

**PRESS RELEASE**

**STATIN DRUG CRISIS**  
**LOOMS LARGER THAN “VIOXX®”**

**FOR IMMEDIATE RELEASE**

**DATED: November 29, 2004**

**TO: All Media Contacts**

**CONTACT: Michelle Gayeski (202-466-6937) for more information**

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Based on scientific evidence (including evidence from cardiologist Peter H. Langsjoen, M.D.), Julian M. Whitaker, M.D. and his Whitaker Health Freedom Foundation petitioned FDA on May 24, 2002 to change the warning labels on the statin drugs to alert consumers to the fact that those drugs deplete co-enzyme Q<sub>10</sub> (CoQ<sub>10</sub>) levels in the blood, inducing myopathies, including cardiomyopathy (heart failure), in many people worldwide. FDA has done nothing in response. The resulting health crisis is maybe worse than the Vioxx® debacle, also created by FDA's failure to act on adverse safety information.

Today Whitaker files a second petition with FDA, notifying that agency of Health Canada's insistence on use of the warning and demanding that FDA do the same without delay. Via counsel, Whitaker has sent letters to the Acting FDA Commissioner Lester Crawford and to Senate Finance Committee Chairman Charles Grassley urging action.

The statin drugs work by blocking the body's production of cholesterol through the mevalonate pathway. The essential coenzyme Q<sub>10</sub> (ubiquinone) also uses that pathway. The statins' blockage of coenzyme Q<sub>10</sub> (the coenzyme essential for energy production in all major muscles, including the heart) can induce rhabdomyolysis and myopathies including cardiomyopathy in patients who use the drugs.

Whitaker's petition and his supplemental petition, filed today, demand that FDA amend the warning information for the drugs to alert physicians and consumers to the CoQ<sub>10</sub>-depleting effects of the statins. Oral consumption of 100-

**200 mg per day of supplemental CoQ<sub>10</sub> can help counteract these effects. On June 12, 1990, Merck obtained a patent for the combination of a statin drug and CoQ<sub>10</sub> for this reason but has not filed a drug application to seek approval of the combination. Health Canada has required statin drug sellers in that country to warn consumers in drug advertising about the CoQ<sub>10</sub>-depleting effects of those drugs.**

**With changes in the National Cholesterol Education Program (NCEP) guidelines increasing the use of statin drugs, the risks of myopathies have increased dramatically, threatening a national health crisis.**

**At 1:00 p.m. EST today (November 29, 2004), the Whitaker Health Freedom Foundation will hold a live telephone call-in press conference concerning the statin drug crisis. Drs. Whitaker and Langsjoen will comment and answer questions. To participate, call (800) 504-8071 and enter code 4666937.**

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