The FDA Misunderstands Science – Endangers Millions of Patients

FDA has no legitimate scientific or medical grounds to refuse Vascepa sNDA approval.
Physician asks FDA to work towards a more logical, fact-based solution.

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Vascepa corrects the most important health issue in America today. That is our diet is creating a nation health crisis because it promotes the development of Type 2 Diabetes and heart disease. Vascepa shows great promise of improving the nation's health and saving Americans billions of dollars in medical costs.

> At the end of the day, that is just smart regulation – ensuring that patients can more rapidly have access to the best that science has to offer."
> *Dr. Margaret A. Hamburg, FDA Commissioner*

A small biotech firm named Amarin (AMRN) has developed a most remarkable pharmaceutical called Vascepa. Amazingly Vascepa is an all-natural product derived from fish oil. The oil is highly refined, extracting the one component (eicosapentaenoic acid) that is best at preventing the "#1" killer above age forty – Coronary Artery Disease or CAD. A large outcomes study - Japan Eicosapentaenoic acid (EPA) Lipid Intervention Study (JELIS) involving 18,000 patients revealed a 50 % reduction in CAD in patients already taking statin medications! But wait the story gets better – Vascepa's side effects are minimal!

Vascepa had previously been approved to treat triglyceride levels (TGs) >500 mg/dl to prevent pancreatitis, however, Amarin desired to receive approval to treat patients with TGs in the 200-500 mg/dl range and already on statins. In order to obtain this Supplemental New Drug Approval (sNDA) Amarin would be required to perform a study that revealed a lowering of TGs with no

effect on LDL (bad cholesterol). This was known as the ANCHOR study. In addition the FDA requested that Amarin start a large outcomes study to determine whether the drug actually does reduce CAD (this is the REDUCE-IT study that is now substantially underway... the cost to Amarin for the REDUCE-IT study - $100 million USD).

Having met ALL FDA requirements of a Special Protocol Assessment (SPA) Agreement and with the above resume in hand the sNDA approval seemed assured.

Margaret A. Hamburg, FDA Commissioner as posted on February 6, 2014 by FDA Voice:
*** “We need to employ the best science in ways that will increase efficiency, productivity and our shared ability to find creative solutions to the challenges that confront us. At the end of the day, that is just smart regulation – ensuring that patients can more rapidly have access to the best that science has to offer." ***

However, that was not to be the case. In October a most bizarre FDA Advisory Committee Meeting (ADCOM) was held in which Vascepa’s bid to be utilized as above was rejected, leaving physicians and patients dumbfounded.

The FDA’s decision may have been based upon a quantum shift in the understanding of the treatment of CAD. However, the correlation of that shift with Vascepa clearly left a monumental gap in understanding. New treatment standards have focused solely on the group of medications called statins causing a major rift in the medical community. It is important to note that the new standards make no mention of TGs, a tacit implication that the existing standards with respect to TGs remained intact. Indeed this is evidenced by the fact that the FDA still posts on its website that TGs > 200 mg/dl should be treated. Statins have revealed significant reductions in CAD. Originally this was attributed to the lowering of LDL (bad cholesterol), however, as the science evolved it became clear that certain non-statin drugs that lower LDL (Zetia) did not reduce CAD – thus the science began to point out that there was something particular to statins that made them successful (most likely their effects on inflammation in arterial walls). The FDA realized that one cannot simply say because a drug lowers a number that it is good or bad – you have to look specifically at the outcomes of that drug itself.

Ironically, the FDA applied the exact opposite logic with Vascepa. They indicated in the ADCOM meeting that since other drugs that lower TGs do not effect CAD neither must Vascepa. Based upon this logic if the drug Zetia would have presented to the FDA prior to statins, statins would have never been approved and millions of life years would have been lost. Most alarming however, the JELIS study which fulfilled the very specific requirements of looking at the particular drugs effect on CAD was not allowed to be presented! Thus the FDA first inappropriately equilibrated all TG lowering medications as being the same and then when offered evidence regarding the specific drug itself refused to accept it. Most incredulously the FDA then said to Amarin - you need to give us the very evidence we just rejected (The results of the REDUCE-IT study)! The small pharmaceutical firm paid 1.7 million USD to the FDA to be subjected to this kangaroo court of logic.

The ramifications of the FDA's action extend much farther than simply this one medication. According to the FDA's own guidelines they cannot revise a SPA Agreement once the endpoints have been agreed upon unless the medication in question is actually causing harm. To allow them to change their minds for reasons entirely unclear and not based upon a sound understanding of the science at hand will significantly reduce small biotech firms desire to innovate causing irreparable harm to our now accelerating understanding of health and disease. With respect to Vascepa and Amarin the FDA's decision to renege on an agreed upon set point may so impact the company that they will not be able to complete the REDUCE-IT study which would be an immense tragedy.

The logical fallacies and inconsistencies of the FDA are far too numerous to document here. Suffice it to say that a grave injustice is being done to the American people. An extremely valuable component of the armamentarium to prevent CAD is being inappropriately removed possibly resulting in millions of lost life years. We call upon Dr. Hamburg and senior FDA officials to right this wrong and assist us in providing the American Public with the best health possible.

SOURCE: The EPA Drug Initiative

The EPA Drug Initiative currently has sponsored two important petitions:

The Citizen's Petitions from many members of EPADI, relative to the FDA's Vascepa SPA rescission decision (Docket number FDA-2013-P-1612), can be found at: http://www.regulations.gov/#!docketDetail;D=FDA-2013-P-1612

An online petition urging the FDA to approve Vascepa for high triglycerides/mixed dyslipidemia can be found here: http://www.thepetitionsite.com/176/817/515/urge-the-fda-to-approve-vascepa-for-mixed-dyslipidemia

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