THE ENDOCRINE SOCIETY

8401 CONNECTICUT AVENUE, SUITE 900 + CHEVY CHASE, MARYLAND + 20815-5817 + TELEPHONE 301.941.0240 + FAX 301.941.0259 + www.endo-society.org

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Cathy A. Groupe
Center for Drug Evaluation and Research (HFD–21),
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
E-mail: *GroupeC@cder.fda.gov*

RE: NDA 21-213, Proposing Over-the-Counter (OTC) Use of LOVASTATIN (MEVACOR)

Dr. Ms. Groupe:

The Endocrine Society appreciates the opportunity to comment on NDA 21-213, a proposal to switch lovastatin (MEVACOR), 20 milligrams a day, to over-the-counter (OTC) to help lower LDL "bad" cholesterol, which may prevent a first heart attack. **As president of The Endocrine Society, I am writing on behalf of our members in opposition to the Rx-to-OTC switch of lovastatin (MEVACOR) as a cholesterol-lowering agent.**

Founded in 1916, The Endocrine Society consists of more than 11,000 physicians and scientists who are dedicated to the advancement, promulgation, and clinical application of knowledge related to endocrinology. The diverse membership represents medicine, molecular and cellular biology, biochemistry, physiology, genetics, immunology, education, industry, and allied health.

While The Endocrine Society recognizes there is an underutilization of statins to treat hypercholesterolemia in this country, we do not believe that moving a statin to OTC status is the solution. The potential of patients losing the benefits of physician supervision by switching statins to OTC status would, in our view, be too great and possibly detrimental to the health of many individuals and to the public.

Our members also have concerns about medicating people who do not need drug treatment, such as many postmenopausal women. Often, these individuals have high serum cholesterol concentrations, but low CHD risk.

Moreover, monitoring the drug's therapeutic effects and side effects is one of the best ways to ensure medicine compliance and to work on the associated risk factors, such as hypertension or diabetes mellitus, that also need attention. OTC status would almost certainly result in a failure to monitor the good and bad effects of this statin. Further, since the use of statins should be long-term, not episodic/short-term, switching to OTC would almost certainly result in a disincentive for a patient to see the physician for evaluation and follow-up.

The Endocrine Society is concerned that decreased follow-up of side effects from fewer laboratory tests and doctor visits, and overall less supervision, would lead to a popular misconception about the use of statins, i.e. that they alone are not sufficient for the prevention and treatment of dyslipidemia. The failure of patients to continue to see the physician would, in effect, reduce the opportunity for the

physician to determine the goals of treatment and educate the patient on the importance of proper diet, exercise, and other aspects of a healthy lifestyle.

Given the predominantly asymptomatic nature of hypercholesterolemia until a catastrophe intervenes, the importance of correct diagnosis of hypercholesterolemia by physicians, of properly counseling such patients about their disease and management program, of appropriately monitoring these patients during therapy for outcomes (good or bad), and of assessing for the presence of co-morbid conditions that could affect management choices, we have strong reservations on the proposal to move even one statin to OTC status. In addition, the use of a statin to lower LDL cholesterol may be only one part of a more complex treatment. While consumers may be able to determine if their LDL cholesterol is between 130 and 170 mg/dl, they are not capable of considering all of the other important factors that must be considered in reaching the correct diagnosis. For these reasons, it is our opinion that the OTC proposal for lovastatin (MEVACOR) would be contrary to the best interests of patients and the public.

In addition to current federal law, The Endocrine Society's position is supported by a U.S. General Accounting Office (GAO) report, based on a thorough analysis of this issue, and concluded:

> "Little evidence supports the establishment of a pharmacy or pharmacist class of drugs in the United States at this time, as either a fixed or a transitional class. The evidence that is available tends to undermine the contention that major benefits are being obtained in the countries that have such a class." (Nonprescription drugs: Value of a pharmacist-controlled class has yet to be demonstrated [GAO/PEMD-95-12, Aug. 1995])

As mentioned above, effective treatment of other diseases often concomitant with hypercholesterolemia, such as hypertension and diabetes, is essential. The Endocrine Society believes that physician counseling to encourage patients to institute lifestyle changes and to take their medications properly is a necessary part of a successful patient management program. However, many consumers would not receive this valuable counseling if all they had to do was purchase OTC lovastatin (MEVACOR).

In conclusion, The Endocrine Society urges the FDA to reject NDA 21-213 and not allow the OTC use of lovastatin (MEVACOR) or any other statin to treat elevated LDL cholesterol. The benefits of physician diagnosis (including other pre-existing conditions), counseling, and monitoring far outweigh any benefit of switching to OTC. If you should have any questions, please contact Janet Kreizman, Director of Programs and Policy Affairs at (301) 941-0200.

Sincerely,

Anthony Means, PhD
President