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	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS THIS REPORT IS BEING SENT TO: **MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**
1	**CORONER** **I am Miss Kirsty Gomersal Area Coroner for County of Cumbria**
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: https://www.legislation.gov.uk/ukpga/2009/25/contents http://www.legislation.gov.uk/uksi/2013/1629/contents
3	**INVESTIGATION and INQUEST** On 3 November 2020, Dr Nicholas Shaw (Assistant Coroner) commenced an investigation into the death of Edward Jorge CAPOVILA who was known as Eddy. Eddy's inquest was opened on 15 March 2021 and concluded on 22 April 2022 following a two-day hearing before me. The medical cause of Eddy's death was: 1a Multi-drug toxicity II Hepatic steatosis The determination was: *Mr Edward Jorge Capovila (who was known as Eddy) died on 30 October 2020 at [redacted] in Barrow-in-Furness as the result of the combined toxic effect of prescribed medication. In administering that medication, Eddy did not intend to harm himself or take his own life.* *Eddy was prescribed nitrazepam, pregabalin and fentanyl (as transdermal patches). Nitrazepam metabolite was present in post-mortem blood but it could not be determined if levels were therapeutic or excessive. Pregabalin was found at 3.6 mg/l which is consistent with therapeutic use. Fentanyl was present at 6.3 µg/l. These medications are central nervous system depressants which have an additive effect when used together.* *No fentanyl patches were found on Eddy's body. On balance, Eddy has administered fentanyl by heating and inhaling it.* The conclusion of the inquest was: Death by misadventure.

4	**CIRCUMSTANCES OF THE DEATH** I found that, on the balance of probabilities, Eddy had administered himself fentanyl by heating and inhaling it. It could not be determined how many patches Eddy had used as none were located on his body or in the house. Eddy had chronic pain which required strong painkilling medication *i.e.* fentanyl. He had also been known to use drugs and had demonstrated drug seeking behaviour. The inquest heard that the amount of fentanyl in a transdermal patch needs to be higher than that taken transdermally. For instance, the patches prescribed to Eddy required 2.7mg fentanyl to release 37.5 µg/hr hour over 72 hours. However, each patch contains 6.3mg fentanyl to maintain the concentration gradient. Even a "used" fentanyl patch therefore contains significant amounts of fentanyl that could be misused. Evidence was heard about the steps taken following Eddy's death. Part of the wider learning was to increase awareness (at local Trust level) of how fentanyl can be abused / misused other than by the application of excess fentanyl patches. The inquest heard that there is relatively little information available about the other ways in which fentanyl can be abused. It is known that heating a fentanyl patch can increase the rate at which fentanyl is dispensed; hence the warnings not to wear patches in a hot bath, for example. Applying a direct heat source onto a patch can release fentanyl so that it can be abused – such as by inhalation (as in Eddy's case). I was told of other means by which released fentanyl can be abused. Given the amounts of fentanyl that remain even in a used patch, a potentially lethal dose of fentanyl can be released for misuse.
5	**CORONER'S CONCERNS** The evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows: As indicated above, I was told that there is relatively little information available about the more unusual ways in which fentanyl can be misused or abused. Given the potential for fentanyl to be misused, as evidenced in Eddy's inquest, I have concern that further deaths may occur in future if action is not taken.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe the **MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY** has 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 **20 June 2022**. 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: [redacted] Eddy's parents. [redacted] Eddy's sister. Lancashire and Cumbria NHS Foundation Trust. University Hospitals of Morecambe Bay NHS Foundation Trust. I have also sent a copy to Bridgegate Medical Centre, Eddy's GP, for information. I am also under a duty to send the Chief Coroner a copy of your response. 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	25 April 2022  Miss Kirsty J Gomersal HM Area Coroner County of Cumbria