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Joseph A. Woelfel

University of the Pacific, jwoelfel@pacific.edu

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Pharmacy Care OTC Status Supported but OTC Status of Statins Denied

Lead author: Joseph A. Woelfel, Ph.D., FASCP, R.Ph., Assistant Editor

Background

On January 14, 2005 the FDA Nonprescription and Endocrinologic & Metabolic Drugs Advisory Committees voted against the OTC marketing of lovastatin 20 mg (*Mevacor Daily*). This follows a similar denial by the committees in July 2000 when lovastatin 10 mg was proposed for OTC consideration.¹

The United Kingdom Model

The model for OTC statin status was set in the United Kingdom (U.K.) with the approval of low-dose *Zocor Heart-Pro* (simvastatin) this past July 2004. *Zocor Heart-Pro* 10 mg is available in a “behind the counter” status. These restricted OTC products require patient-pharmacist interaction prior to the pharmacist providing the statin to a U.K. consumer.² A similar process for the American Pharmacists Association's (APhA's) “Pharmacy Care OTCs” would include product placement and promotion requiring direct consumer-pharmacist interaction with supporting written information and guidance documents. Included in these activities are disease-risk assessment and monitoring.^{3,4}

In the U.K., simvastatin is considered suitable for patients with moderate risk of coronary heart disease. Those individuals include men 55 to 70 with or without risk factors, men 45 to 54 with one or more risk factors, and post-menopausal women 55 to 70 with one or more listed risk factors. The risk factors include smokers, family history of early heart disease, being overweight or obese, and those of south Asian family origin. Their practice guidance document states that it is not necessary to have a patient's cholesterol status to identify them as being at moderate risk and that it is possible to determine moderate risk through an individual's self-reported risk factors. It is suggested that a cholesterol test is a good practice as a baseline prior to therapy and then at least yearly thereafter. Blood pressure measurement is

not a required practice prior to starting therapy but is recommended. Liver function testing is not required. Pharmacists should be involved in the initial sales of simvastatin including discussion of risk factors, healthy lifestyle, contraindications, cautions, adverse effects, and drug interactions. Record keeping of sales and discussions is recommended.⁵

Prior to and after statin OTC status approval in the U.K., there were supporting and opposing comments, some of which were politically based. Others were related to the absence of clinical trials with the 10 mg dose of simvastatin and no trials in an OTC population. Concern was also expressed that OTC statin presence would reduce healthy lifestyle changes. A positive primary preventative measure is that the target population is below the threshold at which the National Health Service provides prescription statin therapy.⁶

The U.S. Decision

The FDA Nonprescription and Endocrinologic & Metabolic Drugs Advisory Committees' decision to reject *Mevacor Daily*'s OTC status and the immediate potential for any other OTC statin's emergence, was based on the committees' opinion that patients would have difficulty in the treatment self-selection process and potential inability to comply with long-term use and testing. Members described that the current OTC system is not adequate for this level of patient responsibility. Many further indicated that they would have voted in favor of the OTC status if a “behind-the-counter” system as in the U.K. were available. This was an undeclared vote in favor of APhA's Pharmacy Care OTC proposal. Additional concerns were expressed relative to fetal risks associated with statins which carry a category X classification.⁷ This concern was evidenced by the committees lack of support for the self-diagnosis results of the Merck-sponsored study: A Consumer Use Study of Over-the-

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Counter Lovastatin (CUSTOM).^{1,8} They felt that the study did not adequately demonstrate lovastatin safety and efficacy in the OTC setting. The CUSTOM study's target population was individuals with LDL-cholesterol in the 130 to 170 mg/dL range. It was a consumer driven and self-selection study open to consumers in an uncontrolled manner. Participants self-selected and self-deselected themselves based on written guidelines and OTC *Mevacor* labeling. The study evaluated the ability of participants to self-manage their therapy without pharmacist or other health care professional involvement. The OTC *Mevacor*-consumer study demonstrated that the participants could appropriately self-select and self-manage their cholesterol over time. Despite the study authors' conclusions, the FDA committees did not feel that there was sufficient safety in this self-guided approach.^{1,8,9}

Pharmacy Care OTCs: A New Drug Class

The CUSTOM study proposed a simulated OTC model for statins. It was limited to a self-selected population, did not evaluate clinical outcomes, and therefore did not demonstrate efficacy.⁸ Ultimately, it was not supported.¹

Statins are an ideal drug category for consideration as a new drug class model. The APhA's Pharmacy Care OTC model new drug class provisions provide the necessary safety and efficacy "frame" for statins. This OTC model would fulfill the need to identify appropriate candidates for statin therapy. Risk factor identification, family, medical, and concomitant therapy history, lifestyle and therapeutic education, adverse event prevention, and monitoring of treatment response for best outcomes would occur with the direct health care professional interaction proposed. Primary prevention of cardiovascular events in patients without known CHD could be achieved for a greater percent of the population.

Changes in U.S. federal statutes and regulations would be necessary to establish this new non-prescription drug class available only from pharmacists and other licensed health care professionals.¹⁰

Alternately, OTC statins could be marketed as any other OTC product, as was proposed by Merck for their *Mevacor Daily* product, with appropriate consumer labeling and guidance documents. Furthermore, manufacturers could

label their proposed-statin OTC products with "behind-the-counter" storage requirements and suggested health care professional recommendations.¹⁰

In Canada, the National Association of Pharmacy Regulatory Authorities has a scheduling system for classification of medications. Schedule I drugs require a prescription. Schedule II therapies ("pharmacist only") may be purchased over-the-counter but are stored in a non-public access area in the pharmacy and require professional intervention by a pharmacist at the point of sale. Insulin and iron products with more than 30 mg elemental iron per dosage form are examples. A third restricted OTC category, Schedule III ("pharmacy only"), is available only in a pharmacy so that the consumer may ask questions of the pharmacist. The pharmacist assists the patient in selecting these medications. Examples include *Advil* (ibuprofen) 400 mg and *Benadryl* (diphenhydramine) 50 mg. With this drug scheduling system available in Canada, OTC statin placement will be favorable.¹¹

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