

Support for FDA Approval of OTC Statin Drugs
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As a cardiovascular disease nutritionist, I support approval of OTC statin drugs. Beyond the potential public health impact of OTC statin drugs on coronary heart disease morbidity and mortality in the United States, there are other benefits that can be realized.

1. OTC statins can be a useful tool for dietitians/nutritionist in practice to help their patents/clients attain LDL cholesterol treatment goals (1). Diet has a modest effect on LDL cholesterol lowering compared with statins (2). The figure on the next page shows the relative contribution of diet versus statin drugs in lowering total and LDL cholesterol. Even maximal dietary intervention does not always lower LDL cholesterol levels sufficiently in individuals who are at moderate risk for coronary heart disease. For these individuals, OTC statins can facilitate meeting treatment goals. Moreover, achieving a positive treatment outcome greatly enhances a dietitian/nutritionist-patient/client relationship thereby facilitating ongoing behavior changes, as well as other behavior changes that promote health. Thus, the potential outcomes of OTC statins extend beyond cardiovascular disease. With improved lifestyle behaviors, including diet and physical activity, risk of other chronic diseases can be decreased. Consequently, OTC statins could have a marked public health impact.
2. The OTC program could beneficially affect the nutritional adequacy of the diet. In addition, it may facilitate meeting recommended dietary and physical activity guidelines. The implementation studies indicate that subjects using OTC statins report maintaining or improving diet and physical activity (3). Given the numerous problems with the dietary and physical activity practices in the U.S. (4), a program that facilitates positive lifestyle changes that could favorably affect public health deserves strong consideration for support. The U.S. diet is low in vitamin E, calcium, magnesium and potassium. It also high in saturated fat, cholesterol and low in dietary fiber. Very small changes in dietary practices can facilitate achieving recommended micro- and macronutrient intakes. For example, using Continuing Survey of Food Intake of Individuals (CSFII) data to define the average American diet (AAD) of adults (which provides 35 to 40 mg of vitamin C), the addition of one orange would contribute an additional 70 mg of vitamin C to the diet thereby exceeding the Recommended Dietary Allowance (RDA), which is 60 mg/day. In addition, inclusion of 8 oz of low fat milk or yogurt to an AAD would achieve the calcium and magnesium RDA, and help meet the recommendation for potassium. Furthermore, just switching from higher to lower fat/lean and fat-free meats and dairy products, respectively can achieve saturated fat and cholesterol recommendations for heart health. These are just a few of many examples.

In summary, I believe because of the many substantive benefits of OTC statins that the FDA should approve them for use. The likely multiple and beneficial health outcomes could have a marked public health impact. Thank you very much for your attention.

References:

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3. Cohen JD. Overview of consumer-use research. National Lipid Association Monograph, Should Consumers Be Given an OTC-Statin Option to Help Reduce Their CHD Risk? Exploring the Evidence. December 2004, pp. 19-24.
4. <http://www.health.gov/dietaryguidelines/dga2005/report/>

Figure. Comparative effects of statin therapy and diet intervention on total (TC) and LDL cholesterol (LDL-C) lowering.

