Doctor explains why a popular statin should not be prescribed

Evidence suggests less benefit than other statins and more harmful side effects

A doctor today reviews why the US Food and Drug Administration (FDA) should have withdrawn the popular cholesterol lowering drug rosuvastatin (Crestor) and why it should not be prescribed.

Writing in The BMJ, Dr Sidney Wolfe, founder and senior adviser to the Health Research Group at Public Citizen, says the evidence of its health benefits has always been weak - and there is now growing evidence that the drug carries a higher risk of harmful side effects.

Last year, rosuvastatin was the most prescribed brand name drug in the US, with 22.3 million prescriptions filled and $5.8bn (£3.9bn; €5.5bn) in sales. Worldwide 2013 sales were $8.2bn, the third highest for any branded drug.

The cholesterol lowering potency of rosuvastatin exceeds all other statins, explains Wolfe. However, its later approval to prevent heart attacks in a very selected group of people, was based on the results of a study which was stopped early, prompting concern that the treatment effects may have been overestimated.
There is also growing evidence that the drug carries a higher risk of serious adverse effects compared with other statins, such as an increased risk of developing diabetes.

Other serious problems were identified before rosuvastatin’s approval, prompting Public Citizen to oppose its approval in 2003, and in 2004 to ask the FDA to ban the drug. These include rhabdomyolysis, a breakdown of muscle fibres that can lead to kidney failure if not promptly treated, and increased levels of blood and protein in the urine that can progress to kidney disease.

Given the evidence of more serious risks and less clinical benefit than other statins how has the drug fared so well for so long, asks Wolfe?

He points to an October 2003 Lancet editorial that said “AstraZeneca has pushed its marketing machine too hard and too fast” and a letter from the FDA to AstraZeneca in December 2004 demanding that it immediately stop an advertisement in the Washington Post containing false and misleading information about Crestor’s risks.

The advert was in response to a Washington Post article entitled “Campaign Waged against Crestor,” discussing safety concerns of the FDA and Public Citizen about Crestor, explains Wolfe. The FDA also wrote to the company again the following year about “misleading superiority claims” for Crestor in other promotional materials.

When patents expired for three other popular statins (simvastatin, pravastatin, and atorvastatin), the rise in generic prescriptions quickly equaled or exceeded the sharp decreases in brand name prescriptions, says Wolfe.

The patent for rosuvastatin expires in 2016, and with it AstraZeneca’s need to promote it. “But for the sake of the public’s health, we must hope that the drug’s disadvantages will
lead to a sharp decline in its use before next year,” he concludes.

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www.bmj.com/cgi/doi/10.1136/bmj.h1388

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