

Scharen, Hilda

From: Suzanne Hughes [shughes@agmc.org]
Sent: Monday, December 20, 2004 4:46 PM
To: Groupe, Cathy; Scharen, Hilda
Subject: NDAC/EMDAC meeting Jan13-14

Dear Ms. Groupe and Ms. Scharen;

I represent the Board of Directors of the Preventive Cardiovascular Nurses Association. Our group respectfully requests the opportunity to deliver an oral statement at the Open Public Hearing on January 14 relative to the proposed switch of Mevacor to over-the-counter status. We feel that the input of the nursing community, which plays a key role in initiatives to prevent cardiovascular disease, is very important. Our overall position is one of conditional support, if certain criteria are met by the sponsor. We want to stress the importance of a responsible public education and marketing effort, and the importance of involving clinical professionals in the follow up of patients who would choose the OTC option. My fellow board members and I have an average of 30 years experience in the field of cardiovascular nursing. We look forward to the opportunity to speak on this very important public health issue. We are in process of creating the final draft of our statement. We would like to request that 5 minutes be allotted for our oral statement.

(background info on PCNA: The Preventive Cardiovascular Nurses Association is a national organization of 2000 professional nurses dedicated to the primary and secondary prevention of coronary heart disease, vascular disease and stroke. Our mission is achieved through professional and public education, through increasing consumer awareness of the importance of cardiovascular risk reduction, and through advocacy of the need for nursing involvement in the care of persons and families at risk for coronary heart disease and stroke.)
www.pcna.net

Thank you for your consideration.

Suzanne Hughes MSN RN

Suzanne Hughes MSN RN
Coordinator
Women's HeartAdvantage
Akron General Medical Center
330 344 1297

Statement of behalf of the Board of Directors
of the Preventive Cardiovascular Nurses Association
January 14, 2005
FDA Advisory Committee Meeting

The Preventive Cardiovascular Nurses Association is a national organization of 2000 professional nurses dedicated to the primary and secondary prevention of coronary heart disease, vascular disease and stroke. Our mission is achieved through professional and public education, through increasing consumer awareness of the importance of reducing cardiovascular risk, and through advocacy regarding nursing's role in the care of persons and families at risk for coronary heart disease and stroke.

The nurses who comprise our board and who authored this statement average well over thirty years experience in the field of cardiovascular nursing. We remember when care of the acute cardiovascular patient was *reactive* rather than *proactive*, and when available strategies for the treatment of dyslipidemia included agents (often poorly tolerated) that were given 3 times daily and which only modestly reduced cholesterol levels and cardiovascular event rates. All of us in this room know that the approval of Mevacor, the first HMG CoA reductase inhibitor, or statin, in 1987, and the agents in the class that followed, has effectively revolutionized pharmacologic treatment of dyslipidemia.

In numerous well-designed clinical trials over the past ten years, involving hundreds of thousands of adults, cholesterol lowering through the use of statins has been found to be remarkably safe and effective. The results of these trials have demonstrated substantial reductions in morbidity as well as mortality. However, of the millions of Americans eligible for treatment with cholesterol-lowering medications, only a fraction receives these evidence-based therapies. Many who begin taking these medications fail to continue therapy over time. Barriers to the initiation of, and persistence with, treatment are complex and multi-factorial. Making a statin available without a prescription is one strategy being explored to close the undertreatment gap. This is an option that may be appropriate for those at moderate risk.

As nurses, we work on the front lines in this field, and we have a vantage point allowing us to see the gap between the evidence-based treatments that are available to lower the risk of both first and subsequent cardiovascular events and what actually happens day to day in clinical practice. Today we are gathered to discuss the possibility of a new mode of access to statin therapy, one which may provide part of the solution to the current problem of under treatment.

The Board of Directors of PCNA acknowledges the potential public health benefit of over-the-counter availability of low-dose statins. We support the concept of the switch to OTC status based upon the satisfaction of the following criteria:

- The research must demonstrate that the population who chooses to use this product is comprised of appropriate candidates for OTC lipid-lowering therapy with regard to age, level of risk, medical history, and baseline lipid levels.
- The research must show that those who elect to use the product follow the instructions on the label with regard to dosage and frequency.

- The research must demonstrate that those who elect to use the product appropriately consult with their health care providers for clinical follow-up.
- The promotion of this product must be accompanied by a responsible marketing campaign targeted to the appropriate population. A comprehensive education program that includes continued emphasis on therapeutic lifestyle change (TLC) should be in place, and interaction with the healthcare system should be encouraged. We believe that potential misuse of the proposed OTC product can be greatly obviated through public education, education in the clinical setting, and responsible promotional strategies.

In closing, we believe that the OTC availability of a statin is likely to be associated with other important public health benefits. More than simply “a box on a shelf,” this new option would allow Americans to take a more active role in their own health and well-being. The associated marketing effort and media response will raise awareness of the importance of treating dyslipidemia as a strategy to reduce overall cardiovascular risk. We believe that this increased awareness will stimulate important dialogue between the public and the healthcare community. This presents a challenge and an opportunity for all of us. In response, we should embrace the opportunity to educate our patients and the public, not only with regard to the use of pharmacologic lipid-lowering agents, but about the central role of nutrition and physical activity on cardiovascular health. The Preventive Cardiovascular Nurses Association is committed to participating in this important campaign that has clear potential to save lives.