"Amarin's Vascepa: Serious FDA Safety and Efficacy Issues - Really?"

A Letter to Dr. Margaret A. Hamburg, FDA

TAMPA, FLORIDA, USA, February 10, 2014 /EINPresswire.com/ -- I want to express my concerns regarding the FDA actions relating to Amarin (AMRN). I approach this not as a medical professional but rather as an investor with a PhD in engineering (Northwestern 1986) and 30+ years of analytical research experience. I know how hypotheses should be tested and scientific conclusions reached. The other evening I was listening to a commercial spot for an FDA approved product. After 15 seconds of well-crafted promotion the commercial proceeded with approximately 45 seconds of cautions and qualifiers listing some horrendous potential side effects for an FDA approved noncritical medication. Yet, I recalled FDA staff stumbling and fumbling at the October ADCOM meeting before finally admitting there were no compelling safety issues associated with Vascepa. In the meantime, a growing body of anecdotal evidence, in many cases supported by science, indicate Vascepa's side effects include such things as improved mood, reduced dry eye, reduced inflammation, improved sleep and energy levels, etc. – with no evidence of safety problems.

After the begrudging acknowledgment that there were not safety issues, the ADCOM meeting stumbled through a virtually incomprehensible discussion of the efficacy of Vascepa. Differences between the special protocol agreement, the FDA voting question language, and the discussion led by the FDA left virtually everybody in the room completely confused or frustrated. While the pursuit of evidence-based justification for expanded application of drugs may be meritorious, the forum for that pursuit should not be an ADCOM meeting with an SPA in effect. If the FDA is inclined to move in that direction it should be done in a transparent manner with a systematically applied strategy with all stakeholders appropriately engaged and with the medical and scientific analyses available that would be appropriate to guide policy and procedural changes to move in that direction. To attempt to change practices in an ad hoc, incremental and nonsystematic fashion was grossly inappropriate and unfair to Amarin. The medical community, both in testimony at the ADCOM and in subsequent communications indicated that they favor expanding the arsenal of products available to treat the target population of the proposed expanded labeling for Vascepa.

Perhaps most troubling was the interpretation of partial results from dated studies of different products, at different dosage levels, and with different target populations, as the basis for implying Vascepa would not be effective in reducing cardiac events. Any research scientist with a modicum of competence would recognize the logic errors in that interpretation. Indeed, the preposterousness of that interpretation coupled with the delayed NCE determination, the clean 74 day letter, the unprecedented post-ADCOM SPA rescission citing "new" science – most of which was available when the SPA was authored, and much of which was preceded and superseded by substantial evidence

both empirical and theoretical espousing the role of EPA in improve heart health – have created suspicions regarding the objectivity and/or competency of FDA in this matter. A robust analysis of this issue would have included reviewing hundreds of scientific articles on EPA which is sole component of Vascepa. These articles describe and explain how EPA lowers chronic inflammation. The clinical significance of EPA's importance has been validated by population studies that indicate the EPA/AA ratio in a population is inversely related to the risk of CVD in a population, even when the LDL-C is the same among the populations compared. The FDA and the panelists showed no indication of being aware of any or all this information.

The ADCOM folly was further highlighted when a panel member questioned why an expanded indication was necessary when doctors could prescribe off label. This stunningly naïve statement was oblivious to economics and health practice standards and raised suspicions as to the fundamental competencies for that ADCOM of at least some panel members. The trivialization of the prospect of delayed patient benefits – particularly with the well-known shortcomings of the available treatment options for the target population – and the economic consequences of delay on the prospect of REDUCE-IT being completed, further undermined confidence that the panelists and FDA staff grasped the full implications of the issues they were impacting. Perhaps most important, the potentially significant precedents regarding evidenced based medicine and the FDA's implicit engagement in determining the medical need for treatment that would result if subsequent FDA actions for other substances are evaluated consistent with how Amarin's application, makes one wonder how well the ADCOM voting question and meeting agenda were thought through.

The post ADCOM SPA rescission appeared to be an attempt to use the cover of the ADCOM vote as a rationalization of what should be a very serious science-based decision made after consultation with the applicant and appropriately qualified medical experts. As the "new science" referenced in the SPA recession was available years ago, why wasn't the SPA rescission discussion held in an appropriate forum in a timely manner so the applicant could plan accordingly?

Obviously, I encourage the FDA to reconsider their previous positions regarding Vascepa and their treatment of Amarin. I realize the natural human tendency is to be defensive when challenged and I recognize there are uncertainties and judgments involved. However, anyone watching the ADCOM with a modicum of objectivity and context would realize the handling of Vascepa by the FDA has been extraordinarily flawed. I encourage you to work toward a much more logical, fact-based and fair path forward.

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