

# Cerivastatin and fatal rhabdomyolysis: not just a safety issue

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Bayer has voluntarily withdrawn cerivastatin from the world market after almost one hundred reported deaths(1) and an unknown number of unreported deaths associated with rhabdomyolysis. It is hard to believe that the European Medicines Evaluation Agency is only now undertaking the first comprehensive safety evaluation of statins since their debut into clinical use prompted by that withdrawal.(2) However, the cerivastatin affair triggers more questions than just regarding the safety of statins (1).

Cerivastatin was approved on the basis of surrogate efficacy. Should we continue to approve drugs on that basis? The use of surrogate end points for reaching conclusions about drug benefits has caused rising concern and the cerivastatin affair confirms that such concern is well justified.(3,4) Disappointingly neither the U.S.A. nor the E.U. authorities have discussed or reviewed this question in response to the cerivastatin withdrawal.

The risk of fatal rhabdomyolysis was found to be higher among patients who received the full dose (0.8 mg/day in the USA and 0.4 mg/day in the EU) and those who received gemfibrozil concomitantly. It is important to ask two additional questions that appear to have the same answer: 1) Why did doctors use cerivastatin this way? 2) How was cerivastatin marketed? Cerivastatin was promoted as “a first line agent for hypercholesterolaemia”, “safe and effective for patients who require aggressive LDL cholesterol lowering to achieve NCEP-recommended targets” (5). We are hoping for some explanation, some re-analysis of the original data from *The Cerivastatin Group (USA)* (6), *The Canadian Cerivastatin Study Group* (7) and *The International Cerivastatin Study Group (Belgium, France, Germany, Israel, Italy, Netherlands, Norway, South Africa, Spain, Sweden and the United Kingdom)* (8) at least.

The cerivastatin fatal rhabdomyolysis affair should be use as an example to stimulate reconsideration of the whole process of drug approval, marketing and use, as occurred after thalidomide was found to cause adverse effects to the foetus. It is not just a safety issue (1).

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