Had we been consulted, we would have raised the concerns that we have expressed in this statement about the potential harm to individual and public health. We would also have collected views from our affiliated organisations including the HIV Pharmacy Association and the National HIV Nurses Association and asked that the public consultation sought the view of HIV patient groups. We would have hoped that as with public consultations on other issues, the Department of Health would have taken our concerns into account to formulate laws with minimal or no risk to patients. We would have requested that HIV was exempt from the Serious Shortage Protocol.

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Witness: Chloe Orkin
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Date:

Statement of Truth:

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

Signed:

Chloe Orkin

(Full Name)

Dated: 25/02/2019