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Vytorin debate heats up ESC

By Tracy Staton

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There's controversy brewing at the European Society of Cardiology meeting in Munich. Today, the now-infamous SEAS study, in which Vytorin not only missed its primary endpoint but appeared to be linked to cancer deaths, will be presented in all its glory, or lack thereof. That alone has incited all sorts of debate among cardiologists, both for and against the Merck/Schering-Plough cholesterol drug.

But the *New England Journal of Medicine* has already published that study and an analysis of it and other data that concluded that the cancer risk was due to chance. Along with it, the NEJM issued a frank editorial, saying that the cancer link shouldn't be attributed to chance "until further data are in." And in the meantime, doctors and patients "are unfortunately left...with uncertainty about the safety and efficacy of the drug."

We'll see how the cardiologists react to the presentation today. But as you know, Vytorin has been no stranger to debate over its efficacy all year--ever since the big study [1] that showed the combo of Zocor and Zetia (ezetimibe) didn't stave off artery-narrowing any better than Zocor alone. The SEAS study seconded that motion, showing that Vytorin didn't keep heart valves from narrowing any better than placebo did. Some cardiologists have recommended that Vytorin be relegated to last-resort status [2], after every other type of cholesterol med has been tried, at least until info from an outcomes study becomes available--but that won't be for several years. Others worry that the media firestorm might put patients off their meds unnecessarily, and dangerously.

For a taste of the debate in the experts' own words, we leave you with these two quotes: (1) "What I worry most about is that patients with coronary disease will stop taking all of their medications because of [the cancer fears]," said Douglas Weaver of Henry Ford Hospital, who grew a bit leery of Vytorin after earlier efficacy questions, but attributes the cancer link to chance. "[It] would be a public health catastrophe." (2) "Ezetimibe is certainly worthy of ongoing study," said Allen Taylor of the Walter Reed Army Medical Center, "but it should not be used in clinical medicine until the justifiable and substantial cloud of uncertainty over it is resolved."