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Dispensing Models for the Safe and Effective Use of Statins

Good afternoon. My name is Cindy Reilly and I am the Director of Clinical Standards and Quality at the American Society of Health-System Pharmacists (ASHP). ASHP is a professional association with over 30,000 members and represents pharmacists who practice in hospitals and organized health systems, including ambulatory care clinics, home care, and long-term care. I appreciate the opportunity to present the views of ASHP on the proposed over-the-counter use of lovastatin.

The effectiveness of HMG co-reductase inhibitors, or statins, in reducing LDL-C has prompted calls for more widespread use of these therapies, including suggestions for their reclassification to OTC status. ASHP does not support this reclassification because the Society does not believe that current nonprescription dispensing models provide the safeguards required to ensure the safe and effective use of these therapies. However, the Society does believe that alternative models for dispensing these valuable medications should be explored and I will address a proposed model at the conclusion of my comments today.

ASHP believes that statins are most effective and should be used only as part of a multimodal approach to reducing the morbidity and mortality associated with coronary heart disease, or CHD. This multi-pronged approach includes drug therapy in conjunction with diet and exercise interventions. ASHP also believes that evaluation and management of lipid disorders should be guided by the recommendations of the National Cholesterol Education Program, the latest of which are contained in the Adult Treatment Panel III, or ATP III guidelines. Those guidelines identify statins as the drug of choice

for most patients who require lipid-lowering therapy; numerous studies have shown that statins are effective for both primary and secondary prevention in CHD. Therefore, interest in enhancing consumer access to these therapies is not without merit.

OTC Status Not Appropriate

To approve reclassification of lovastatin to OTC status, FDA must find that the proposed product meets the criteria outlined by the Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act. Consistent with those criteria, ASHP believes that any dispensing model for statins should:

- identify appropriate candidates for therapeutic intervention based on cholesterol levels and other risk factors,
- allow patients and health care providers to monitor response to treatment, including the occurrence of adverse drug events, and
- maximize the effectiveness of treatment by encouraging adherence to drug and other therapies.

It is important to note that higher CHD risk is present when individuals have 2 or more risk factors. Therefore, ASHP believes that before statin therapy begins, a cardiac risk assessment should be performed by a competent health care professional who can work with the patient to develop the optimal treatment plan based on treatment guidelines and the patient assessment.

Although the proposed LDL-C labeling attempts to ensure appropriate use according to the ATP III guidelines, ASHP believes that statins are not suitable for OTC status because the anticipated real-use conditions under that model do not provide for the circumstances I've just outlined. While the earlier CUSTOM study and the new label comprehension studies demonstrate some positive results, it is important to note that those studies were not designed to demonstrate effectiveness of therapy in a nonprescription model and were conducted in small populations under controlled conditions.

After statin therapy starts, ongoing evaluations are needed to assess the patient's response and to monitor for adverse drug events, such as myopathy. Although adverse events from statins are rare at the low dose proposed for the nonprescription formulation, they can occur. The wider use encouraged by OTC status will include statin use by individuals with multiple disease states and those taking potentially interacting medications. Because statins are a chronic therapy, new risks may develop as the patient's health status changes. For these reasons, use of statins requires ongoing vigilance. The existing model for OTC medications would place the entire burden for performing these functions on the patient and would likely result in increased adverse drug events.

For these reasons, ASHP believes that reclassification of statins to OTC status is not advisable. At the November 14th FDA public meeting, ASHP expressed support for behind-the-counter, or BTC, availability of certain drug products. The Society believes

that BTC availability of statins would provide a significant health benefit to consumers, who would be able to draw on the education, training, and experience of pharmacists to help assess their need for the medication, and their appropriate use in the context of a comprehensive disease management program. In conclusion, ASHP would support the implementation of a pharmacist-managed BTC system that would enhance the safe use of the lovastatin by avoiding duplicative statin therapy and alleviating concerns that patients in the highest risk groups for cardiovascular disease might receive OTC therapy at suboptimal dosing. I thank you for your time and consideration of ASHP's comments.