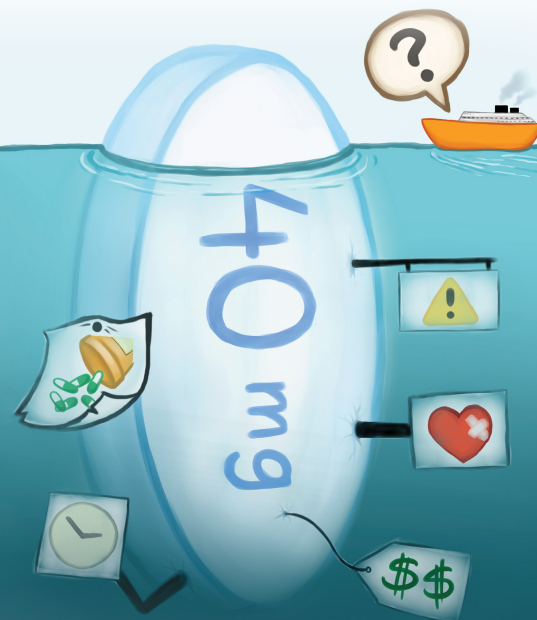


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Over-the-Counter Statins

A GATEWAY TO MISUSE



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ABSTRACT

One in four Canadians over the age of 20 are at a significant risk of developing cardiovascular disease.¹ Despite their proven efficacy as a lipid-lowering therapy for patients at risk, statins continue to be under-prescribed and underused. Proponents of over-the-counter statins argue that increased accessibility will improve usage and lighten the economic burden of cardiovascular diseases.² Furthermore, statins have proven to be clinically effective at low doses. Despite these potential benefits, statins should not be approved as over-the-counter drugs as they are accompanied by greater risks of misuse compared to prescription statins. Over-the-counter approval of statins would set precedence as the first approval of a drug made specifically for treating chronic diseases. This opens up the possibility for future prescriptions to be approved as over-the-counter drugs that will be accompanied with their unique benefits and inevitable risks.

INTRODUCTION

Cardiovascular disease (CVD) is a class of heart diseases primarily caused by the narrowing of blood vessels. Elevated cholesterol, high blood pressure, and smoking status are some significant risk factors of CVD.³ The Framingham risk score, an assessment tool that estimates a patient's risk of developing CVD over the next ten years, is computed using these risk factors.⁴ This score is then used by clinicians to determine whether a patient is at high, intermediate, or low risk of CVD. Usually, patients at intermediate and high risk are prescribed statins as a preventative therapy.³ Statins are prescription drugs that decrease the synthesis of cholesterol and can lower one's risk of CVD by 20–25%.⁵ The clinical efficacy of statins has been shown in numerous studies and validated by the United States Food and Drug Administration (FDA).^{5–8} While 18 million Canadians are currently at intermediate risk of CVD, only four million receive cholesterol-lowering therapy.⁸ Those left untreated constitute one-third of Canada's coronary artery disease cases.⁸ Herein lies the treatment gap.

Improvement of statin use in Canadians has been lackluster, increasing by only five percent in patients from 1992 to 2009.¹⁰ This poses a significant problem since statins are the primary method used by the healthcare industry to reduce CVD.³ Approval of over-the-counter (OTC) low-dose statins, which would not require prescriptions, presents a potential solution to narrowing the treatment gap. Through easier accessibility, OTC statins may effectively combat barriers to treatment, including long physician wait times and expensive physician visit costs.

BENEFITS OF BRIDGING THE TREATMENT GAP

A ten-year cost-effectiveness model of the United States drug market was used to predict the effects of a switch to OTC statins on usage, disease burden, and health care costs. The model found the introduction of OTC statins would result in a 27% increase in usage. Such a change would lead to 293,492 fewer major vascular events and 135,299 fewer revascularization procedures, a treatment to bypass blocked arteries, in the next decade.⁸ This would ultimately save 10.8 billion dollars in health care costs.⁸ The reduction in physician office visits would further save nine billion dollars.⁸

Given these benefits, Merck & Co requested to have their OTC statin, Lovastatin, approved by the FDA. If Merck & Co received approval, it would have set precedence as the first pharmaceutical company to sell an OTC drug intended for treating chronic diseases, which could vastly affect future OTC drug approval.⁹ However, the FDA rejected this request due to a number of risks associated with unregulated statin use, sparking controversy around OTC statins.¹¹ We believe that the FDA should not approve OTC statins due to the increased potential for misuse, low adherence, and adverse drug interactions involving statins.