ANDREW JAMES COX
Assistant Coroner for Plymouth Torbay and South Devon

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO: Medicines Regulatory Healthcare Authority,** 151 Buckingham Palace Road, Victoria, London SW1W 9SZ
1	**CORONER** I am ANDREW JAMES COX, Assistant Coroner for Plymouth Torbay and South Devon
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. http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7 http://www.legislation.gov.uk/uksi/2013/1629/part/7/made
3	**INVESTIGATION and INQUEST** On 29 March 2016 I commenced an Inquest into the death of Muriel Ann Brett, 69. This concluded at the end of the Inquest hearing on 26 April 2017. The conclusion of the inquest was that Muriel had died from a known but rare complication of an elective surgical procedure. The medical cause of death was given as : 1 (a) Right Pneumonia; 1 (b) Perforated Oesophagus (stented); 1 (c) Valvular Heart Disease (Operated 11 March 2016 and 12 March 2016)
4	**CIRCUMSTANCES OF THE DEATH** Muriel suffered with severe aortic stenosis. She underwent an aortic valve replacement procedure on 11 March 2016. At surgery the first replacement valve was felt by the operating Surgeon to be defective. It was explanted and a second replacement valve then implanted. Muriel underwent a second operation on 12 March 2016 at which time blood and clots were removed to prevent the risk of cardiac tamponade. Muriel underwent three transoesophageal echocardio graphs (TOE) on different dates by different clinicians. On 20 March 2016 an oesophageal perforation was identified which was stented. I found that it was more likely than not that the cause of the perforation was the insertion of the probe at one of the TOE procedures. It was not possible to say from the evidence which examination had caused the perforation. Muriel sadly deteriorated and died in Derriford Hospital, Plymouth on 20 March 2016. Subsequent investigation carried out independently on behalf of Edwards Lifesciences (of the explanted valve) had been unable to identify any defect with it.
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.

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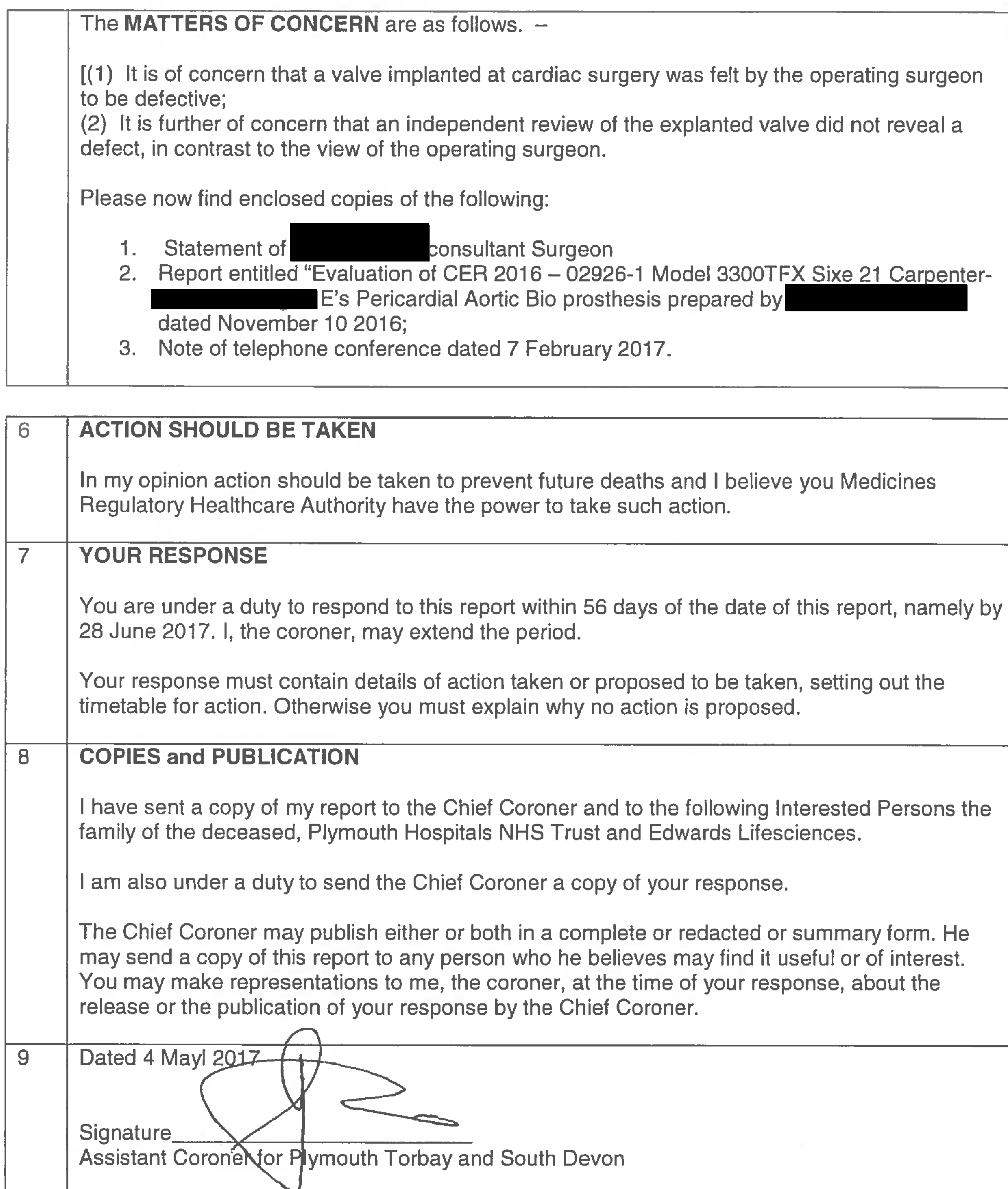

	The **MATTERS OF CONCERN** are as follows. – [(1) It is of concern that a valve implanted at cardiac surgery was felt by the operating surgeon to be defective; (2) It is further of concern that an independent review of the explanted valve did not reveal a defect, in contrast to the view of the operating surgeon. Please now find enclosed copies of the following: 1. Statement of [redacted] consultant Surgeon 2. Report entitled "Evaluation of CER 2016 – 02926-1 Model 3300TFX Sixe 21 Carpenter-[redacted] E's Pericardial Aortic Bio prosthesis prepared by [redacted] dated November 10 2016; 3. Note of telephone conference dated 7 February 2017.

6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you Medicines Regulatory Healthcare Authority 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 28 June 2017. 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 the family of the deceased, Plymouth Hospitals NHS Trust and Edwards Lifesciences. 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	Dated 4 Mayl 2017 Signature________________________ Assistant Coroner for Plymouth Torbay and South Devon