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Prepared Comments of Bob Dufour, R.Ph.

Wal-Mart Stores, Inc.

Before the

Nonprescription Drugs Advisory Committee (NDAC)

And the

Endocrinologic and Metabolic Drugs Advisory Committee

For consideration of

The safety and efficacy of Mevacor as an OTC product.

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Comments for the FDA Advisory Committee Meeting on Mevacor OTC

Committee members, my name is Bob Dufour. I am the Director of Pharmacy Professional Services and Government Relations for Wal-Mart Pharmacy. Wal-Mart Pharmacy operates in formats that include Sam's Clubs, Neighborhood Markets, Wal-Mart Supercenters, and Wal-Mart Discount Stores. Wal-Mart Pharmacy is in 49 states with nearly 3,500 pharmacies and over 10,500 pharmacists on staff. On average, over one hundred million consumers shop at Wal-Mart each week. I am here today to present comments on the consideration of Mevacor as an OTC product.

Prescription statins have improved the health of millions of consumers by lowering cholesterol levels. If the FDA determines that Mevacor is appropriate as an OTC product the opportunity to better millions of more lives will be possible. Historically, products that have moved from Rx to OTC status have increased both the accessibility of the product and the affordability. Consumer awareness of proper cholesterol levels may also heighten with the availability of statins as OTC products.

Preliminary plans have been discussed between Wal*Mart and Johnson & Johnson-Merck in anticipation of OTC approval. These plans have included:

- 1) Testing in a limited number of stores a "Heart Health" section which would make customers aware of testing kits and other heart health products. This section, if successful, could then be implemented in more stores as demand for OTC statins increase.
- 2) Broadcasting a continuing education program available to all of our pharmacists via our Satellite network. The objectives of this program include:
 - a) Recall important concepts regarding lipid metabolism and pharmacology of statins.
 - b) List cholesterol goals for American adults and discuss the "treatment gap" between those goals and current reality.
 - c) Discuss the clinical evidence that supports the move toward broader access to and treatment with statin medications.
 - d) Identify the types of people who would benefit from access to nonprescription statin medications.
 - e) Describe how pharmacists might best interact with self-treating patients to ensure optimal outcomes from nonprescription statin therapy.
- 3) Support from Johnson & Johnson-Merck at Wal*Mart Health Fairs to increase awareness by consumers of their cholesterol levels. This support would include funding for consumers to have their cholesterol tested as well as information about proper cholesterol levels.
- 4) Wal-Mart and Johnson & Johnson-Merck will further discuss the use of other Wal-Mart vehicles to increase awareness after the launch, including Wal-Mart

TV, Wal-Mart radio, pharmacy bag programs, displays, and in-store demonstrations/ information programs.

Wal-Mart has provided input to Johnson and Johnson-Merck on consumer friendly packaging. Our emphasis has been on patients knowing when and when not to take an OTC statin. Johnson & Johnson-Merck has included warnings for consumers when Mevacor OTC is not appropriate and a 4 step process for consumers to determine if Mevacor OTC is appropriate.

The American Pharmacist Association has advocated for a Pharmacy Care OTC category. Wal-Mart would be able to limit distribution from our warehouses to pharmacies if the FDA determines this category is necessary.

Wal-Mart Pharmacy recognizes the significance of the decision FDA is considering. If the FDA decides that Mevacor would be appropriate as an OTC product, millions of consumers who are at a moderate risk for coronary heart disease would have Mevacor OTC available as an affordable option. I appreciate the opportunity to be heard today. Wal-Mart Pharmacy is committed to providing affordable healthcare for our customers and associates. Thank you.