REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **The Secretary of State for the Department of Health** **Richmond House** **79 Whitehall** **London** **SW1A 2NS**
1	**CORONER** Julian Fox, assistant coroner for the coroner area of South Yorkshire (West).
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. Schedule 5 to those Regulations provides: (1) Where— (a) a senior coroner has been conducting an investigation under this Part into a person's death, (b) anything revealed by the investigation gives rise to a concern that circumstances creating a risk of other deaths will occur, or will continue to exist, in the future, and (c) in the coroner's opinion, action should be taken to prevent the occurrence or continuation of such circumstances, or to eliminate or reduce the risk of death created by such circumstances, the coroner must report the matter to a person who the coroner believes may have power to take such action. (2) A person to whom a senior coroner makes a report under this paragraph must give the senior coroner a written response to it. (3) A copy of a report under this paragraph, and of the response to it, must be sent to the Chief Coroner.
3	**INVESTIGATION and INQUEST** On 8th April 2011 I commenced an investigation into the death of John Michael Bailey, who was born on 10th February 1937. The investigation concluded at the end of the inquest on 6th September 2013. The conclusion of the inquest was that Mr Bailey died from lung fibrosis which was due to Amiodarone toxicity and which went undiagnosed for a period, because of a lack of awareness of the symptoms for his condition.
4	**CIRCUMSTANCES OF THE DEATH** Mr Bailey died as a consequence of Amiodarone induced pulmonary fibrosis (APF). I was told during the inquest that Amiodarone is a drug commonly used to treat cardiac rhythm disorders and that APF is a recognised but relatively rare complication associated with it (occurring in between 2% and 4% of cases but with the risk rising in cases where higher doses of the drug are used). In about 10% of cases, APF will be fatal – roughly 0.2% to 0.4% of those who receive the drug. It can be effectively treated in most cases by the withdrawal of Amiodarone and the provision of steroids. It is understood that such treatment is more likely to be effective if commenced soon after

	the onset of symptoms and that the risk of mortality increases if treatment is delayed. There is no definitive diagnostic test to screen for APF, so it has been suggested that there should be a low threshold for clinicians to suspect it and act where patients present with symptoms suggestive of APF.
5	**CORONER'S CONCERNS** During the course of the inquest 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. – (1) There was an absence of clear protocol guidance for primary care physicians and the absence of a robust system to ensure that patients were provided with clear information about the management of their Amiodarone. It was accepted by all witnesses that good protocols provide considerable assistance to primary care physicians who may lack experience in managing Amiodarone and its side-effects and may help prevent unnecessary deaths. (2) There was also inconsistency between the Shared Care Protocols developed by different Trusts and in this case, a clear inconsistency between the Shared Care Protocols used by neighbouring Trusts. This localised approach to developing Shared Care Protocols may give rise to a repeat of the circumstances of this case. (3) It is possible that a lack of consistency between different areas may also give rise to a risk where health care practitioners transfer jobs between those areas.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action. Although I am satisfied that diligent steps have been taken locally to improve both the content of the protocol and its profile amongst relevant medical staff, there would be merit in ensuring that steps are taken nationally to ensure that medical personnel are aware of the risk of APF, and the steps that should be taken to reduce that risk. I offer the following points for your consideration: 1. That a National Shared Care Protocol might be devised so as to ensure consistency between all Trusts in the management of Amiodarone. The specifics of that Protocol are plainly a matter for consultation with specialists in the management of that drug and its complications. However the following may be worthy of consideration: 1.1. The Protocol could define clearly the division of responsibility for the management of Amiodarone between primary and secondary care physicians; 1.2. The Protocol could set out the need for regular review of patients (6 monthly was adopted in this case) and define what tests should be carried out at each review; 1.3. The Protocol could provide that baseline tests are carried out and recorded clearly and communicated to the patient's GP at the time of first prescription. 1.4. The Protocol could require questions to be asked of the patient at each review regarding symptoms of cough or breathlessness; 1.5. The Protocol could require that patients are informed in clear terms at the time that the drug is initiated and at each review what signs and symptoms they are to watch out for and instructed to see their GP as soon as possible if those symptoms present. 1.6. The Protocol could provide a clear process to be adopted in circumstances where a patient presents to their GP with new symptoms of breathlessness or cough. 1.7. The Protocol could require that the patient's GP sets up warnings on the

	practice computer system so that GPs who review the patients who attend between their regular reviews know that the patient is taking Amiodarone and alert them to the possible signs and symptoms of Amiodarone toxicity and to the existence of a Shared Care Protocol. 1.8. The Protocol could require that the GP is provided with, and kept informed of, contact details in the event that their patient presents with symptoms of Amiodarone toxicity. 2. That a monitoring card could be provided to patients who are taking Amiodarone, similar to that provided to patients who are taking Warfarin therapy. That monitoring card could also contain warnings to the patient about symptoms suggestive of Amiodarone toxicity and contact details for their GP and/or hospital clinic in the event that those symptoms manifest.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 3rd November 2013. 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. Mr Bailey's family 2. The Chief Executive, Sheffield NHS Foundation Trust 3. The Chief Executive Sheffield Primary Care Trust 4. [redacted] 5. 6. 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	**9th September 2013** *Julian Fox*