A 2009 fetal monitor recall that arguably should have been class I

TO THE EDITORS: I read the recent article by Janetos et al1 with great interest. The purpose of this letter is to bring attention to a class-II recall during the time period of the study by Janetos et al1 that, it is arguable, should have been class I: the recall of Avalon fetal monitors (Philips, Amsterdam, the Netherlands) in 2009.2 The Philips urgent medical device recall letter stated that there had been several complaints regarding inaccuracies in fetal monitoring tracings with potential for serious fetal or maternal morbidity or mortality.2 In 2014, when I prepared a letter regarding this recall for publication,2 I was able to access on the Philips company website the following documents: the recall letter, an addendum including instructions for use, and a confirmation-of-receipt form for the former 2 documents to be signed and returned to Philips indicating that all the providers using the monitors had been informed. Recently, I have been unable to find these documents on the Philips website, and this has increased my concern that providers currently using these monitors are not being adequately informed of the potential risks in a systematic and ongoing way. All 3 are documents are referred to on the US Food and Drug Administration (FDA) site, which also refers to 1551 of the monitors being in commerce worldwide in multiple countries.1 Without an ongoing system to alert providers, it is possible that a class-II recall, even if sufficiently severe in classification, may lead to greater risks than a class-I recall. Freeman et al,4 although not explicitly naming the Avalon monitors, refer to >20 cases of adverse outcome due to signal ambiguity (blending of the maternal and fetal heart rate signals by fetal monitoring equipment) resulting in 3 stillbirths and 12 cases of cerebral palsy due to neonatal encephalopathy and a resultant FDA recall of fetal monitors. Classifying a fetal monitor recall as class I based on a “reasonable probability of serious adverse consequences or death”5 is challenging given the low absolute risk of adverse neonatal outcomes in obstetrics but the potential for a significantly increased relevant risk with a problematic monitor. Therefore, although not strictly speaking meeting criteria for inclusion in the study by Janetos et al,1 I do believe the Avalon fetal monitor recall merits mention in this letter.

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REFERENCES

REPLY

We appreciate Dr Kiely’s insightful comments related to the Avalon fetal monitors (Philips, Amsterdam, the Netherlands). In November 2009, the manufacturer sent an urgent medical device recall notice to users describing a higher rate of inaccuracies in ultrasound-derived fetal heart readings from their Avalon monitors compared to their older Series 50 fetal monitors. The notification provided an instruction for use addendum describing the differences between the Series 50 and the Avalon monitors. The recall was worldwide affecting 1551 units. Shortly thereafter, the US Food and Drug Administration (FDA) considered the recall complete.1 However, in spite of the potential dangers, the company did not recommend discontinuing its use.2 As noted by Dr Kiely, there is an ongoing, potential risk from the use of the monitor.

This case raises several points relevant to medical device safety. First, this case raises the robustness of the FDA classification of recalls. Class-I recalls are for products that have a “reasonable chance” of causing serious injury or death whereas class-II recalls could cause a “reversible health problem” or have a “slight chance” of serious injury or death. An ad hoc committee of FDA scientists is responsible for classification based on a health hazard evaluation. This evaluation accounts for multiple factors such as whether any injuries have already occurred, the population at risk, and the likelihood of occurrence of the hazard. Second, this case raises the question of a recall strategy’s adequacy. The FDA, in conjunction with the manufacturer, develops a response strategy to inform stakeholders of the recall and the specific action that needs to be taken. Additionally, the firm is