Regulation 28: REPORT TO PREVENT FUTURE DEATHS

NOTE: This form is to be used **after** an inquest.

	REGULATION 28 REPORT TO PREVENT DEATHS **THIS REPORT IS BEING SENT TO:** **The Royal Pharmaceutical Society** **The National Institute for Health and Care and Excellence**
1	**CORONER** I am Michael Spencer, Assistant Coroner for East Sussex.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On 18 June 2021 I commenced an investigation into the death of Joshua Fynn ASPREY aged 19. The investigation concluded at the end of the inquest on 15 March 2023. I determined that the medical cause of Joshua's death was: **1a Multiple injuries.** In box 3 of the record of inquest I recorded as follows: **Joshua Asprey died on 14th June 2021 from multiple injuries after deliberately jumping from a cliff** [redacted] In box 4 of the Record of Inquest, I recorded a conclusion of: **SUICIDE**
4	**CIRCUMSTANCES OF THE DEATH** 1. Joshua Asprey was 19 years old at the time of his death. He had a history of anxiety. 2. On 27 May 2021, Joshua attended a telephone consultation with his GP reporting that he was feeling depressed. He was commenced on sertraline, [redacted] 3. On 11 June 2021, Joshua attended a further telephone consultation with his GP and his dose of Sertraline was raised to [redacted] 4. The GP did not discuss with Joshua in either consultation any risk of suicidal ideation associated with commencing or increasing the dose of Sertraline. The GP relied on the British National Formulary ('BNF') which does not identify suicidal ideation as a risk of prescribing Sertraline. 5. Following the increase of his dose of Sertraline, Joshua began to have thoughts contemplating suicide. 6. On 14 June 2021, Joshua took his own life by deliberately jumping from a cliff [redacted]

	[redacted] 7. Joshua left a suicide note on his computer in which he wrote: "*The reason for my current state of thoughts and plans is probably due to suicidal thoughts caused by a side effect of changing from* [redacted] *dosage of sertraline. However, while this is the trigger in the short term, these thoughts have existed and persisted within me for many years now and to blame solely the medication would be unjust*." 8. There was insufficient evidence on which to conclude that there was a causative link between the increased prescription of sertraline and Joshua's death.
5	**CORONER'S CONCERNS** During the course of the investigation my inquiries revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows: (brief summary of matters of concern) 1. The evidence heard during the course of the inquest highlighted an inconsistency between the literature provided by the manufacturer of sertraline (the patient information leaflet ('PIL')) and the British National Formulary ('BNF') produced by the Royal Pharmaceutical Society (latest version: BNF 85, March 2023). 2. The PIL contains a list of "uncommon" side effect of suicidal behaviour, which includes the following in bold: "**Cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2)**." 3. The BNF relating to Depression (3.4, p395) and the use of Antidepressant Drugs states under the heading "Suicidal depression and antidepressant therapy" (p397): "*The use of antidepressants has been linked with suicidal thoughts and behaviour; children young adults and patients with a history of suicidal behaviour and particularly suicidal behaviour are particularly at risk. Where necessary patients should be monitored for suicidal behaviour, self-harm or hostility, particularly at the beginning of treatment or if the dose is changed*." 4. The section of the BNF relating to SSRIs (p401) also identifies "*suicidal behaviours*" as a potential uncommon side-effect. 5. However, the section with respect to sertraline does not specifically identify suicidal tendencies at all, although it does identify "thinking abnormal" as an uncommon side effect (p.405). 6. I am concerned that there is a risk that a medical practitioner consulting the BNF with a view to determining dosage and treatment with Sertraline will be unaware of the potential risk of the onset of suicidal behaviour and/or would not consider it necessary to discuss that risk with the patient. The evidence heard at the inquest suggested that it would not be appropriate or practical for GPs to consider PILs before prescribing. 7. On the other hand, the PIL and BNF are intended for different purposes. It may be that the evidence of risk of suicidal ideation associated with Sertraline specifically (as opposed to SSRIs) is so low that it need not be referred to in the BNF, notwithstanding its inclusion in the PIL. Nevertheless, this is a matter of concern that would in my view benefit from further consideration.

6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you (and/or your organisation) have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by **30 June, 2023**. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons: 1. [redacted] (Joshua's parents) 2. The GP. 3. Sussex Police. I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it. I may also send a copy of your response to any person who I believe may find it useful or of interest. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response about the release or the publication of your response by the Chief Coroner.
9	**Dated: 05/05/2023**  **Michael SPENCER** **Assistant Coroner for** **East Sussex**